MACRA Episode-Based Cost Measures: Wave 5 Measure Development 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: Wave 5 Measure Development

1.2 Dates

The Call for Public Comment ran from February 18, 2022, to April 1, 2022.

1.3 Project Overview

The Centers for Medicare & Medicaid Services (CMS) has contracted with Acumen, LLC, to develop episode-based cost measures for potential use in the Merit-based Incentive Payment System (MIPS) to meet the requirements of the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The contract name is "Physician Cost Measures and Patient Relationship Codes (PCMP)." The contract number is 75FCMC18D0015, Task Order 75FCMC19F0004. As part of its measure development process, Acumen gathers input from groups of stakeholders and experts, including this opportunity for interested parties to submit comments on the candidate episode groups for development in Wave 5.

This Call for Public Comment invites stakeholders to submit comments on which episode-based cost measures to develop for the upcoming Wave 5 of measure development. As background, in Waves 1-3, Acumen obtained input on measure prioritization by convening experts in Clinical Subcommittees (CS). These CS were structured around a clinical area or type of measure. We met with the CS to discuss and vote on preferred episode groups.

Wave 4 used a public comment approach in 2020 – 2021 to allow for broader and more flexible stakeholder participation in light of new challenges that clinicians and specialty societies were facing. We continued this public comment approach for Wave 5.

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 Currently Accepting Comment webpage
- Hosting 2 office hours sessions for specialty societies to address questions

- Posting a presentation recording with additional information[1]
- Sending multiple email notifications to various relevant stakeholders and email lists (i.e., CMS listserv, Measures Management System listserv, Acumen general stakeholder mailing list, the PFAnetwork listserv,[2] and a targeted specialty society outreach list)

We received 32 comments via email and survey response.

- We received comments from 28 organizations and 11 individuals; 5 comments were from person and family stakeholders.
- The verbatim text of each submitted comment is presented in Appendix A.

[1]CMS, "The MACRA Wave 5 Cost Measure Development Presentation," Quality Payment Program Webinar Library (February 2022), https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1848/MACRA%20Wave%205%20Cost%20Measure%20Development.pdf

[2] The PFAnetwork listserv is an email list of Person and Family Advisors (PFAs) maintained by PFCCpartners.

2 STAKEHOLDER COMMENTS: FEEDBACK ON WAVE 5 CLINICAL AREAS AND MEASURE CONCEPTS

This section summarizes the feedback received on the Anesthesia Care (Section 2.1), Diagnostic Radiology Procedures (Section 2.2), Oncological Care (Section 2.3), Post-Acute Care (Section 2.4), Rheumatoid Arthritis (Section 2.5), Ophthalmologic Conditions (Section 2.6), Kidney Transplant Management (Section 2.7), and Cholecystectomy (Section 2.8) clinical areas and measure concepts considered for measure development in Wave 5.

2.1 Anesthesia Care

This section summarizes the feedback on the Anesthesia Care clinical area. The following subsections describe comments on the scope of a potential measure, the range of complications and other follow-up services that may be reasonably influenced by clinicians, issues with attributing anesthesia care to clinicians, potential opportunities for improvement, preliminary trigger codes, indicators of quality, potential Clinician Expert Workgroup (hereafter referred to as "workgroup") composition, and other concerns and feedback.

2.1.1 Measure Scope

Stakeholders generally preferred a measure concept for anesthesia practice for surgical procedures rather than pain management.

Anesthesia Practice for Surgical Procedures

Commenters suggested several potential approaches to constructing a measure that focuses on the care provided by anesthesia clinicians, including anesthesiologists and certified registered nurse anesthetists (CRNAs). A stakeholder provided details around different anesthesiology practice areas, 2 of which are related to operative or surgical care:

- **Traditional practice**: assessment of a patient's condition prior to anesthesia/surgery, preoperative management of current medications, review of diagnostic studies, determination of available anesthetic options, creating a plan with the patient and obtaining consent, intraoperative management of anesthesia, monitoring and maintenance of physiologic functions, and immediate postoperative care.
- **Advanced, more comprehensive practice**: deeper engagement in preoperative preparation including optimization services to address medical conditions that may include patient nutrition, tobacco use, diabetes control, and other comorbidities that often take place weeks ahead of planned surgery; postoperative management of pain with interventional procedures or pharmacologic therapy during hospitalization and after hospital discharge; and fluid management.

One suggested approach was not to create a stand-alone anesthesia cost measure, but rather to include anesthesia specialists in the attribution methodology for existing procedural episode-based cost measures (currently only attributed to the clinician billing the procedure) and assign them a percentage of the episode costs. A stakeholder noted that this would be more appropriate than developing a stand-alone anesthesia cost measure because the nature of surgery involves a team of clinicians, including surgeons, anesthesia specialists, and other specialists, making it challenging to identify which costs should be considered as related to anesthesia.

A few stakeholders provided input on anesthesia-focused measures ranging in scope. One suggestion was to focus on perioperative anesthesia care for various surgeries with a short timeframe (e.g., 24 to 48 hours after surgery). A commenter noted that complications related to anesthesia typically occur within that time period and that anesthesia specialists should not be held responsible for surgical complications that are unrelated to anesthesia. Another stakeholder suggested broadly assessing anesthesia care across many types of procedures as preferable to a more narrowly defined one, but they acknowledged that either could be developed.

Pain Management

Many stakeholders expressed concerns about a pain management cost measure, with several noting that the subjectivity of pain creates many challenges for a potential measure. It also would apply to a smaller subset of clinicians than an anesthesia-focused measure. A commenter provided details about the types of pain management services that anesthesiologists provide:

- **Acute pain management services**: includes multimodal pain management, prescribing oral or injected opioid and nonnarcotic analgesics, and/or providing interventional pain management utilizing epidural or peripheral nerve block techniques. The goal is to minimize the use of addictive opioids, alleviate patient discomfort, and optimize recovery.
- **Chronic pain management services**: care of patients with the full spectrum of painful disorders including musculoskeletal disease, painful nerve conditions, or traumatic pain. Similarly, approaches include pharmacologic therapy, especially management and prevention of opioid dependency and interventional procedures.

All commenters providing input on this topic agreed that acute and chronic pain management should be considered separately; several also questioned how these would be identified. An example was that facet injections was listed as a potential trigger code for acute pain management when they are provided for chronic circumstances. A stakeholder noted that in addition to the trigger methodology, the measure would need to account for the transitions from acute to chronic pain and the evolution of the pathology into other conditions. One suggested approach on how to differentiate acute from chronic pain was to consider the relevance of acute pain to surgical procedures while chronic pain could be non-surgical or further removed from surgery.

Several stakeholders commented that a pain management measure would face many challenges, given the limitations of claims data. The subjectivity of pain reduces the degree of influence over costs that clinicians may have in other clinical areas, as pain severity or duration is not reflected in claims data. A commenter noted that this reduces the cost variation that the measure would be able to capture and limit the opportunity for improvement. A few stakeholders also noted that claims data cannot distinguish the appropriateness of costly services which could be provided due to poor performance (e.g., neuromodulation devices due to inadequate treatment), as part of routine, high-value care (e.g., routine battery replacement), or appropriately escalating treatment given patient assessments and feedback about pain. A few commenters suggested that other clinically related services should include opioids, injections, surgeries, nonsurgical neurostimulating systems, drug screenings, physical therapy, and imaging.

Some commenters highlighted concerns with attribution for the pain management measure. One perspective was that CRNAs should not be attributed due to the extensive licensure and training for pain medicine specialists; however, CRNAs might be appropriate to include if the measure framework accounted for team-based, physician-led care. A stakeholder noted that a pain management cost measure would have substantial overlap with the Low Back Pain measure currently under development in Wave 4.

2.1.2 Services within Clinician Influence

Several stakeholders provided input on potential complications that could be included in an anesthesia practice-focused cost measure:

- Postoperative nausea and vomiting
- Unplanned reintubation
- Untreated hypothermia
- Nerve injury
- Consults with other clinicians (e.g., ophthalmologist, otolaryngologist, dentist) for complications such as corneal abrasion and airway or dental injury
- Urgent acute complications (e.g., kidney injury, pneumothorax, respiratory failure, return to operating room)

However, many commenters highlighted the challenges with identifying and including complications specific to anesthesia care. Some of these complications cannot be identified through claims data, others are very rare and would be considered outliers, and other potential complications may not be able to be parsed out from other care (e.g., surgical complications). A stakeholder also noted that billing limitations and inconsistencies in diagnosis coding limit the measure's validity. First, anesthesiologists and their groups do not receive a separate payment for operative and preoperative clinics, which contributes to improving patient outcomes and

preventing complications. Second, services that anesthesiologists provide in the operating room are not separately billable from the overall procedure, even for complications that arise in the delivery of anesthesia. Third, anesthesiologists may bill time spent in the post-anesthesia acute care unit (PACU) as part of their anesthesia time, rather than through a separate claim or billing code. In light of these challenges, a commenter preferred an alternative approach which would instead assess clinicians providing anesthesia services on a series of quality metrics aimed at mitigating patient risk, which could then be used as part of evaluating potential cost effectiveness areas.

2.1.3 Attributing Episodes of Care to Clinicians

Many stakeholders noted the difficulties with parsing out the role of clinicians providing anesthesia service as distinct from other members of a larger team involved in surgical procedures. Commenters pointed to the range of specialties that could be involved, depending on the procedure (e.g., critical care, obstetrics, ambulatory care), all of whose skills and experience may in turn affect the role of the anesthesia specialist. A cost measure would need to account for the different costs that would be expected, depending on the exact nature of the anesthesia clinician's role for a given patient. Stakeholders also raised the impact of the facility on costs, including the lack of control of the attributed anesthesia clinician on supplies and equipment and the role of the surgeon and facility in determining protocols that limit the ability of the attributed clinician to influence costs. To address this, the suggestion was to attribute episodes to surgeons and the facility as well.

2.1.4 Opportunities for Improvement

A few stakeholders provided input on areas for cost improvement:

- Implementing anesthesia plans to meet patient goals that are appropriate for their needs
- Care coordination
- Reducing length of stay
- Preventing surgical site infections
- Enhanced Recovery After Surgery (ERAS) programs: best practices from pre-operative to post-discharge care that improve patient outcomes (e.g., return to function, reduce stress response to surgery)
- Manage post-discharge care (e.g., using nerve blocks, non-pharmacologic approaches, and non-opioid based-pharmacologic measures)

Commenters also noted limitations such as the difficulty of defining episodes that focus on the role of the anesthesia clinicians where their performance cannot be disentangled from other members of the care team. A suggestion was to conduct analyses into various surgery types

and compare the intensity and duration of follow-up care to identify potential areas for improvement.

A few stakeholders cautioned that there would need to be ways to account for cost differences that could appear more cost-effective but which, in fact, are low-quality care. Factors suggested include social determinants of health and place of service (e.g., ambulatory surgical center versus inpatient).

2.1.5 Preliminary Trigger Codes

No comments were targeted at the list of preliminary trigger codes that were shared during the public comment period. However, one commenter noted an issue with billing codes for anesthesiologists; they explained that anesthesiologists often are not involved in the billing of the services (e.g., when it is the anesthesia billing department staff that bills), which complicates how episodes may be linked to specific providers.

2.1.6 Quality Alignment for Assessing Value

Commenters emphasized the need for quality measures around the patient experience, especially for outcomes including:

- Pain
- Postoperative nausea and vomiting
- Memory of the procedure
- Quality of life, such as return to function
- Patient satisfaction

A stakeholder noted that a cost measure should also be able to provide meaningful information to patients to make informed choices about their care. This is challenging as patients often consider that greater cost represents more care provided. Including anesthesia within or creating complementary anesthesia cost measures to procedural episode-based cost measures would help patients better understand the overall costs of care to Medicare.

One commenter suggested that a different approach is to use quality measures to assess anesthesia care, which could then complement facility-level cost saving initiatives. These quality metrics could assess adherence to best practices designed to mitigate patient risk. As an example, anesthesiologists contribute to reduced surgical site infections by administering prophylactic antibiotics, ensuring normothermia, and managing the patient's glucose levels. Those quality measures could be an indicator for how the expected cost of treatment, including length of stay and risk of complication, could be assessed.

2.1.7 Workgroup Composition

Stakeholders mainly suggested specialties that should be included in either an anesthesia or pain management measure. These included anesthesiologists, CRNAs, and physiatrists. One commenter noted that CRNAs are involved in every aspect of anesthesia services from pre-assessment and consent to recovery.

2.2 Diagnostic Radiology Procedures: Screening Mammography

This section summarizes the feedback on the Diagnostic Radiology Procedures clinical area. The following subsections describe comments on the potential scope of the mammography measure, suitable timeframes to capture radiologists' overall influence in mammography, other viable measure concepts for radiologists, types of services that may capture opportunities for improvement and differentiate between clinician performance, preliminary trigger codes, indicators of quality, and potential workgroup composition.

2.2.1 Mammography Measure Scope

Commenters generally preferred focusing a cost measure on screening mammograms, which could be constructed in varying ways. One approach is using the screening mammography service - standard and with tomosynthesis - as a trigger. The episode would then capture services for screening and diagnostic mammograms, further imaging (e.g., ultrasound, magnetic resonance imaging [MRI]), biopsy with or without imaging guidance, and localization (e.g., needle, wire). A stakeholder noted that this approach of using the screening as a trigger and assessing care through to biopsy would be a clinically sound approach to capturing the broadest patient cohort. It also is an area where radiologists have direct control. A commenter suggested focusing on female patients over the age of 40.

Commenters responding to the question of whether to define a patient cohort using newly occurring cancer diagnoses after the mammography trigger did not support this approach, noting that it would capture only a small percentage of cases. A stakeholder cited that for every 1,000 screening mammograms, only five are expected to yield a cancer diagnosis.

A different approach to defining the measure scope suggested by a commenter is to use the clinical endpoint as the trigger; that is, a particular procedure with a breast cancer diagnosis rather than using the initial mammogram as the trigger. This episode would then be defined to have a lengthy pre-trigger period as the episode window, including the initial screening mammogram plus other related services. The advantages of this suggested approach are that it accounts for variation in screening frequency (described below) and may better control for clinical variation.

2.2.2 Timeframe to Assess Care after Mammography

Commenters suggested a range of episode window lengths which would capture different aspects of care. Some options were:

- 90-120 days: This would avoid capturing services for interval breast cancer (breast cancer that is diagnosed after a screening exam yielded negative results but before the next screening)
- 12-15 months: This would allow the measure to capture both a cancer diagnosis and return to annual screening, allowing time for a delay in the annual screening
- 24-47 months: This would be the appropriate timeframe to capture biennial screenings

2.2.3 Accounting for Heterogeneity

Stakeholders noted that it would be difficult to account for the different levels of resource use that depend on the mammogram findings. The expected costs would differ depending if the finding was normal, abnormal/benign, or abnormal/malignant. However, the outcome of the mammogram is not available in claims data. Similarly, there are also potential cost savings in improving the management of incidental findings. For example, episodes where a radiologist recommends no follow-up should be compared to episodes where a radiologist did not provide explicit guidance. The latter may have higher costs with additional imaging and the involvement of other specialists.

A few stakeholders identified patient risk factors that would affect costs in a mammography measure. A suggestion was to exclude patients with high-risk conditions, including genetic susceptibility or personal or family history of malignant neoplasm of breast. While there are International Classification of Diseases, 10th revision (ICD-10) diagnosis codes for these factors, it is not clear how reliably these are coded. Race and ethnicity can also play a role in genetic risk factors; this may mean higher rates of diagnostic imaging for certain patients. A commenter noted the impact of disabilities and social determinants of health, which can result in longer delays between screenings. Another patient factor highlighted by a commenter was whether women have dense breasts, as clinicians may order a breast ultrasound and MRI. There may also be geographic variation in mandates for these additional imaging services.

Patient compliance rates were also noted as factors that affect cost. Specifically, patients may not follow radiologists' recommendations for follow-up or diagnostic imaging ("lost to follow-up"); as such, these episodes are likely to appear cheaper than other episodes where patients do seek follow-up care. This could skew provider scores where radiologists with higher "lost to follow-up" rates appear cheaper than those with lower rates. A stakeholder noted that around 9-12 percent of patients, in their experience, fall within this description.

2.2.4 Attribution

Commenters noted challenges with attribution, since many services that would be included in this measure would be ordered by another clinician rather than the radiologist, limiting the degree to which radiologists can influence costs. One exception is that radiologists can order a diagnostic mammogram based on the findings of a screening mammogram.

Another stakeholder emphasized the need to carefully consider the unique features of a cost measure for radiological care, as this does not fit within a traditional framework for episode-based cost measures. They also expressed that there is a need to increase radiologists' opportunities to participate in value-based care, as they currently are unrecognized for their efforts in care coordination.

2.2.5 Opportunities for Improvement

Stakeholders identified many areas for cost and broader improvements in care:

- Reducing follow-up imaging (e.g., unnecessary or repeat testing)
- Using more effective imaging technology for earlier cancer diagnosis
- Shorter treatment and lower costs of cancer treatment, although these effects may not be observed during the episode
- Using the less invasive needle biopsies rather than surgical biopsies
- Improving care coordination and management for incidental findings
- Reducing over-diagnosis of benign incidental findings
- Reducing unnecessary therapies (e.g., biopsies, surgeries)
- More effective and efficient breast cancer detection
- Improved population screening

2.2.6 Preliminary Trigger Codes

A few commenters shared input to remove codes from the list of draft triggers provided in the posting:

- Only use screening mammography (Current Procedural Terminology/Healthcare Common Procedure Coding System [CPT/HCPCS] 77067) as the trigger code with ICD-10 diagnosis Z12.31; do not use any of the other listed treatment codes
- Do not use breast computed tomography (CT) codes (CPT/HCPCS 0633T – 0638T), as they are temporary codes for emerging technology, services, procedures, and service paradigms, are not widely used, and have variable coverage.

2.2.7 Quality Alignment for Assessing Value

Commenters emphasized the need to link a cost measure with quality metrics. Specifically, they suggested the following metrics that would balance a breast cancer screening

cost measure, including a number of current and former MIPS quality measures that could be used to create a MIPS Value Pathway (MVP):

- Former MIPS Qualified Clinical Data Registry (QCDR) measures for cancer detection rates, recall rates, and true/false positive rates
- MIPS quality measures on incidental finding imaging measures
- Measures under development for timeliness of post-screening services (e.g., from screening to diagnostic mammography or biopsy)
- Measures for cancer detection rates, positive predictive values (PPV) 1, 2, and 3 at 12 months following a screening mammography
- Hospital Outpatient Quality Reporting (OQR) Program with four Outpatient Imaging Efficiency (OIE) measures, including breast cancer screening recall rates (OP-39)

2.2.8 Other Viable Measure Concepts

One stakeholder identified lung cancer screening as a viable option for a cost measure, but expressed their preference for developing a breast cancer screening measure first. A lung cancer screening measure could use a similar framework as the breast cancer screening measure where the trigger code is an initial screening exam.

2.2.9 Clinician Expert Workgroup Composition

One commenter highlighted the following specialties to include in a potential workgroup: diagnostic radiologists (breast imaging specialists), primary care providers, radiation oncologists, and oncologists. They also recommended including individuals with measure development experience and individuals with relevant medical coding knowledge.

2.3 Oncological Care: Cancer

This section summarizes the feedback on the Oncological Care clinical area for a cancer cost measure. The following subsections describe comments on accounting for cancer staging/severity, potential measure scope, non-drug services that may capture opportunities for improvement, preliminary trigger codes, indicators of quality, potential workgroup composition, and other concerns and feedback.

2.3.1 Accounting for Cancer Severity

Many stakeholders provided feedback on one of the key challenges identified in the call for public comment: how to account for cancer severity with claims data, particularly through the use of diagnosis codes and treatment services. Commenters noted the limitations of claims data and other challenges of accounting for cancer severity due to the high degree of heterogeneity and the quickly evolving knowledge in this area. Stakeholders mainly focused their comments on breast and prostate cancer.

Diagnosis Codes

While stakeholders were divided on whether ICD-10 diagnosis codes could be used to account for cancer severity, all commenters responding to this question agreed that diagnosis codes could not be used in isolation to identify all the aspects of severity that would be needed for a cost measure. Stakeholders provided examples of specific types of diagnosis codes that could be used for risk adjustment:

- Secondary malignancies: ICD-10 codes C77.0 to C79.9 indicate a spread to lymph nodes, organs, and other distant sites
- History of cancer: ICD-10 codes Z85.00 to Z85.9 indicate patients who have been successfully treated yet still require some management for the aftereffects of treatment, or patients who have recovered and are now being managed for a second primary cancer

Some commenters noted that diagnosis codes, in combination with other information from claims data, could appropriately identify severity. A few of the suggestions were closely related to the use of services or treatment as a marker of severity (discussed below), for example the presence of diagnosis codes for services that indicate the degree of treatment required (e.g., hospitalizations) or for services on different dates. Some commenters also suggested considering the position of a diagnosis code on a claim (e.g., primary diagnosis) or whether a diagnosis code is the first occurring within a lookback period as part of examining severity. However, diagnoses alone as a proxy for severity would be misleading.

Other stakeholders expressed concerns about the limitations of diagnosis codes. Several commenters noted that cancer research and knowledge is evolving so quickly that diagnosis codes cannot reflect the range of clinical factors that affect severity and treatment pathways. An example of this was genetic characterization, which is now known to be inherently connected to severity and cost of care. Stakeholders also stated that diagnosis codes are not specific enough: one commenter gave the example of C50.511 (malignant neoplasm of the lower-outer quadrant, right female breast), which would be the same diagnosis given to an early-stage breast cancer patient who is responding positively to hormonal therapy as a late-stage breast cancer patient whose disease has recently progressed and requires multiple chemotherapy and immunotherapy treatments.

Treatment Services

Stakeholders provided examples of treatment that indicates severity for specific types of cancer, with prostate cancer receiving the most detailed comments. A commenter cautioned that there are risks with the approach of using observed services (cost) to predict expected cost. Beyond the examples specific to each type of cancer, one suggestion was to consider the length of treatment, including non-cancer treatments (e.g., physical and occupational therapy and speech language pathology).

Prostate cancer

A few stakeholders commented generally that prostate cancer seemed to be a good candidate for a cancer care cost measure. One reason cited was the fact that treatment has guidelines for different stages (e.g., those detailed in the National Comprehensive Cancer Network [NCCN] guidelines); additionally, while using treatment to classify severity is imperfect, it is unlikely to be systematically inaccurate across providers. One commenter explicitly noted that using claims data alone would be feasible for prostate cancer, although it would be improved by linking to tumor registry data.

A stakeholder suggested focusing on localized prostate cancer, which would then be adjusted for levels of risk. This measure focus could be defined by an incident prostate cancer diagnosis occurring with any of the following services:

External beam radiotherapy with adjustment for up to 3 years of concurrent androgen deprivation therapy (ADT) (e.g., none, less than 6 months, or 6 months to 3 years)

Brachytherapy with or without ADT or external beam radiotherapy

Radical prostatectomy

Repeat biopsy within 18 months (regular biopsies indicate ongoing surveillance)

A few commenters suggested examining services furnished by particular specialties as an indicator of low-risk cancer as different specialties interact with different stages of the disease. One example was that urologists often treat low-risk prostate and bladder cancers (e.g., through surveillance, surgery, or radiation), while more severe cases tend to be handled by hematologists and oncologists (e.g., with therapeutic interventions). However, another suggestion was to consider evaluation and management (E&M) services by urologists, radiation oncologists, and medical oncologists all as part of identifying low-risk prostate cancer.

Several stakeholders noted types of treatment and diagnoses that further indicate low-risk prostate cancer. One approach was to consider low-risk, castrate-sensitive prostate cancer episodes as those receiving only first-line androgen deprivation and/or anti-androgen therapies. Another suggestion was that a prostate biopsy without imaging, prostatectomy, or radiation therapy indicates low-risk cancer, although there was also acknowledgement that there are many scenarios where surgery or radiation are used for low-risk cancer (e.g., for young patients or where there is strong family history).

A few commenters provided examples of services that indicate intermediate- and high-risk cancer. One comment noted that imaging such as CT scan of abdomen and/or pelvis, MRI of pelvis and/or prostate, bone scan, or positron emission tomography (PET) scan, are indicative of

higher risk cancers. Another suggestion was to consider high-risk, castrate-resistant prostate cancer episodes as those where other chemotherapies and/or immunotherapies are present.

A stakeholder detailed approaches to identifying locoregional and metastatic prostate cancer as other types of cancer that should be accounted for. Indicators of locoregional prostate cancer include: external beam radiotherapy and proton therapy, brachytherapy and external beam radiotherapy, or radical prostatectomy with or without external beam radiotherapy, each with 2 to 3 years of concurrent ADT. Metastatic prostate cancer can be identified through diagnosis codes for primary prostate cancer and secondary metastatic sites, including bony metastases, combined with either imaging (e.g., bone scan, CT scan, PET scan) within 2-3 months of a new diagnosis, or ADT. The limitation with using imaging to identify severity is that claims data cannot distinguish where imaging is appropriate. For ADT, this could be an indicator of metastatic cancer with or without abiraterone, apalutamide, docetaxel, or enzalutamide.

Breast cancers

A few stakeholders shared examples of services that indicate low- and high-risk breast cancer, although one challenge in general is how to distinguish treatment intent (e.g., cure, control, palliation), given the different goals and cost utilization for each type. Low-risk episodes could be identified by those where the only treatment is long-term endocrine therapy (e.g., anastrozole, exemestane, letrozole, or tamoxifen). Human epidermal growth factor receptor 2 (HER-2) positive breast cancer episodes can be indicated by targeted therapy (e.g., trastuzumab, ado-trastuzumab emtansine, fam-trastuzumab deruxtecan, pertuzumab, and/or margetuximab). High-risk breast cancer can be indicated by: chemotherapy, immunotherapy, surgery, radiation therapy, and history of transplantation.

Bladder cancers

A commenter provided examples of treatment that differentiates low- and high-risk bladder cancer. Low-risk cancer could be defined as those where the only treatment is Bacillus Calmette-Guerin (BCG) or mitomycin. High-risk bladder cancer can be indicated through chemotherapy and immunotherapy.

Claims Data Limitations

Several stakeholders expressed concerns about the overall limitations of claims data in identifying cancer severity, beyond the use of ICD-10 diagnosis codes. A few commenters noted that differences in service utilization and cost are driven by factors that are not captured in claims data, including: cancer histology, molecular characteristics, genetic classification, cancer stage, line of treatment, oral chemotherapy, and goals of therapy. One specific scenario was provided as an example of the difficulty of identifying risk with claims data: a post-diagnosis hospitalization for cancer could be conflated with a hospitalization related to post-biopsy sepsis.

Stakeholders highlighted that another challenge was accounting for the role that social determinants of health (e.g., ICD-10 codes Z55 to Z65.9) plays in the costs of care. Treatment plans may need to be modified where there are barriers to accessing care, such as targeting less frequent visits for a patient without access to reliable transportation. Patients with these concerns may also require a higher level of care and services from social workers, dieticians, navigators, and other specialists.

2.3.2 Measure Scope

Almost all stakeholders preferred a cost measure focused on one type of cancer rather than a measure that encompasses multiple types of cancer, with breast and prostate cancer receiving the most comments. Commenters noted that it was important to construct measures and risk adjust for each cancer type to predict costs more accurately, given the uniqueness of each cancer type. Only one commenter suggested a broad measure that could focus on oral chemotherapy treatment for breast, renal, and prostate malignancies.

A few stakeholders commented that a breast cancer cost measure could focus on early stage cancer as a narrowly defined disease site with well-defined treatment. Another potential scope was for patients who receive a lumpectomy, partial mastectomy, or simple mastectomy and subsequently receive radiation therapy or chemotherapy. This measure would help address the measurement gap for oncology and build out the care continuum with existing surgical procedure cost measures. A commenter highlighted the significant cost burden to Medicare represented for breast cancer and the potential for cost improvement due to the cost of drugs as reasons in support of developing this measure.

Several stakeholders provided input on the scope of a prostate cancer cost measure. A few commenters recommended focusing on incident (new) or early-stage prostate cancer which could be done by examining the C61 code (for "malignant neoplasm of prostate") in combination with the timing of diagnosis. Focusing on new prostate cancer addresses the challenges presented by the typical duration of prostate cancer being 8 to 10 years with different treatment due to changing severity over time, ranging from radical prostatectomy (an inpatient surgery) to radiation therapy, which is typically outpatient. One stakeholder stated that a cost measure could focus on prevalent (existing) prostate cancer, or both incident and prevalent cancer. The high cost to Medicare and the potential for use in an MVP was noted by a few stakeholders as a reason in support of this measure for development.

Stakeholders commented on other potential cancer care measures:

- Lung cancer (2)
- Colon cancer (2)
- Ovarian cancer (1)

- Pancreatic cancer (1)
- Non-Hodgkin's lymphomas (1): this measure area would assist in creating a broad measure covering the majority of hematologists and oncologists

A few commenters provided input on other features that a cancer care measure should have to be effective, including the need for analyses into areas of cost that are within the attributed clinician's influence (e.g., side effect management, hospital visits, or emergency department utilization) to help define an appropriate scope for the measure. Another source to inform the measure scope is the Oncology Care Model (OCM) Alternative Payment Model where a stakeholder noted that reductions in total episode payments were concentrated in higher-risk episodes for lung, lymphoma, breast, prostate, and colorectal cancer; as such, focusing on higher-risk cancer was suggested as a potential focus. An episode window would need to be greater than 6 months to capture cost savings and value (e.g., cancer patients who tolerate and maintain their current disease status tend to have higher costs than patients who cycle on and off therapy with little change in outcomes beyond 6 months). Patients with multiple primary cancers were highlighted by a commenter as a cohort to exclude as they would not be comparable with single-cancer populations, requiring a higher volume of treatment (e.g., multiple localized surgeries, chemotherapy, immunotherapy, radiation therapy, supportive care drugs).

2.3.3 Non-Drug Services that Capture Opportunities for Improvement

Stakeholders generally agreed that chemotherapy drug infusions can dominate the cost of cancer care, and several supported excluding those costs in favor of other types of services that indicate variation. One rationale for this exclusion is that clinicians have no influence on the prices of chemotherapy drugs and often do not have low-cost alternatives with similar efficacy. Especially with the rise of treatments specific to patient genomics, clinicians have little influence on the choice and intensity of these services. The OCM also showed that there was no impact on Part B chemotherapy or Part B generally, and no impact on Part D costs; a stakeholder also cautioned that including Part D costs could make beneficiaries with Part D coverage appear to be more costly compared to beneficiaries without Part D coverage.

Commenters identified many non-drug services that represent opportunities for cost improvement for prostate cancer, such as where there is variation in practice patterns or where there are high rates of inappropriate use:

- Diagnostic work-up (e.g., imaging and testing)
  - Pre-diagnosis MRI
  - Post-diagnosis MRI, CT, bone scan, PET-CT, genomic testing
- Admissions and emergency department visits
  - After particular types of care, including prostatectomy and radiation therapy

    - During particular types of care, such as while on systemic therapy for metastatic prostate cancer
- Use of active surveillance in the management of low-risk and low-intermediate risk prostate cancer
- Therapies
    - Hypofractionated external-beam radiation therapy
    - Proton therapy
    - Short-term or long-term ADT
- Treatment for side effects and comorbidities
    - Surgery for treatment of incontinence
- Supportive care and drug agents (e.g., denosumab injections and bisphosphonates can both be used to prevent loss of bone density in patients without renal impairment, but they have markedly different cost)
- Occupational therapy for pain management, daily activity modification, energy conservation, and other functional improvements
- End of life care
    - Palliative care and hospice
    - Services in the last 14-30 days of life (e.g., ICU admission, chemotherapy, other systemic therapy)
    - Therapies that align with patient goals

2.3.4 Preliminary Trigger Codes

There was some support for the preliminary draft trigger codes included during the public comment period for various types of cancer. Some stakeholders also suggested removing codes that are unrelated to chemotherapy delivery in the draft list:

- **Breast cancer**: CPT/HCPCS 0581T Cryotherapy ablation: this code is unrelated to other breast cancer trigger codes. It also reflects an emerging therapy, which is not yet finalized as a Category III CPT code.
- **Prostate cancer:** CPT/HCPCS 55700 Biopsy of prostate gland: this code is unrelated to the other prostate cancer triggers and may be more appropriate for a procedural measure attributed to surgeons or pathologists rather than oncology professionals.

A few stakeholders expressed concerns that using chemotherapy trigger codes would distort the type of care and practices being attributed. There is a wide range of care that breast cancer patients may receive that would not be captured unless the patient received chemotherapy beforehand. Such services include neoadjuvant (pre-operative) chemotherapy, adjuvant (post-operative) chemotherapy, or both, surrounding a surgical tumor resection, targeted radiation

therapy visit, or stem cell transplantation. Another concern was that attribution may be avoided by initiating chemotherapy treatment in an infusion clinic or hospital outpatient setting. A commenter also noted that Part D drugs should not be used as trigger codes due to differences in beneficiary coverage.

2.3.5 Quality Alignment for Assessing Value

Stakeholders suggested a range of quality indicators that would be important to pair with a cancer cost measure to be able to assess value in care, which can span many performance periods. A few stakeholders noted that balancing cost with quality metrics is critical to ensuring that clinicians are able to select the treatment that is the most appropriate for their patients. While several commenters noted that there is a lack of applicable quality measures in MIPS, stakeholders identified the following indicators of quality to align with a cost measure:

- Outcome measures in general
  - Treatment response rate, such as through surgical and medical interventions
  - Downstream consequences, such as rehabilitation and occupational/speech-language therapy
- Survivorship measures and other long-term outcome measures to guard against potential incentives to stop providing continuous maintenance therapy
  - Progression-free survival
  - Overall survival
- Patient-centered quality measures (e.g., Patient-Reported Outcome Performance Measures or PRO-PMs)
  - Patient goals and values, including quality of life, comfort, family burden, individual cost, life expectancy
- Appropriate use measures to account for costly services which provide better outcomes and cost savings over a longer period
  - Cell and gene therapies
  - Adherence to preferred treatments within clinical pathways

2.3.6 Workgroup Composition

Commenters generally supported including oncologists (medical, radiation, surgical, hematologic, etc.) and other health care professionals who diagnose and treat cancer in inpatient and/or outpatient settings (e.g., urologists for some low-risk prostate cancer cases), as well as medical coding experts in a workgroup. A few stakeholders also suggested additional perspectives and specialties to include:

- Pharmacists

- Occupational therapy experts
- Palliative care professionals
- Long-term care and hospice professionals

2.3.7 Other Concerns and Feedback

One commenter noted that recently added billing codes related to chronic care management, complex care management, principal care management, transitional care management, and advance care planning should not be discouraged as they were in the Oncology Care Model, which barred some of these codes. The commenter cited the importance of beneficiaries' access to these care management services as they complement new models in the delivery of patient-centered, comprehensive cancer care.

One commenter suggested prioritizing a benign prostatic hyperplasia cost measure over prostate cancer based on the input from the Wave 2 Urological Disease Management Clinical Subcommittee.

2.4 Post-Acute Care (PAC)

This section summarizes the feedback received on the Post-Acute Care clinical area. The following subsections describe comments on addressing patient heterogeneity, approaches for attributing clinicians to episodes, opportunities for improvement, preliminary trigger codes, indicators of quality, potential workgroup composition, and other concerns and feedback.

2.4.1 Addressing Patient Heterogeneity

Commenters described approaches to address the heterogeneity of patients across PAC settings, primarily via stratification and risk adjustment for setting and other factors regarding the stay/event or patient. They recommended stratification or risk adjustment for the following items: unique conditions (e.g., congestive heart failure, wound care, depression, dementia) with sufficient case volume, medical complexity (e.g., whether the patient has multiple chronic conditions), Patient Driven Payment Model (PDPM) categories (e.g., the point system for the non-therapy ancillary [NTA] category) or case-mix groups, risk-adjusted Hierarchical Condition Category (HCC) score, CMS' HCC model, a marker for frailty, short versus long-term care patients, and socioeconomic disparities (e.g., presence of social support). For skilled nursing facilities (SNFs), one commenter suggested a focus on patients undergoing rehabilitation with a goal of discharge to home.

Commenters noted that the various PAC settings are very different from one another, and they stressed that cases within each PAC setting should only be compared with each other. For example, one comment emphasized that long-term care hospitals (LTCHs) are unique in that they treat critically ill and medically complex patients for a longer span of time and with

different requirements and levels of access for care, services, and supervision than the other settings. A comment emphasized how short-term rehabilitation patients in SNF are very different from LTCH patients. A commenter noted that LTCHs require a physiatrist involved in the patient's care while SNFs do not. Another commenter described a study that demonstrated that the various PAC settings have significant differences in terms of patient age and primary diagnoses (e.g., dementia and depression), which yields differences in functional status upon admission across the settings. One commenter noted that home health agencies (HHAs) cannot be assessed similarly to institutional settings like SNFs and inpatient rehabilitation facilities (IRFs).

2.4.2 Attribution Approaches

Commenters emphasized that the PAC settings are very different and recommended tailored attribution methodologies to account for these differences. One comment stressed that attribution must consider the attributed clinician's opportunity to manage care. For the institutional settings like IRF and LTCH, some commenters agreed that the attribution approaches used for the Medicare Spending Per Beneficiary (MSPB) Clinician measure and the acute inpatient medical condition episode-based cost measures is a useful starting point for PAC attribution. Similarly, one comment recommended an approach in which a primary care provider (PCP) with the plurality of services during the stay/event is attributed to the PAC episode. A commenter stated that clinicians do not have as much influence over PAC decisions and cost as the facilities, recommending that PAC costs not be attributed to individual clinicians. One commenter recommended that a technical expert panel (TEP) discuss the topic of PAC attribution to provide more detailed recommendations based on relevant data.

Some commenters highlighted specific types of clinicians for PAC attribution across the various settings. For example, a commenter described a study demonstrating how physiatrists in SNFs may yield cost improvements regarding length of stay and admissions to emergency departments and hospitals; they noted that physiatrists have an important role across PAC settings (e.g., LTCHs), though their involvement is not currently mandated for SNFs. Commenters acknowledged that a unique attribution approach would be needed for home health (HH). While one commenter recommended attribution for the clinician signing the initial HH certification, another commenter advised against this and instead recommended attributing to the patient's PCP or clinician that recertifies the HH care. This latter commenter noted that clinicians signing the initial HH certification have no influence over subsequent HH utilization.

2.4.3 Opportunities for Improvement

Commenters provided input on the types of services that reflect opportunity for improvement in PAC. Primarily, the noted that therapy (i.e., physical therapy, occupational therapy, and speech language pathology) is a key component for opportunity for improvement,

as patients are in PAC for rehabilitation. Commenters noted that the access to therapy, as well as the intensity and quality of the therapy, plays a significant role in overall PAC cost; one commenter noted that stinting on therapy may result in longer lengths of stay, higher readmission rates, and more adverse events (i.e., falls, complications). One commenter noted there is opportunity for improvement in follow-up care and preventative and primary care considerations, citing that home safety assessments by occupational therapists may prevent risks for falls or complications. A patient/caregiver commenter noted their preference for PAC facilities that kept their appointments, communicated clearly and routinely, and listened to their perspective and preferences (e.g., for wanting physical therapy). One commenter also cited opportunity for improvement in staff training.

2.4.4 Preliminary Trigger Codes

Commenters provided some insights into the codes or approach for triggering PAC episodes. One commenter recommended triggering with therapy care codes from the 97000 series of physical medicine and rehabilitation current procedural terminology (CPT) codes. Another commenter noted that while there are many rehabilitation codes for International Classification of Diseases, 10th revision (ICD-10), they should be used in conjunction with codes for other patient characteristics (e.g., functional status, age, presence of comorbid conditions) to establish clinically coherent and comparable patient cohorts. Another commenter mentioned it may be useful for SNF episode triggering if there is a facility code that indicates whether the patient is undergoing short-term rehabilitation with the expectation of discharge to the home.

2.4.5 Quality Alignment for Assessing Value

Commenters shared some insights on indicators of quality that they recommended be evaluated alongside the cost of a potential PAC episode-based cost measure. Commenters noted the following should be evaluated from a quality perspective alongside cost: functional status, quality of life, patient-reported outcomes, staff training (e.g., bedside protocol), and patient progress as determined by a set plan or timeline. One commenter also noted that a potential PAC episode-based cost measure ought to be considered in connection with the applicable value-based purchasing (VBP) programs and quality reporting programs (QRPs) for the PAC settings.

2.4.6 Workgroup Composition

Commenters generally recommended that a PAC workgroup include various types of clinicians and providers, primarily physiatrists and therapists (i.e., physical therapists, occupational therapists, and speech language pathologists). One commenter recommended the workgroup include clinicians and providers with experience in hands-on patient care across the settings, including for items such as bathing, feeding, and grooming. A commenter also

recommended consideration for all other clinicians involved throughout the trajectory of PAC and health care economists.

2.4.7 Other Concerns and Feedback

Commenters shared other concerns and related feedback for a potential PAC episode-based cost measure. One commenter noted there was a proposed MVP for fall prevention, suggesting a PAC cost measure may align with it. Another commenter recommended that the prospective payment systems (PPSs) for the PAC settings be developed or updated using a uniform approach, such as the approach used for developing the IRF PPS.

2.5 Rheumatoid Arthritis

This section summarizes the feedback on the Rheumatoid Arthritis clinical area. The following subsections describe comments on measure scope and patient cohort, accounting for severity of the condition, opportunities for improvement, preliminary trigger codes, indicators of quality, potential workgroup composition, and other concerns and feedback.

2.5.1 Measure Scope and Patient Cohort

Most stakeholders supported the measure focusing on new patients due to challenges with accounting for the greater complexity in treatment for patients with advanced stages of rheumatoid arthritis. A few commenters noted that a measure focusing on care for new patients would capture early diagnosis and conservative non-pharmacological interventions (e.g., physical therapy plan) that improve care management, which can reduce medication needs and other costly services. One commenter explained that focusing on new patients would help address Part B and D measurement challenges, which will make it easier to incorporate patients with advanced stages of rheumatoid arthritis at a later stage. Stakeholders commented on the complexity of risk adjusting for later-stage rheumatoid arthritis, which would be necessary to account for higher costs (e.g., due to cumulative disease burden requiring expensive interventions like joint replacements, use of multiple biologics, or higher disease activity).

A few commenters preferred a measure with both new and existing patients for a more balanced perspective on the actual costs. This may capture opportunities for improvement around slowing disease progression and breaking the cycle of relapse and remission. One commenter also suggested including patients at key decisions points (e.g., when changing medications or hospitalized).

2.5.2 Accounting for Severity

Stakeholders generally agreed that it would be challenging to use claims data to capture severity. Some commenters did suggest factors that could indicate severity in claims data, including: continued use of steroids, comorbidities like premature coronary artery disease (CAD), lymphoma, interstitial lung disease, and vasculitis, a history of orthopedic surgery (e.g., joint replacements), extra-articular manifestations, prescription or biologic use and/or length of use, clinician care duration, and other imaging or radiographic progression. Several stakeholders also pointed out limitations to the use of many of these factors; for example, comorbidities that are associated with severity may be rare (e.g., vasculitis) or actually reflect poor quality of care. A commenter also noted the need to examine factors related to severity, such as social determinants of health and geographic variation in care.

Other commenters suggested data sources beyond claims data that could be used to assess patient severity. Relevant disease activity indices include: the Routine Assessment of Patient

Index Data 3 (RAPID3), Clinical Disease Activity Index (CDAI), and the Simple Disease Activity Index (SDAI) for rheumatoid arthritis. A few stakeholders noted serology and laboratory testing results that would also be useful, such as: erythrocyte sedimentation (SED) rate, C-reactive protein (CRP), complete blood count (CBC), rheumatoid factor (RF), antibodies to cyclic citrullinated peptides (CCP), and multi-biomarker tests. Another comment was that while there are various severity measurement tools, they are not uniformly used in primary care practices to be able to account for severity.

2.5.3 Opportunities for Improvement

Many commenters highlighted challenges with considering drugs as part of cost improvement opportunities. Some stakeholders suggested that precision medicines through predictive drug response testing may aid in finding the best medication sooner, allowing patients to achieve remission earlier, potentially reducing their risk of comorbid conditions such as coronary heart disease and lymphoma. However, others cautioned that therapeutic strategies can differ with impacts that may not be able to be captured by a cost measure, including the fact that treatment costs are often driven by the choice in therapeutic strategies. Another concern was that novel therapies have higher up-front costs with clinical outcome benefits that would only become apparent over a longer time horizon than an episode window; as such, a stakeholder recommended excluding such novel therapies. A commenter also noted that biologic disease-modifying antirheumatic drugs (bDMARDs) costs more than DMARDS but can decrease expenses elsewhere.

Stakeholders suggested other areas for cost improvement besides medication. These include: habilitation and rehabilitation, preventative options like durable medical equipment (DME), physical therapy, side effects from medications, and treatment in inpatient and ambulatory settings. A few commenters recommended examining the costs from all clinicians involved in providing care services for rheumatoid arthritis, such as physical therapists, ancillary providers, and physicians.

2.5.4 Preliminary Trigger Codes

Several stakeholders provided recommendations for the preliminary trigger codes:

- Adding codes
  - Self-administered drugs in addition to clinician-administered drugs
- Removing codes
  - Codes that do not relate directly to rheumatoid arthritis (e.g., enteropathy arthropathy and ankylosing spondylitis)

- A stakeholder suggested cross-referencing the diagnosis codes with the American College of Rheumatology (ACR) list of ICD-10 diagnoses codes used in related MIPS quality measures

2.5.5 Quality Alignment for Assessing Value

Stakeholders noted the need for metrics that involve the patient perspective and stressed the importance of avoiding unintended consequences, such as discouraging necessary treatments that can improve quality of life. For example, adaptive equipment represents high cost but also improves quality of life. One commenter expressed interest in having the ACR work in collaboration with CMS to improve quality measures, as they have access to clinical data on hundreds of thousands of rheumatoid arthritis patients through the QCDR titled Rheumatology Informatics System for Effectiveness (RISE) that tracks performance on MIPS and QCDR quality measures.

2.5.6 Clinician Expert Workgroup Composition

Several stakeholders suggested a range of specialties and other providers to include in a potential workgroup: rheumatology, physical medicine and rehabilitation, occupational and physical therapy, and DME suppliers. A few commenters also noted various specialty societies and professional associations focusing on rheumatology that should be involved.

2.6 Ophthalmologic Conditions

This section summarizes the feedback on the Ophthalmologic Conditions clinical area. The following subsections describe comments on various questions asked in the posting regarding potential cost measures for Age-related Macular Degeneration (AMD), retinal detachment, and other viable measure concepts. The questions for these measure concepts involved measure scope and patient cohort, identifying clinicians providing care, accounting for factors affecting treatment, opportunities for improvement, indicators of quality, potential workgroup composition, and other concerns and feedback.

2.6.1 AMD

Stakeholders generally did not support this measure concept, highlighting significant challenges with developing a measure that combines two different patient populations that comprise different treatment strategies. Several commenters particularly noted their concerns around the inclusion of drug costs, small sample sizes, and unobservable results within an episode window that would limit the validity of the measure.

Measure Scope and Patient Cohort

Stakeholders suggested a range of scope constrictions for the ophthalmologic conditions measure concept that focuses on data validity, population considerations, drug costs, and general concerns about the measures construction. One commenter recommended against a cost measure

that contains both dry and wet AMD because their treatment protocols and costs are vastly different. They identified that costs become widely variable if a patient develops wet AMD and begins regular treatment with anti-Vascular Endothelial Growth Factor (VEGF) drugs administered by a retina specialist.

The commenters also highlighted specific populations for the measure to consider. One of the commenters advocated for including diabetic and elderly patients; however, another commenter noted that neither the wet or dry AMD populations are suitable due to CMS and Medicare Administrative Contractor (MAC) reimbursement policies. They explained that 10 to 20 percent of dry AMD patients develop severe vision loss, which is out of the physician's control and that there are only over-the-counter treatments (e.g., AREDS 2 antioxidants). Separately, for wet AMD, the initial vision loss is the greatest predictor of visual outcome, regardless of the drugs used.

Identifying Clinicians Providing AMD Management

Several commenters suggested potential ways to appropriately identify the managing clinician for AMD episodes:

- Fundus exams indicate management of a patient's AMD chronic condition
- Referrals to a retina specialist (in addition to identifying a managing clinician, earlier referrals can reduce later stage complications)
- Office visit with dry AMD diagnosis cases often indicate the clinician is managing without anti-VEGF injections
- ICD-10 diagnosis codes for dry and wet AMD, if coded accurately
- Injections by retina specialist
- Follow-up care with general ophthalmologist

However, a stakeholder expressed concern about being able to parse out clinical management due to the variability in treatment options. It is difficult to identify the clinician managing wet AMD other than providing anti-VEGF injections. Identifying the physician managing a patient's dry AMD is also difficult because the patient may have other ocular comorbidities, such as cataract or glaucoma that are managed by another ophthalmologist.

Accounting for Factors Affecting AMD Clinical Treatment

Several stakeholders noted the challenges with using claims data to account for the effect of patient risk on costs due to variations in treatment costs, individual patient considerations, and any pre-existing conditions that can affect treatment strategies. They further mentioned that quality cannot be measured from claims data for dry or wet AMD. Quality indicators include change in visual acuity (which is affected by atrophy, subretinal fibrosis, and other factors for which there is no treatment) and findings on the ophthalmologic exam or ancillary testing. A

stakeholder noted that drug and treatment types will change over time based on patient follow-ups.

Opportunities for Improvement

A majority of stakeholders highlighted challenges in identifying areas for cost improvement due to the nature of drug treatments, including the long timeframe for when benefits would accrue. Several commenters expressed concern about the lack of control over Part D drug prices (e.g., pharmacy benefit managers, rebates, drug purchasing agreements), the difficulty of accounting for high-cost but highly effective drugs (e.g., novel AMD treatments), and the general concern about dis-incentivizing necessary care. For example, a more injection-frequent strategy is aligned with clinical trial protocols and results in better outcomes but could appear more expensive. A few commenters raised concerns that Medicare protocols that require a certain sequence of drugs and limited Medicare coverage of prescriptions limit the extent to which a measure can reflect clinician cost improvement. Another commenter detailed factors outside of the clinician's control that would be difficult to account for and which would limit the potential for using less expensive repackaged bevacizumab; these factors include prior lack of success with repackaged bevacizumab, access issues, patient refusal, and risk of endophthalmitis, cardiovascular events, and inflammation.

One perspective was that new medications and delivery systems would create a significant shift in how AMD is treated within the next 3 to 5 years, rendering a potential measure on this topic soon obsolete. Costs are likely to dramatically decrease for anti-VEGF therapy treatments due to biosimilars availability and diminished access to repackaged bevacizumab.

Stakeholders generally expressed the need for better alignment with quality measures, noting the lack of available measures in MIPS and how AMD under-treatment results in worse patient outcomes. As discussed above, commenters noted the indicators of quality that are not available in claims data (e.g., visual acuity).

2.6.2 Retinal Detachment

Commenters generally expressed concern about the viability of this measure due to the low frequency of this procedure. A few stakeholders estimated that clinicians would have less than 15 episodes per year, creating challenges with statistical validity.

Measure Scope and Opportunity for Improvement

Some stakeholders noted that positive outcomes would not become apparent until after the end of the episode window. Commenters were divided on how to define an episode, with one perspective being that a finite window was necessary to determine success for an operation while another opinion was that a window should be based on clinical endpoints to define the window.

An example of longer-term results was that the use of silicone oil will keep the retina in place, but the actual results may not become observable until after the episode window ends.

A few commenters noted that much of the variation in cost related to the procedure are not within the control of the retina specialist (e.g., due to the lack of control in drug prices). These generally are due to the place of service, such as where the Hospital Outpatient Department (HOPD) or Ambulatory Surgery Center (ASC) determines the type of anesthesia used. A stakeholder also stated that factors like disease chronicity, number of retinal tears, location of retinal tears, presence or absence of vitreous hemorrhage, and family history of retinal detachment are variables outside of the clinician's control, which would significantly affect costs. One commenter recommended the measure may check for history of posterior vitreous detachment or retinal detachment to help account for differences in pre-existing conditions that may impact the likelihood of treatment success.

Several stakeholders have highlighted their concerns with claims data and the measurement tools used by the measure. One commenter noted that ICD-10 codes would need even more granularity to properly describe the type and severity of a particular case and other risk factors (e.g., future retinal detachment) may contribute to differences in costs. A stakeholder stated that it would be challenging to increase the measure's impact and viability using the single-operation success rate or visual acuity. The former would incentivize the usage of less effective alternatives like silicone oil, while dis-incentivizing pneumatic retinopexy surgeries. A commenter noted that claims data cannot provide the necessary variable measurements to incorporate visual acuity outcomes in a cost measure.

2.6.3 Other Viable Measure Concepts

A few stakeholders noted their preference for developing a glaucoma-focused measure for optometrists, which would increase the ability of optometrists to participate in MIPS. While supportive of a glaucoma measure, a commenter noted the inadequacy of Part D drug cost data to stratify care by prescribed drugs and disease severity.

2.6.4 Clinician Expert Workgroup Composition

Several stakeholders provided input on who should be included in a potential workgroup, including optometrists and retina specialists.

2.6.5 Other Concerns and Feedback

A stakeholder highlighted support for further ophthalmologic (and including optometrist) cost measures development, as many optometrists participate in MIPS but their costs are reweighted due to a lack of applicable cost measures.

A stakeholder recommended conducting research and testing to identify clinician-controllable, generalizable cost levers as part of development. This approach would involve going beyond claims data to determine how the clinician is able to prescribe lower-cost drugs (e.g., researching clinicians' knowledge of long-term drug costs and pricing schemes), assessing whether low-cost clinicians' practices can be nationally scaled.

2.7 Kidney Transplant Management

This section summarizes the feedback on the Kidney Transplant Management measure concept. The following subsections describe the comment we received on alignment with Chronic Kidney Disease (CKD) and End-Stage Renal Disease (ESRD) measures in ongoing development, potential consequences for including or excluding kidney transplant patients from kidney care cost measurement, and indicators of quality.

2.7.1 Alignment with CKD/ESRD Measures

The commenter expressed appreciation for the interest to develop a kidney transplant management measure, as complementing the existing CKD/ESRD measures would provide a more holistic picture of kidney care. Appropriately measuring post-transplant care could help to guide providers towards reducing progression of kidney disease and improving patient and caregiver outcomes. The commenter shared statistics highlighting the high-cost of post-transplant care (e.g., readmissions) and underscored the impact of patient education and transition care on patients and Medicare. Addressing transplant costs in MIPS may also appropriately reward nephrologists and other clinicians for slowing the progression of kidney disease.

2.7.2 Potential Consequences

The commenter raised the potential for the measure to alleviate disparities in kidney care. African-Americans account for a disproportionate share of ESRD patients, and they are at greater adjusted mortality risk than the rest of the population. The comment stated a cost measure could help address these and other health disparities by accounting for transplant costs, which may incentivize providers to address early-stage kidney disease.

2.7.3 Quality Alignment for Assessing Value

The commenter expressed support for including kidney disease in an MVP framework, arguing that capturing kidney transplant management through a MIPS episode-based cost measure may also support future MVP development and implementation. Excluding kidney transplant patients from the suite of MIPS cost measures may make any kidney disease MVP less relevant for those clinicians involved in the care management of these patients.

2.8 Gastrointestinal Surgery: Cholecystectomy

No comments were targeted at the cholecystectomy cost measure concept during the public comment period. For this period, we asked questions on measure scope, accounting for emergent and non-emergent cases, services within the influence of proceduralists, opportunities for improvement, preliminary trigger codes, indicators of quality, potential workgroup composition, and other concerns and feedback.

2.9 General Stakeholder Comments: Other Feedback

This section summarizes the other general items of feedback from this comment period not directly aligned with the sections above. One commenter emphasized the importance of the cost measures assessing care holistically for the patient, suggesting that the measures not be focused on a specific disease or condition. They noted that measurement should also factor in the preferences of patients and caregivers (e.g., extending life, comfort, cost efficiency, access to loved ones). A commenter noted that the opportunity for improvement criterion should also consider variation between clinicians of different disciplines. Another commenter noted there should be a process for identifying and correcting cost measure information before final scores are implemented.

3 OVERALL ANALYSIS AND RECOMMENDATIONS

We appreciate the engagement of stakeholders, including person and family stakeholders, with this Wave 5 public comment opportunity. We considered all the feedback received during the public comment period, as it is key to our measure prioritization and development approach. We also conducted empirical analyses to evaluate and further explore items identified via public comment. Based on the public comments, exploratory analyses, and agency priorities, CMS has approved the following cost measures for Wave 5 development: (i) Prostate Cancer, (ii) Rheumatoid Arthritis, and (iii) Kidney Transplant Management.

These 3 measures were selected for Wave 5 development for their strong potential to meaningfully assess clinician cost performance in line with CMS priorities. From public comment and analyses, we believe that prostate cancer would be an appropriate starting point to measure types of cancer due to the feasibility of using administrative claims data for measure construction and its potential to be impactful in a value construct. A kidney transplant management cost measure would further the priority area of kidney care and ensure comprehensive coverage alongside the CKD and ESRD measures for a patient population with high care needs.[3,4] Finally, we believe that a rheumatoid arthritis measure would address measurement and coverage gaps; it also is a clinical topic on which we received support during both the Wave 4 public comment period[5] and this Wave 5 comment period.

At this time, we are not proceeding with developing cost measures for the remaining clinical areas on which we sought public comment for Wave 5. These clinical topics may, however, be considered for future development as we believe that they represent important potential areas for value assessment within MIPS. We appreciate the input from stakeholders about ways to conceptualize measures focusing on anesthesia and diagnostic radiological care, given that these clinical roles differ from the roles in treatment and management of conditions on which other cost measures focus. A PAC cost measure has strong potential to be impactful; however, there is a high degree of heterogeneity within each PAC setting which a cost measure would need to account for. We are not proceeding with developing cost measures for ophthalmologic conditions at this time, but we recognize that there are strong potential clinical

[3] Acumen is developing CKD and ESRD cost measures. The CKD/ESRD workgroup convened on September 23 and October 4, 2021, to provide detailed clinical input to help inform the development of these measures. The CKD/ESRD workgroup will reconvene in 2023 after a national field test of the CKD and ESRD draft measures.

[4] CMS, "Chronic Kidney Disease/End-Stage Renal Disease (CKD/ESRD) Workgroup Meeting Summary", https://www.cms.gov/files/document/summary-ckdesrd-workgroup-webinar.pdf.

[5] CMS, "MACRA Episode-Based Cost Measures: Wave 4 Measure Development Public Comment Summary Report", https://www.cms.gov/files/document/wave-4-public-comment-summary.pdf.

topics that could be explored in future Waves to address measurement gaps and opportunities for cost savings.

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 without the questions intact.

1.1 List of Verbatim Comments

1.1.1 Comment Number 1

- **Date:** 02/18/2022
- **Submitter Name, Credentials, and Organization:** Michael Saitta, MD
- **Comment Text:** Include patient at key decision points as well, such as established patients changing medications or logging a hospitalization.

  There is no good way to do this.

  Variations in overall cost.

  None.

  ancillary providers vs physicians

  have major stakeholders such as American College of Rheumatology or Coalition of State Rheumatology Organizations, nominate qualified people for the workgroup

1.1.2 Comment Number 2

- **Date:** 03/10/2022
- **Submitter Name, Credentials, and Organization:** Lisa Schoyer
- **Comment Text:** for my son, the anesthesiologist, and the post-anesthesia care unit team. good care: pre-procedure review, including being able to share medical history that could inform the administration of anesthesia; acknowledging past anesthesiologists' challenges, confirming what the anesthesiologist would be watching out for (review documented response to various anesthesia drugs - e.g. "coming out of sedation mid-surgical procedure," coding blue on demerol, having HCM with a pressure gradient above 90mmHg); knowledgeable caregiver's access to patient at bedside in PACU who recognized signs of

pain in a nonverbal, developmentally delayed individual with a rare genetic syndrome that had quirky metabolic responses to meds. Complications occurred when the anesthesiologist assumed their experience gave them such confidence that caregiver's input was not necessary, and naive; also when caregiver was not allowed into the PACU during post-anesthesia recovery. My being by my son's bedside also helped me mitigate potential infection to a central line, when the RN did not follow the same sanitary precautions I was taught when replacing the central line lumens (no hand-washing, no gloves before handling the new lumens). It appeared that protection of airway was the only focus; infections being something that could be handled later, if any developed. This was at a tertiary care hospital with a national reputation. Follow-up care: ramping up g-tube feeds to pre-NPO levels rate complications when the doctors insisted that the "rule" of increasing 10cc/hr at the slowest level should be fine. When I couldn't convince them, I had to allow them to follow their protocol, with the caveat that when my son started vomiting, they would reduce the rate to an increase of 5cc/hr. At a pediatric tertiary care hospital, post-surgery extubation scheduled to be removed after 72 hours was inexplicably removed at 24 hrs - which then required re-intubation. Additionally, pain management was not appropriately addressed such that even the ICU RN who saw evident pain wasn't able to get the doctors' attention to alleviate (not sure if this would have still been under the purview of the anesthesiology department)

careful and respectful interview of the patient and patient's family for history; invitation to engage, to the capacity of the family member, including no guilt if the family member does not want to be involved; contributing to the patient's medical records ANY lessons learned to better-personalize the patient's care. I have since learned the code blue for the demerol was due to an 'overdose' effect, but the medical records did not spell that out. Important outcome: no surprises in report of outcome based on the patient's history and what was done -- if there were potential complications before anesthesia that were identified and prepared for, and a complication did occur, was it one of the anticipated complications - and did the mitigating strategies work? If not anticipated, document lessons learned for next anesthesiologist to be aware and prepare.

I can't think of any cost concerns. I have seen and experienced both good and bad approaches, so I assume that the "cost" is to ensure that best practice is provided consistently. The biggest difference I was was difference of personality - those who cared about the patient v. those who cared more about their prowess.

2 situations: 1) the person taking the biopsy in one situation, 2) the protocol by which a biopsy was taken - which involved a radiology tech, a surgeon, and anesthesia (team). The radiology staff were excellent, sympathetic, and apologetic about the protocol.

1) poor care: never meeting the person performing the biopsy - before being laid face-smashed-down and breast hanging through hole in table, nor afterwards - and when I explained my discomfort not knowing a) what to expect or b) who it was who manipulated my breast, was told "he's very busy and doesn't have time for that." Good care: the opposite of all above.

2) poor care: having wire placed to point to area in breast for the biopsy done in a building different from where the surgery was done, such that I, in a hospital gown, had to be wheeled out the building, to the sidewalk on a busy street, wait for a car to transport me a 1/2-block, to and through the front of the hospital to the outpatient surgery suite, a bumpy

ride that kept twanging the wire, causing concern that it had moved, as well as having no privacy at all; and then waiting over 7 hrs (requiring being moved from the outpatient surgical area, which closed during the 6th hour of waiting) for the procedure "because emergencies kept pushing you down the priority list"; not having an interview with the surgeon before the procedure to anticipate what was going to be done; being told to appreciate what she did to potentially save my life when I expressed my astonishment at the size of the biopsy (1x2x3cm out of my size A cup breast - which I learned only after reading the surgery report I was allowed to look at when it was posted). Good care: anticipatory guidance, respect for privacy, consideration of the patient's comfort, respecting the patient's time.

case 1) n/a cases 2) addressing hospital patient-centered policy/procedure, logistics and staffing/scheduling problem

1) ensuring patient receives walk-through of entire procedure, and meets or at least sees a photo image of the doctor in advance if the doctor is too busy to meet in person, and to have the courtesy of introducing him/herself face-to-face with the patient before starting the procedure - do not dehumanize the patient - measure how the patient felt treated - mental wellbeing is important as a resiliency factor, particularly if the test finds a problem. 2) the patient's dignity is effectively considered. Having to spend time in a hospital gown with a wire stuck in my breast on a city street to get from one building to another, and having to go through the main entrance, was a shock for me, not anticipated - and I felt trapped.3) evidence of team cohesion - how do you change that culture?? what incentives might be made? a merit-based friendly competition?

Developing an intrinsic reward system is the challenge - job satisfaction v. billing & revenue...

1.1.3 Comment Number 3

- **Date:** 03/11/2022
- **Submitter Name, Credentials, and Organization:** Anonymous
- **Comment Text:** Nurse;anaesthesiologist;surgeon Preop prep;procedural incidents;postop recovery

  Interactions gaining medical history, explaining procedures why and what to expect. Listen to the patient and respond. Check that information is received.

  Peop anxiety; post op success and minimal adverse events

  Was all the equipment, supplies and personnel billed for necessary?

1.1.4 Comment Number 4

- **Date:** 03/11/2022
- **Submitter Name, Credentials, and Organization:** Dean Roche
- **Comment Text:** Home health agency. Had visiting nurse and physical therapist. Services included monitoring vital signs and medication, providing advice and support to family caregivers. Physical therapist provided essential motor skill support, and in our case, rehabilitation to help family member walk again.

In our case, we "fired" our first agency due to not keeping appointments, not "listening" and just saying their viewpoints. They told us PT would be a waste of time. In contrast the new agency always kept appointments, communicated regularly, made follow-up calls, explained what they were doing and why...they became trusted members of our support team.

not only number of visits but patient progress against a predetermined plan/timeline that is coordinated with clinical staff.

I wouldn't adjust costs/payments up front...I would have a common baseline fee structure. However, I would use performance metrics to determine future payments...say at the end of 6 months or a year, if performance metrics fall below a certain level, then future payments for the coming year would be marked down a certain percentage off the norm for the upcoming year.

1.1.5 Comment Number 5

- **Date:** 03/14/2022
- **Submitter Name, Credentials, and Organization:** Kara Webb, American Optometric Association
- **Comment Text:** We appreciate the efforts of the Centers for Medicare & Medicaid Services (CMS) to identify additional clinical areas that could increase the share of doctors who can report a Merit Based Incentive Payment System (MIPS) episode-based cost measure. CMS has specifically noted that there are concerns with a lack of cost measures for ophthalmologists. The same concerns exist for doctors of optometry as well. Many doctors of optometry participate in MIPS, but typically have the cost category reweighted due to a lack of applicable measures. Developing additional cost measures would allow these doctors to more fully participate in MIPS.

  CMS has proposed two new clinical areas of focus for potential cost measures-- the chronic management of Age-related Macular Degeneration (AMD) and the Retinal Detachment procedure. The AOA would appreciate the opportunity to take part in any Clinician Expert Workgroups for the candidate episode groups related to these areas of patient care. With clinical knowledge and expertise in caring for patients with AMD and retinal detachments, doctors of optometry could contribute to the development of measures that are impactful.

  Both AMD and retinal detachments are complex areas of patient care. Inferring AMD clinical outcomes from claims data could be a significant challenge, especially given variances in treatment costs and individual patient considerations and pre-existing conditions which may lead to certain interventions being selected over others. The work of any Clinician Expert Workgroups will be critical for the development of viable cost measures.

  CMS has also requested feedback on additional clinical areas of care that would be strong candidates for development. We believe a glaucoma focused measure could be a fruitful area of focus for doctors of optometry.

1.1.6 Comment Number 6

- **Date:** 03/15/2022

- **Submitter Name, Credentials, and Organization:** Steve Gnatz, MD, MHA, Integrated Rehab Consultants[6]
- **Comment Text:** Specifically related to the SNF population, we believe that patients undergoing rehabilitation with a goal of discharge to home represent a distinct cohort of patients where efforts to improve cost effectiveness can be enhanced. In the IRF environment, it is a CMS requirement that a "rehabilitation physician" be involved in their care. However, currently there is no such requirement in the SNF. We have shown (attached) that physiatrist-led rehabilitation in the SNF leads to lower return to acute care rates, lower lengths of stay, and other cost savings. At the very least, CMS should recognize that patients in short-term rehab programs in a SNF, with a goal of discharge home, represent a fundamentally different patient population from those in LTC - even if they may appear similar based on their medical conditions. While we believe that rehabilitative efforts in the LTC patient population often lead to enhanced quality of life for these residents, we acknowledge that the cost-effectiveness of such efforts are more difficult to establish. The cost effectiveness of a more universally present physiatric "mind-set" of maximizing patient independence, minimizing institutionalization, and establishing appropriate length of stay, would be a welcome in the SNF level of care.

  In the IRF prospective payment system (PPS) model, we believe that the stratification of patient diagnoses, medical acuity/comorbidities, and other characteristics (age, etc.) fairly robustly captures the essential elements needed to predict costs in that level of care. But the IRF model was based on years of foundational work by FIM-UDS and others that is altogether lacking in the SNF and HH levels of PAC. We also acknowledge that the much simpler process that resulted in PDPM has started the move toward a future PPS in the SNF. It remains to be seen if this process can maintain validity in terms of costs of care moving forward. Our suggestion is to take the same approach to developing PPS in all levels of PAC - that is to carefully stratify patients based on characteristics that define their needs and only then define the payment model. As noted in the prior comment, we believe that physiatrists have a major role to play in cost containment in all PAC levels of care and that CMS should mandate their involvement for any patient undergoing a rehabilitation program in any level of PAC.

  Costs based on a sufficiently granular analysis of patient characteristics should have limited variation. When outliers are present, they often represent factors unrelated to medical issues - such as absence of social support or other socioeconomic disparities. Accounting for these "non-medical" conditions would go a long way toward reducing the variability or at least recognizing its role in health care costs.

  Trigger codes for patients requiring rehabilitation cover almost the entire ICD-10, but when combined with other characteristics such as functional status, age, presence of comorbid conditions, etc. will be more easily stratified into a clinically coherent patient cohort. If there was a facility code for short-term rehab in a SNF with the expectation of discharge home, that might be helpful in sorting patients.

[6] This commenter attached a research abstract for his survey response: "Effects of Physiatric Consultation in Post-acute Care". Journal of the American Medical Directors Association, 20(3), B27.

We have previously proposed a cost measure as a part of an MVP proposal on fall prevention. We would be glad to see such a cost measure move forward.

Physiatrists, other clinicians involved in PAC, health care economists.

1.1.7 Comment Number 7

- **Date:** 03/19/2022
- **Submitter Name, Credentials, and Organization:** Barbara Burdett
- **Comment Text:** [redacted] had prostate cancer and was treated [redacted] in Salt Lake City, Utah. He was seen by an oncologist, radiologist, surgeon, urology, and primary care physician.

  Regular follow-up is important and necessary. He had complications following radiation and was unable to complete the treatment due to bladder complications. He is regularly evaluated and it has been seven years.

  A cancer free diagnosis should be the ultimate outcome. However many times treatment causes additional concerns, ie radiation and bladder functions which diminishes value.

  A cancer diagnosis can be a life-long concern as treatment can cause additional damage that will be a life altering challenge. In addition, cancer can metastasize later that would be difficult to assess the cost of care.

1.1.8 Comment Number 8

- **Date:** 03/22/2022
- **Submitter Name, Credentials, and Organization:** Rachel Groman, American Association of Neurological Surgeons and Congress of Neurological Surgeons
- **Comment Text:** The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) are concerned about Acumen developing a cost measure for a condition involving pain when it is impossible to judge the severity of this condition and response to interventions from claims data alone. Representatives from our organizations have been intimately involved in developing episode-based cost measures previously released. They have repeatedly encountered challenges regarding the failure of these cost measures to simultaneously account for quality or outcomes (e.g., in the context of the Low Back Pain measure). This unresolved shortcoming would be especially problematic for a cost measure focused on pain management. Acumen states that a goal is to reduce "unnecessary" costly injections. Yet, the methodologies applied to cost measures to date have provided no way of deciphering which interventions are necessary and which are not.

  The AANS and CNS recommend against moving ahead with a pain management cost measure at this time due to methodological constraints that limit the ability to evaluate which interventions are necessary and which are not in the context of cost. However, if Acumen ultimately decides to embark on the development of a pain measure, we strongly urge it to include neurosurgeons in the measure development workgroup. Neurosurgeons play a critical role in pain management, treating a range of acute and chronic pain conditions, including atypical facial pain (trigeminal neuralgia), chronic and acute back pain, failed spinal surgery, phantom limb pain, stroke and headache. Members of the AANS/CNS

Section on Pain are also involved in numerous clinical trials and developing clinical practice guidelines related to pain.

1.1.9 Comment Number 9

- **Date:** 03/22/2022
- **Submitter Name, Credentials, and Organization:** Anne Hubbard, MBA, American Society for Radiation Oncology
- **Comment Text:** The American Society for Radiation Oncology [7] is writing in response to the Wave 5 MIPS Cost Measure Development Proposal issued by the Centers for Medicare and Medicaid Services (CMS) and Acumen, LLC. The Wave 5 Measure Development document includes a proposal to establish a cost measure associated with prostate cancer. ASTRO appreciates the opportunity to provide comments on this segment of the overall proposal.

  According to the proposal, a prostate cancer episode would be triggered by a pair of services billed by the same clinician group that indicate the start of a care relationship to treat prostate cancer, such as outpatient evaluation and management (E&M) services or chemotherapy when paired with prostate cancer diagnosis codes.

  Before responding to the specific questions related to the measure, we recommend that CMS and Acumen acquaint themselves with the National Comprehensive Cancer Network (NCCN) guidelines specific to prostate cancer. Review of the guidelines will give CMS and Acumen a clear understanding of the variety of prostate cancer stages that exist, as well as the variety of treatment options that each stage may involve. Variation in the cost of treating prostate cancer can be attributed to these factors and must be considered as part of any measure development activity.

  Question 1: Other cost measures have used algorithms as proxies to identify conditions of interest to account for differences in expected costs. For example, the diabetes cost measure that was added to MIPS in 2022 stratifies patients into sub-groups for Type 1 and Type 2 diabetes based on independent indicators (e.g., share of Type 1 or Type 2 diagnosis codes over a year-long period), and the degree of agreement across these tests. How should this measure account for differences in costs due to cancer severity using administrative claims data?

  The proposal cites ICD-10 diagnosis codes in combination with or without secondary malignancy site codes, as well as a combination of ICD-10 data with hospitalizations or multiple outpatient visits as a potential for measuring cancer severity. While these claims-based data points may be helpful, they are limited and could potentially misinform the true severity of the disease if used as a proxy for staging prostate cancer.

[7] ASTRO members are medical professionals practicing at hospitals and cancer treatment centers in the United States and around the globe. They make up the radiation treatment teams that are critical in the fight against cancer. These teams include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists, and social workers. They treat more than one million patients with cancer each year. We believe this multidisciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services.

Cancer staging is the most accurate way of understanding the severity of the diagnosis and the related treatment requirements associated with care delivery. For prostate cancer, staging as well as risk stratification, are the key considerations in understanding the differences in modality of treatment used, as well as the expected costs associated with treatment.

The proposal also states that it would compare any classification system against other indictors in claims data and check whether patients identified are receiving services that would be expected for that state or level of severity. In order to do this, CMS and Acumen need only refer to NCCN guidelines as a resource for determining the services expected by disease stage. Again, the challenge comes in collecting data on disease stage and risk category to make that determination.

Question 2: Are other types of cancer preferable for measure development, such as breast or lung cancer? Should we consider a broad cancer measure that stratifies patients by type of cancer and stage, and if so, what would that measure need to account for to ensure clinically meaningful comparisons?

Given that prostate cancer has a variety of stages and treatment scenarios that run the gamut between radical prostatectomy, which involves inpatient surgery, and radiation therapy, which is typically delivered in the outpatient setting, it may be reasonable to consider a more narrowly defined disease site with more distinct treatment regimes. Early-stage breast cancer for example may be worth exploring.

As a result of the Wave 1 cost measures development work, CMS and Acumen established the *Lumpectomy, Partial Mastectomy, Simple Mastectomy Measure*. This measure evaluates the risk-adjusted cost to Medicare for beneficiaries who undergo partial or total mastectomy for breast cancer during the performance period. The cost measure score is the clinician's risk-adjusted cost for the episode group averaged across all episodes attributed to the clinician's role in managing care during each episode from 30 days prior to the clinical event that opens, or "triggers," the episode through 90 days after the trigger.

Patients who are treated for breast cancer with a lumpectomy, partial mastectomy, or simple mastectomy are frequently referred to a radiation oncologist and/or a medical oncologist for further treatment with radiation therapy and/or chemotherapy. Because CMS and Acumen have already established the surgical cost measure, it would be reasonable to consider a post-surgical cost measure specific to the radiation oncology and medical oncology services that are delivered as part of the overall cancer care continuum.

Additionally, since patients are already identified under the surgical cost measure, this may alleviate the complexity of capturing the intended patient population. We would welcome a dialogue with CMS, Acumen and our colleagues at the American Society for Clinical Oncology to further discuss how such a measure would be developed and implemented.

Question 3: Given that drug costs dominate costs of care across types of cancer, what are other opportunities for cost improvement? That is, what types of services are clinically related to the treatment and management of cancer that could distinguish variation in care?

As discussed in our response to Question 2, rather than focus on prostate cancer, an opportunity may exist with the establishment of a breast cancer cost measure to further explore the cost of drugs related to cancer treatment. We would encourage CMS and Acumen to give this further consideration.

Finally, while we recognize in this most recent proposal that CMS and Acumen are taking a different approach to selecting measures for development, we thought it important to revisit previous discussions. In Waves 1-3, Acumen obtained input on measure prioritization by convening experts in Clinical Subcommittees (CS), including one on urology that met in the spring of 2018. The CS discussed and voted on preferred episode groups which prioritized the groups for future measure development[8]. That exercise included prostate cancer treatment, which came in behind Kidney Stone Removal or Destruction and Procedure Benign Prostatic Hyperplasia. Work began on kidney stone removal, which resulted in the establishment of a Renal or Ureteral Stone Surgical Treatment measure. We are somewhat surprised that Acumen would decide to jump to prostate cancer rather than begin work on establishing a cost measure for Procedure for Benign Prostatic Hyperplasia or consider building on existing measures as suggested above.

1.1.10 Comment Number 10

- **Date:** 03/25/2022
- **Submitter Name, Credentials, and Organization:** Emily L. Graham, Coalition of State Rheumatology Organizations
- **Comment Text:** The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist.

  Today, we write to share feedback on the development of episode-based cost measures in the Rheumatoid Arthritis (RA) clinical area as part of the MACRA Episode-Based Cost Measures (Wave 5) Call for Public Comments. Generally, these comments are consistent with our prior feedback on Wave 4, but have been updated to address new questions being posed and reflect innovations in this disease area.

  General Comments

  We appreciate the challenge in developing an episode-based cost measure for RA (e.g., identifying the patient cohort and accounting for certain costs) and understand why the Centers for Medicare and Medicaid Services (CMS) prioritized other clinical areas during Wave 4. As we've noted in prior comments, there are no appropriate resource use measures for rheumatologists under the Quality Payment Program (QPP) Merit-Based Incentive Payment System (MIPS) and Advance Alternative Payment Model (AAPM) tracks. Given the agency will soon implement a MIPS Value Pathway (MVP) for Advancing

[8] Episode Group Prioritization Survey Results – MACRA Episode-Based Cost Measures Clinical Subcommittees – Urologic Disease Management. April 2018

Rheumatology Patient Care in CY 2023, we agree it would be useful to attempt development of a more applicable measure of costs in RA.

As it did during Wave 4, Acumen highlights potential opportunities for improvement associated with variation in treatment (i.e., drug options) and efficient monitoring/imaging/therapy, including for adverse effects to treatments. With respect to treatment options, we previously shared that RA medications span across Part B ("medical" or "physician-administered") and Part D ("pharmacy" or "self-administered"), and emphasized that all pharmaceutical costs must be considered when evaluating resource use for RA. We appreciate that Acumen discussed the inclusion of Part D drugs as part of its Wave 4 Frequently Asked Questions (FAQ) document, which states that "Part D should be considered on a case-by-case basis," and that "[m]easures where Part D makes up a substantial portion of care or where assessing clinician performance may be incomplete without Part D could be candidates for including Part D drugs."

Unfortunately, the list of "trigger codes" that would start an episode only includes physician- administered drugs, without any mention of self-administered drugs (see screenshot below) [screenshot redacted], which is inconsistent with sentiments outlined above.

Measuring the use of Part B drugs alone inappropriately penalizes physicians whose patient population may require office-administered medications, and puts them at a disadvantage over their peers who may prescribe more self-administered drugs covered under Part D, since the former would appear more costly than the latter. Worse, it has the potential to influence treatment decisions as physicians are perversely incentivized to prescribe Part D drugs when Part B drugs may be more appropriate for the patient. **Any resource use measurement for RA must include both physician- and self-administered drugs.**

Response to Key Questions

Question 1: Stakeholders have suggested focusing on newly diagnosed rheumatoid arthritis patients. Since this would result in lower beneficiary and cost coverage, is there a way to define a broader (yet still clinically coherent) patient cohort that could represent a viable measure? For example, are there opportunities for improvement in later stages of the disease?

Focusing on newly diagnosed RA patients is a reasonable first-step toward measuring RA costs-of-care. This would allow the agency and its contractor, with feedback from stakeholders and the Technical Expert Panel (TEP), to address anticipated challenges with measuring Part B and Part D drugs, among other potential challenges. Once the expected "kinks" have been addressed, expanding the measure denominator – or developing additional measures – to account for patients in later stages of RA disease would be more reasonable.

Question 2: Using claims data, how should the measure account for differences in costs due to rheumatoid arthritis severity or patients' responses to medication? Some example approaches include: linking severity to prescription/dialogic use, using the claims based index of rheumatoid arthritis severity (CIRAS), using the presence of extraarticular manifestations (e.g., pulmonary, ocular), and looking for the presence of other comorbidities or services (e.g., coronary artery disease, lymphoma, lung disease, vasculitis, and side effects from medications).

We noted previously that accounting for differences in RA severity are accomplished with the use of disease activity indices (subjective) and blood-based testing (objective). Commonly used disease activity indices include the Routine Assessment of Patient Index Data 3 (RAPID3), Clinical Disease Activity Index (CDAI) for RA, and Simple Disease Activity Index (SDAI) for RA. These patient reported outcome tools are frequently used alongside objective assessments and laboratory testing, such as erythrocyte sedimentation (sed) rate, C-reactive protein (CRP), complete blood count (CBC), rheumatoid factor (RF), antibodies to cyclic citrullinated peptides (CCP), and occasionally multi-biomarker tests designed for RA. Together with the clinical judgement of the rheumatologist, these tools can help in the assessment of disease activity and point the way to the best treatment for the patient.

Regarding certain types of services or diagnoses available via claims that may be useful in identifying various levels of severity, we suggest considering the continued use of steroids, the presence of comorbidities, such as premature coronary artery disease (CAD), lymphoma, interstitial lung disease, vasculitis, and side effects from medications (e.g., corticosteroids), as well as consultations with other specialties, a history of orthopedic surgery, particularly joint replacements. and certain other laboratory findings (double positive RF and CCP), and imaging (radiographic progression).

With regard to patients' responses to medications, we note that innovations in precision medicine have led to the development of new predictive drug response testing tools in RA. As we shared in comments to CMS' Molecular Diagnostics (MolDX) program, there are no published studies to suggest the optimal sequence of different therapies following non-biologic DMARDs. The rheumatologist's clinical assessment and shared decision making with the patient is the best approach but can result in several treatment failures before the optimal regimen is found. This new predictive drug response testing may aid in finding the best medication sooner, allowing patients to achieve remission earlier, potentially reducing their risk of comorbid conditions such as coronary heart disease and lymphoma.

Concluding Remarks

Regardless of whether CMS prioritizes RA for Wave 5 or postpones to a later time, we again emphasize that cost and resource use measurement should not bias treatment decisions, nor penalize them for delivering clinically appropriate care in the best interest of their patients. Again, whether the solution is to remove Part B drug costs or to incorporate Part D drug costs, **the most important thing is that episode-based cost measures do not have an adverse impact on practice patterns and do not discourage treatments that best meet the needs of the patient.**

1.1.11 Comment Number 11

- **Date:** 03/25/2022
- **Submitter Name, Credentials, and Organization:** Ralph Kohl, American Association of Nurse Anesthesiology
- **Comment Text:** The AANA welcomes the opportunity to comment on the Wave 5 Measure Development feedback survey. We thank the Centers for Medicare & Medicaid Services (CMS) and Acumen for considering anesthesia care as a clinical candidate area and for allowing CRNAs to participate in panels and subcommittees on previous Waves. Our

comments are focused on the survey questions on anesthesia care, cross-cutting questions for wave 5 candidate groups, and participating on Wave 5 development.

Background of the AANA and CRNAs

The AANA is the professional association for Certified Registered Nurse Anesthetists (CRNAs) and student registered nurse anesthetists (SRNAs). AANA membership includes more than 59,000 CRNAs and SRNAs, representing about 90 percent of the nurse anesthetists in the United States. CRNAs are advanced practice registered nurses (APRNs) who personally administer more than 50 million anesthetics to patients each year in the United States and are included among the nation's most trusted professions according to Gallup.[9] Nurse anesthetists have provided anesthesia in the United States for 150 years, and high-quality, cost-effective CRNA services are in high demand. CRNAs are Medicare Part B providers and since 1989 have billed Medicare directly for 100 percent of the physician fee schedule amount for services. CRNAs also play an essential role in assuring that rural America has access to critical anesthesia services, often serving as the sole anesthesia provider in rural hospitals, affording these facilities the capability to provide many necessary procedures.

CRNAs are involved in every aspect of anesthesia services including a pre-anesthesia patient assessment, obtaining informed consent for anesthesia administration, developing a plan for anesthesia administration, administering the anesthetic, monitoring and interpreting the patient's vital signs, and managing the patient throughout the surgery and recovery. CRNAs also provide acute, chronic, and interventional pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and in some states are the sole anesthesia providers in nearly 100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities. Nurse anesthesia predominates in Veterans Hospitals and in the U.S. Armed Services. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers (ASCs), pain management facilities, and the offices of dentists, podiatrists, and all types of specialty surgeons.

Numerous peer reviewed studies have shown that CRNAs are safe, high quality and cost effective anesthesia professionals who should practice to the full extent of their education and abilities. According to a May/June 2010 study published in the journal Nursing Economic$, CRNAs acting as the sole anesthesia provider are the most cost-effective model for anesthesia delivery, and there is no measurable difference in the quality of care between CRNAs and other anesthesia providers or by anesthesia delivery model.[10] An August 2010 study published in Health Affairs showed no differences in patient outcomes when anesthesia services are provided by CRNAs, physicians, or CRNAs supervised by physicians.[11] Researchers studying anesthesia safety found no differences in care between nurse

[9] Gallup "U.S. Ethics Ratings Rise for Medical Workers and Teachers (December 22, 2020), https://news.gallup.com/poll/328136/ethics-ratings-rise-medical-workers-teachers.aspx

[10] Paul F. Hogan et al., "Cost Effectiveness Analysis of Anesthesia Providers." Nursing Economic$. 2010; 28:159-169.

[11] B. Dulisse and J. Cromwell, "No Harm Found When Nurse Anesthetists Work Without Physician Supervision." Health Affairs. 2010; 29: 1469-1475. http://content.healthaffairs.org/content/29/8/1469.full.pdf

anesthetists and physician anesthesiologists based on an exhaustive analysis of research literature published in the United States and around the world, according to a scientific literature review prepared by the Cochrane Collaboration, the internationally recognized authority on evidence-based practice in healthcare.[12] Most recently, a study published in Medical Care (June 2016) found no measurable impact in anesthesia complications from nurse anesthetist scope of practice or practice restrictions.[13]

The importance of CRNA services in rural areas was highlighted in a recent study which examined the relationship between socioeconomic factors related to geography and insurance type and the distribution of anesthesia provider type.[14] The study correlated CRNAs with lowerincome populations and correlated anesthesiologist services with higher-income populations. Of particular importance to the implementation of public benefit programs in the U.S., the study also showed that compared with anesthesiologists, CRNAs are more likely to work in areas with lower median incomes and larger populations of citizens who are unemployed, uninsured, and/or Medicaid beneficiaries.[15] This information highlights the importance of CRNAs who provide high-quality, evidence-based care to millions of Americans living and working in rural and underserved areas. Allowing them to participate in rural emergency hospitals will increase needed access to care for patients who live in these areas.

4.1.1 Anesthesia Care

Response to Question 1: Previous stakeholder feedback has identified some anesthesiarelated complications such as airway injury from intubation, untreated hypothermia, and nerve injury for a peripheral block. Since these may be infrequent, are there other services for complications or other follow-up care that could differentiate good care from poor care? That is, if a cost measure is centered on anesthesia services for a type of surgery, what sort of complications and other follow-up services may be reasonably influenced by the clinician providing the anesthesia services rather than the surgeon alone?

We believe that the episode group measures should accurately account for the true cost of providing anesthesia care services and should accurately attribute anesthesia care services to the proper clinician. Typically, complications around anesthesia happen within 24 to 48 hours after surgery; therefore, the attribution of complications should be limited to the perioperative setting. We believe it is critical that CRNAs should not be responsible for overall surgical complications that are unrelated to anesthesia.

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[12] Lewis SR, Nicholson A, Smith AF, Alderson P. Physician anaesthetists versus non-physician providers of anaesthesia for surgical patients. Cochrane Database of Systematic Reviews 2014, Issue 7. Art. No.: CD010357. DOI: 10.1002/14651858.CD010357.pub2. http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD010357.pub2/abstract

[13] Negrusa B et al. Scope of practice laws and anesthesia complications: No measurable impact of certified registered nurse anesthetist expanded scope of practice on anesthesia-related complications. Medical Care June 2016.

[14] Liao CJ, Qurashi JA, Jordan LM. Geographical Imbalance of Anesthesia Providers and its Impact on the Uninsured and Vulnerable Populations. Nurs Econ. 2015;33(5):263-270.

[15] Liao, op cit

One area of service that may be reasonably influenced by the clinician providing the anesthesia services rather than the surgeon is the use of techniques such as anesthesia enhanced recovery after surgery (ERAS®) programs. ERAS® is a patient-centered, evidence-based, pain management strategy employed by CRNAs to reduce the need for opioids, improve patient outcomes and reduce costs.[16] Using specific protocol-driven enhanced recovery after surgery pathways improves patient outcomes by reducing the patient's stress response to surgery, shortening the overall hospital length of stay, and accelerating the return to normal daily function. For example, the enhanced recovery pathway for total hip arthroplasty engages the entire perioperative team with the patient to limit care variation that improves outcomes and patient satisfaction. A total hip arthroplasty that includes minimally invasive surgical techniques and multimodal pain management with motor sparing regional anesthesia allows the patient to eat, drink and walk/exercise soon after recovery from anesthesia. The patient's pain management plan of care begins pre-procedure and continues through post-discharge using techniques such as regional anesthesia including placement of epidural catheters, targeted peripheral nerve blocks, non-pharmacologic approaches, and non-opioid based pharmacologic measures.

As ERAS® pathways have been implemented, patient engagement in their own plan of care has improved return to preprocedure health on the day of surgery. CRNAs play an integral role in these episodes of care, in both inpatient and outpatient settings, as proper anesthesia services management can make a tremendous difference in terms of improving patient flow, patient safety, and ultimately in cost savings.[17] Conversely, research shows that suboptimal care in the preoperative, intraoperative, or postoperative phases of surgery may compromise care, resulting in poor patient outcomes and unnecessarily higher healthcare costs.[18] Facility and population specific ERAS® protocols engages the patient and the multidisciplinary team in the plan of care and continued assessment of patient status to optimize care, decrease complications, decrease time to discharge, improve outcomes and lower cost of care by limiting variation in care. CRNAs provide many ERAS® elements of care to optimize the patient to return to normal activity and diet, including minimally invasive surgical techniques, giving the patient a carbohydrate beverage at least two hours before surgery, maintaining patient warmth during the procedure and also providing multimodal pain management services to minimize or eliminate use of opioids.

Response to Question 2: Should we develop a broad anesthesia measure for all types of procedures, or would it be better to develop something narrower (e.g., anesthesia for joint replacement)? If a narrower measure is preferred, what scope of services would help capture anesthesia care services provided by anesthesiologists and CRNA broadly? If a broad measure is preferred, would sub-grouping by procedure type be useful?

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[16] AANA Enhanced Recovery After Surgery, https://www.aana.com/practice/clinical-practice-resources/enhanced-recovery-after-surgery

[17] See for example Rice AN, Muckler VC, Miller WR, Vacchiano CA. Fast-tracking ambulatory surgery patients following anesthesia. J Perianesth Nurs. Apr 2015;30(2):124-133. Also see Kimbrough CW et al. Improved Operating Room Efficiency via Constraint Management: Experience of a Tertiary-Care Academic Medical Center. Journal of the American College of Surgeons 2015; 221: 154-162

[18] 10. Miller TE, Roche AM, Mythen M. Fluid Management and Goal-Directed Therapy as an Adjunct to Enhanced Recovery After Surgery (ERAS). Canadian Journal of Anesthesia 2015; 62 (2)" 158-168

What categorization of procedure type would be clinically coherent for a broad anesthesia measure?

While an argument could be made for both the development of a narrower or a broader measure, we believe a broader measure would be better to develop. Under the broader umbrella, ERAS, as outlined above, would apply to a substantial share of anesthesiologists and CRNAs.

Response to Question 3: What other related services, besides injections, could be included in an interventional pain management measure? For example, if injections are not successful at managing pain, what would a clinician focusing on pain management care provide as the next line of treatment? What sorts of services would a patient with poorly managed pain receive that would be different in frequency or intensity than a patient with well-managed pain?

Interventional pain management is distinct from surgical pain management. Interventional pain management requires the use of multimodal pain multimodal pain management that "addresses the full range of an individual patient's biopsychosocial challenges, by providing a range of multiple and different types of therapies that may include medical, surgical, psychological, behavioral, and integrative approaches as needed".[19] CRNAs who provide interventional pain management provide comprehensive patient-centered pain management to optimize recovery. CRNAs practice in accordance with their professional scope of practice, federal and state law, guidelines, and facility policy to provide acute and chronic pain management services. As an example of employing techniques outside of injections, it is not uncommon for CRNA chronic pain management practitioners to provide the placement and management of nonsurgical neurostimulating systems. In addition, CRNAs may perform drug screenings or may order services such as physical therapy and imaging. While these are not an exhaustive list of the services that a CRNA performing interventional pain management may utilize, these examples show the vast range of services that could be provided.

Response to Question 4: Should a measure on interventional pain management focus on acute pain management (e.g., local anesthetics such as facet injections), chronic pain management (e.g., local pain intervention such as treatments for tendonitis or carpal tunnel), or both? Using claims data, what approaches could we consider to help identify chronic versus acute interventional pain management?

We find that acute pain management would be surgically related while chronic pain management would be related to non-surgical pain or to chronic pain resulting after surgery. This should be very easy to differentiate using claims data.

5.1 Cross-Cutting Questions for All Wave 5 Candidate Episode Groups

Response to Opportunity for improvement: What kinds of services can reflect that the candidate episode group has sufficient opportunities for improvement? For example,

[19] National Academy of Medicine. 2011. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. Washington, DC: The National Academies Press

cost measures generally include services reflecting variation in treatment options, intensity/duration, follow-up care, complications, and more.

Determining which procedural episode group, by CPT and Trigger codes, could benefit from regional anesthesia given for acute pain management and or ERAS® protocols, crossed referenced with actual techniques used, could potentially lead to measures reflecting variation in treatment options, intensity/duration, follow-up care and complications. The challenge with this is to accurately capture these elements tied to anesthesia services. There can be a lot of variability in patients who undergo the same type of procedure in terms of intensity and duration, patient physical status factors, and follow-up care and complications will be given the same types of procedures. We believe it is possible to capture patients with similar characteristics, but there may be issues with not having several large populations with the same characteristics.

Response to Trigger codes: Trigger codes define the patient cohort for the measure. The preliminary set of draft trigger codes we propose is in the accompanying Preliminary Specifications of Wave 5 Candidate Episode Groups workbook. We solicit comment on this list of draft trigger codes to help inform the patient cohort. What modifications can we apply to these draft trigger codes to ensure a measure represents a clinically coherent patient cohort and also sufficient impact and coverage?

Identifying a trigger code that could benefit from regional anesthesia performed by an anesthesia provider and or ERAS® protocols used could be beneficial and measurable. However, while trigger codes in concept are a good idea, they are not always practical. As an example, many anesthesia providers go to work to perform an anesthetic. The anesthesia billing department staff will submit a bill for the service provided. In one instance, the patient has an issue such as hypothermia, but that issue is not reflected in the initial submitted bill as no trigger code is submitted. The issue becomes tricky as it is not clear who is responsible for submitting this code and how that trigger code would be linked to the provider. Furthermore, the question is whether it is appropriate to submit a trigger code about an issue the anesthesia provider has no idea is being submitted and potentially being penalized as a result of that trigger code.

Response to Additional concerns: Are there any other concerns that may be present with assessing the care of patients in this clinical area? If so, what are some potential approaches to address these concerns for a cost measure?

We have concerns that there are instances in which the anesthesia provider may be not in full control with respect to the use of ERAS® protocols. For example, if a surgeon or facility is not willing to allow the provider to perform regional anesthesia techniques for post-op pain control or institute ERAS® protocols, anesthesia providers will be limited in what they can measure.

5.2 Participation in Wave 5 Development

Response to Wave 5 Workgroup Composition: Are you interested in participating in Wave 5? You may submit input on which specialties and stakeholders should be considered for the workgroup, as well as contact information for outreach related to clinician expert workgroup composition if anesthesia or interventional pain management is selected for development.

The AANA has members who are interested in participating in Wave 5. The AANA and CRNAs should be included for the anesthesia and interventional pain management clinical expert workgroup composition if these topic areas are selected for development. CRNAs are involved in every aspect of anesthesia services including a pre-anesthesia patient assessment, obtaining informed consent for anesthesia administration, developing a plan for anesthesia administration, administering the anesthetic, monitoring and interpreting the patient's vital signs, and managing the patient throughout the surgery and recovery. CRNAs also provide acute, chronic, and interventional pain management services. As advanced practice registered nurses, CRNAs are uniquely skilled to deliver pain management in a compassionate and holistic manner. CRNAs provide chronic pain management services in various settings, such as hospitals, ambulatory surgical centers (ASCs), offices, and pain management clinics. By virtue of education and individual clinical experience and competency, a CRNA may practice chronic pain management utilizing a variety of therapeutic, physiological, pharmacological, interventional, and psychological modalities in the management and treatment of pain.

Response to Are you interested in participating in Wave 5: Would you be interested in nominating someone for the workgroup? We will include you in future emails related to the nomination period later in spring 2022 - please include the name and email address of all interested parties.

The AANA would be interested in nominating someone for a workgroup on anesthesia and interventional pain management measures.

1.1.12 Comment Number 12

- **Date:** 03/26/2022
- **Submitter Name, Credentials, and Organization:** Christina L. Gaffney
- **Comment Text:** Hines VA Hospital

Option for Ultrasound screening rather than traditional flattening mammogram.

Genetic testing.

Immediate diagnostic evaluation with the doctor.

Ultrasound.

Was my [redacted] and her Primary Care Provider. He was obtuse, if not absolute to lack of patient fears. Empathy. Willingness to answer questions. Positive comments on survival. Ability to offer an agenda for care.

Provide adequate information regarding next steps.

Willingness to assist in the process and work with other doctors involved with testing, options, surgery, etc.

Co-pays became problematic. Time off work quickly ate up sick days and vacation days and nearly caused termination. Time off work was financially hindering and resulted in a domino effect in every way. So laws protecting the jobs during care are integral to treatment for cancer.

1.1.13 Comment Number 13

- **Date:** 03/27/2022
- **Submitter Name, Credentials, and Organization:** Jennifer Moser, CNA, CMAA, Jenny Cares
- **Comment Text:** I have worked in an LTC facility and in my opion care should be more patient/resident specific instead of how a coorporation thinks care should be provided.

  Each person should be cared for as the reason for being their not treat a rehab patient as a resident with dementia would be treated.

  The biggest thing needs to be trainin g for all staff working in those settings. The staff are not trained long enough or properly to provide various types of care.

  Bedside manners!!!!!

  Again the biggest thing is bedside manner and training.

  Have those clinicians actually done hands on patient care? IE bathing, feeding, grooming etc?

  Yes.

  I would say there is always room for improvement in every aspect of life so yes room for improvement would be an understatement.

1.1.14 Comment Number 14

- **Date:** 03/28/2022
- **Submitter Name, Credentials, and Organization:** Alanna Goldstein, MPH, American Geriatrics Society
- **Comment Text:** The American Geriatrics Society (AGS) greatly appreciates the opportunity to provide feedback to the Centers for Medicare and Medicaid Services (CMS) and Acumen, LLC on episode groups to consider for Wave 5 of the Merit-based Incentive Payment System (MIPS) cost measure development to meet the requirements of the Medicare Access and CHIP Reauthorization Act (MACRA). The AGS is a nationwide, not-for-profit society of geriatrics healthcare professionals dedicated to improving the health, independence, and quality of life of older people. Our 6,000+ members include geriatricians, geriatrics nurse practitioners, social workers, family practitioners, physician assistants, pharmacists, and internists who are pioneers in advanced-illness care for older individuals, with a focus on championing interprofessional teams, eliciting personal care goals, and treating older people as whole persons. The AGS believes in a just society – one where we all are supported by and able to contribute to communities and where ageism, ableism, classism, homophobia, racism, sexism, xenophobia, and other forms of bias and discrimination no longer impact healthcare access, quality, and outcomes for older adults and their caregivers. The AGS advocates for policies and programs that support the health, independence, and quality of life of all of us as we age.

  As the healthcare providers for older adults—particularly those with multiple chronic and complex conditions—the AGS believes that care should be provided from a team-based and

person-centered perspective, focusing on the whole person and what matters to the patient. In order to provide person-centered care, it is critically important to understand the patient holistically, considering the complexity of the multiple conditions, medications, symptoms, as well as the patient's values and preferences. We are concerned that with the current episodic approach, patients with multiple chronic disease will be treated as though these conditions exist independently of one another.

The AGS appreciates the opportunity to review the episode groups for consideration of the Wave 5 MIPS cost measure development and share our recommendations which we hope you will consider as you move through the cost measure development process.

The AGS strongly supports striving for the optimal result for the overall patient. Geriatrics health professionals focus on the 5Ms of geriatrics: Multimorbidity, What Matters, Medication, Mentation, and Mobility. Multimorbidity describes the older person who has more complex needs often due to multiple chronic conditions, frailty, and/or complex psychosocial needs. What Matters, Medication, Mentation, and Mobility describe the four main areas where geriatrics health professionals focus their clinical attention and form the basis for the age-friendly health systems framework that is focused on ensuring that all older people have access to this type of coordinated care, while also making sure personal needs, values, and preferences are at the heart of that care. We believe that the cost performance of each condition should not be separated and that cost performance evaluation should consider the cost of treating the patient, not their individual conditions, given that the costs of the multiple conditions overlap extensively and are heavily influenced by the comorbidities. Disease-by-disease cost performance evaluation would illustrate a distorted picture of the overall cost performance that may be misleading with unintended negative consequences. One such unintended consequence of the episode concept is the inherent change of focus from the well-being of the whole person to the cost of isolated aspects of care.

For many years, chronic diseases varied dramatically in their costliness over different time periods. As an example, a patient with coronary artery disease may have low costs during multiple time periods and then have a myocardial ischemia with significantly high costs over another time period. We are concerned that this implies that one provider may be considered more cost effective if they did not treat a patient with myocardial ischemia than another provider who provided care for a patient who had a myocardial ischemia in the same time period. Furthermore, attribution of costs to a particular disease- or condition-based episode group would be particularly challenging considering that most older adults have multiple chronic diseases and providers typically address multiple conditions during a single encounter.

The episodic-based approach also presents concerns in the draft episodes for oncological care. For instance, the consideration of treatment options for prostate cancer should include the patient's values (e.g., life expectancy, comfort, family burden, individual cost), health literacy of caregivers, availability of post-acute options that are also accessible to family members, and several other factors that currently cannot be measured. We believe it would be crucial to ensure that these factors and other similar concerns are taken into consideration when providing care for patients with cancer for sound medical care and should not be a disincentive.

One of the fundamental tenets of caring for all patients and in particular for those with multiple concerns—including social determinants of health that negatively impact the patient—is remaining focused on the whole person and not exclusively on any one specific issue. We are concerned that the current approach of cost measure development uses an episode perspective in efforts to quantitate the appropriateness of medical care, especially care for older people. Geriatrics health professionals treat people with several overlapping medical and social issues, priorities, and expectations where the outcome of successful treatment is fungible. At times, the treatment is to extend life while in other instances the goal is comfort, cost efficiency, access to support from loved ones, or addressing other concerns. The AGS supports treating the whole person rather than the individual concerns in isolation using an episodic approach, particularly when used to measure care for individuals with multiple issues, whether the care is medical, psychological, and/or social.

1.1.15 Comment Number 15

- **Date:** 03/29/2022
- **Submitter Name, Credentials, and Organization:** Sharmila Sandhu, American Occupational Therapy Association
- **Comment Text:** International Classification of Diseases, 10th Revision (ICD-10) diagnosis codes with or without secondary malignancy site codes, cancer as a primary diagnosis, first use of cancer diagnosis following a designated lookback period, the number of medical claims on separate dates in combination with identified ICD-10 diagnosis codes (2) A combination of healthcare claims data, such as ICD-10 diagnosis codes and hospitalizations or multiple outpatient office visits (3) Length of treatment, including non-cancer treatments like occuptaional therapy, PT or Speech therapy (Look at the KX modifier for outpatient therapy?)

  Breast cancer, Lung cancer, Ovarian cancer.

  Use of occupational therapy for pain management, daily activity modification, energy conservation, etc.

  Patient Reported Outcomes as well as: Outcomes measures in general, considering not only a surgical or medical intervention, but also the downstream costs of all care involved (including rehab. therapy such as OT, PT, SLP).

  Will be important to include post- procedure/treatment rehab care.

  Yes. Please consider including an AOTA representative as part of the cancer rehab care considerations. I have an occupational therapy expert in mind that we can provide.

  AOTA and APTA jointly commissioned Dobson DaVanzo and Associates in 2018 to examine the relationship between occupational therapy and physical therapy intensity (treatment amount per case), patient functional status, and readmissions (outcomes) in inpatient rehabilitation facilities, skilled nursing facilities, and home health agencies.

  Medicare administrative claims and functional assessment data were studied to measure therapy utilization and the reported need for assistance with core activities of daily living, including self-care and mobility, at the start and end of a post-acute care stay following

patient discharge from an acute hospital. The study examined data collected from January 2015 through December 2016.

The study found certain significant differences by setting. Almost a third of HHA patients compared to nearly half of SNF and IRF patients have a diagnosis of depression. SNFs served the highest percentage of patients with dementia- 45% of SNF patients had a diagnosis of dementia compared to 31% of IRF patients and 20% of HHA patients.

i. There were also differences in the age of patients. SNFs serve a greater percentage of patients ages 85+ while HHAs serve more patients ages 65-74 and IRFs serve more patients ages 75-85.

ii. Primary diagnosis also varies greatly by settings. Almost half of patients with stroke receive care are in an IRF. Almost half of patients with CHF receive care in SNF. Almost two thirds of patients with joint replacement receive care from HHA.

iii. With these differences by age group and diagnosis (as well as eligibility criteria for different PAC settings), it's perhaps unsurprising that we see differences in functional status at admission. Patients admitted to IRF have the most functional impairment, while patients admitted the HHA have the least functional impairment/are more independent at admission. Functional status of patients admitted to SNFs falls in the middle.

iv. Again, the study shows just how different the patient populations are within each setting, which is the major reason why the study didn't look across all settings when examining therapy provision and outcomes. That is, it wouldn't have been appropriate to put patients from all settings into a single analysis. These results also suggest that creating fair site-neutral payments would be extremely challenging.

AOTA supports consideration of subgrouping, distinguishing patients with complex medical conditions, dementia, or depression, behavioral health issues or those who receive rehabilitation.

Also consider separating the short term post-acute residents from the longer term ones to study any key differences. Finally, special attention needs to be given to the home health care and home health agency provision of services setting. HH can't be studied in an identical way to SNF and IRF.

See above answer regarding the HH setting. AOTA recommends specific TEP agenda items and discussions regarding clinician attribution as part of this cost measure discussion. This is a very challenging question and experts will need to have the best data in front of them to make these determinations, knowing that not all PAC settings are the same and, in fact, there are key differences that make each setting important to be considered on its own accord.

Follow-up care, preventative and primary care considerations, such as home safety assessments. Occupational therapists are increasingly being asked by families and caregivers upon return to the home setting from a PAC stay or acute hospitalization to conduct a home safety assessment to assure that the home setting is safe and free of falls risks, etc. that can lead to re-institutionalization. This is a key role of an occupational therapy professional.

This will require review of the CPT Manual Phys Med and Rehab 97000 series of codes for therapy care.

The cost measures must be considered in connection with the VBP and QRP programs in the following PAC settings: SNF, IRF, LTCH, HH.

The patient variability and long term failure to consider the medical and preventative needs of the whole patient, especially in PAC settings. ALso, the special payment concerns and incentives of Medicare payment vs. dual eligible Medicare/Medicaid residents and how payment source might impact on quality of care and payment incentives overall.

OTs, PTs, and SLP therapy professionals must be represented on TEP for their unique contribution in providing skilled therapy to patients over sometime lengthy plans of care.

Yes, AOTA definitely is interested in putting forth an expert to advise this cost measure.

We reiterate that non-physician professionals, including rehab therapists, currently do not have any cost measures to report on and that restrains them from participating fully in MIPS and being part of an MVP. Common sense measures for therapists, with input by therapy experts, in necessary.

1.1.16 Comment Number 16

- **Date:** 03/29/2022
- **Submitter Name, Credentials, and Organization:** Bev McFall, COMT, Physicians Network Services
- **Comment Text:** Diabetics and the elderly.

  fundus exams would show this, charting by the gen. Ophthalmologist any changes in the macular or retina which they do already and any referrals to a Retina specialist for next level of treatment. Our doctors do this already but some Ophthalmologists or Optometrist's continue to treat when they should have referred the patient to the specialist earlier.

  You cannot expect a higher case volume per clinician, but define who is allowed to do the injections/ A retina Specialist for severe diagnosis and follow ups for a general Ophthalmologist. Any changes they go back to the Retinal Doctor.

  Have a measure code for history of Posterior Vitreous Detachment or Retinal detachment.

  Defined as previous, on going problem Follow up for glaucoma or new diagnosis.

  Follow up for glaucoma patients by the actual ophthalmologist not a coa.in a private practice. situations.

  Medication list to be expanded to include all generics. Often we have to change a scripted glaucoma medication because Medicare doesn't cover it. The medication is by class and not general but the pharmacy gives you what is covered and its the same class of glaucoma drop,. Each Glaucoma drop does something different and there is a reason its needed for the patient.

If the fundus was not seen for whatever reason and the patient was dilated, the cpt code would reflect this. But it doesn't mean it was not attempted and time was spent trying to achieve the results. We need an alignment measure for quality of care.

In skilled nursing facilities the need to better assess a patient in a wheel chair rather than bedside for those patients that can get up but wont. Time spent getting the results. , a code Patients that are bedbound and time was spent a code for a difficult exam maybe.

1.1.17 Comment Number 17

- **Date:** 03/30/2022
- **Submitter Name, Credentials, and Organization:** Allison Madson, MPS, American Society of Retina Specialists
- **Comment Text:** On behalf of the American Society of Retina Specialists (ASRS), we write to you today to oppose the development of two proposed measures included in the Wave 5 Call for Comment: Age-related Macular Degeneration (AMD) and Retinal Detachment Repair.

  ASRS is the largest retina organization in the world, representing over 3,500 board certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases. The mission of the ASRS is to provide a collegial open forum for education, to advance the understanding and treatment of vitreoretinal diseases, and to enhance the ability of its members to provide the highest quality of patient care.

  ASRS strongly supports efforts to improve quality and lower cost through prudent resource use, however, both of these proposed measure concepts present unique challenges that would make it difficult to develop measures at this time. For AMD, we are concerned that including the cost of Part B drugs (which are set by the manufacturers, and not the physicians) would incentivize undertreatment or the use of inferior, less-expensive drugs, potentially leading to poorer visual outcomes particularly in the absence of any associated quality measures. For retinal detachment repair, the average retina specialist would likely not have a large enough sample of surgical cases on a yearly basis to create a statistically valid measure. Our concerns on each of these proposed measures are detailed below, along with responses to the questions posed in the survey.

  AMD

  Types of AMD

  As noted in the comment solicitation, the cost of treating patients with AMD can vary greatly. The cost of care for patients with the less-severe—but vastly more prevalent—dry AMD can be minimal to the Medicare program with periodic monitoring visits to assess for conversion to wet AMD and over-the- counter vitamin supplements the only associated costs. If Acumen developed a measure for patients with dry AMD alone in both eyes, the cost differences would not be great enough to distinguish lower cost versus higher cost ophthalmologists. This is contrary to section 3.2 of the wave 5 call for public comment where it requests that “variation in measures helps distinguish performance across individual providers.” Treatments for patients with dry AMD who develop geographic atrophy are under development, but not yet approved.

The cost of care becomes much more variable if a patient develops wet AMD—a completely different manifestation of disease—and begins to require regular treatment with anti-vascular endothelial growth factor (anti-VEGF) drugs administered by a retina specialist and paid through Medicare Part B. The cost of these drugs can differ based on whether the drugs are FDA-approved and manufactured for use in the eye or used off-label and compounded for ocular use—which is less expensive. The physician can choose which drug to use, but the clinical outcome is not based on the price of the drug. There is no proven method to prevent conversion to wet AMD so a cost measure based on conversion would not be possible.

Part B Drugs

When a patient with wet AMD needs anti-VEGF treatment, most retina specialists begin with off-label bevacizumab (Avastin) that must be compounded for ocular use. Many commercial payers and Medicare Advantage plans have implemented step therapy protocols requiring Avastin as the first line of treatment for AMD. While some patients are well-controlled with Avastin, it is not FDA-approved for ocular use. Some patients, however, do not respond to Avastin or may have underlying health conditions that require the use of a branded FDA-approved drug manufactured for use in the eye. There are currently two branded drugs that are used most frequently to treat AMD: aflibercept (Eylea) and ranibizumab (Lucentis). Other approved therapies e.g.: pegaptanib (Macugen) and brolucizumab (Beovu) are currently less frequently used, and a port-delivery system (Susvimo) and faricimab (Vabysmo) have only recently been approved. The cost of each of these drugs is significantly higher than Avastin, however, those prices are set by the manufacturers and not the physician.

While the current Part B buy-and-bill drug system reimburses physicians at average sales price (ASP) +6%, thereby creating a theoretical incentive for physicians to choose the most expensive drug, real world data does not bear this out. Based on a survey ASRS conducted in 2016 in response to a now- defunct Innovation Center Part B demonstration model, we found that drug acquisition and overhead expenses for injectable drugs that have their own unique HCPCS J codes was, on average, 98.9% (range 96.5% to 103.2%) of total payments. Subsequent studies from independent groups, such as the Medicare Payment Advisory Commission (MedPAC), have also found little to no correlation between the cost of the Part B drug and prescriber behavior.

While overall we oppose the development of an AMD measure at this time, if one were to be created, it would have to exclude the cost of drugs. Physicians have no control over their price and the cost differential between the branded and off-label drugs is so significant, it would render statistically undetectable any differences in cost that are directly within a physician's control, such as frequency of various retinal imaging procedures and the level of E&M office visits charged for the visit.

Treatment Patterns and Quality Outcomes

The decision to move from Avastin to a branded agent is appropriately at the discretion of the physician and patient. Retina specialists have unique training in diagnosing and considering the individual factors of a patient's disease. Retina specialists have several options for treatment patterns and dosing, depending on the individual patient. Some may follow a monthly dosing schedule, pro ne rata (as needed), or treat-and-extend method. It is

difficult to predict what treatment pattern may work best for an individual patient at the outset and whether adjustments to the regimen may be necessary as treatment progresses.

It has been shown in randomized clinical trials of wet AMD that Lucentis and Eylea are better than Avastin at drying the retina which is the primary way retina specialists monitor the response to anti- VEGF therapy. This allows some patients who have difficulty returning for monthly office visits to be treated less frequently with a more expensive anti-VEGF drug than Avastin. Less frequent treatment also improves compliance for returning to the office since many of these elderly, visually impaired patients require transportation by family members or paid carriers to physician offices. The unpredictability and diverse responses make it difficult to compare patients for a cost measure.

While there may be differing opinions among retina specialists about the ideal anti-VEGF dosing, there is broad agreement that undertreatment is the key predictor of whether a patient has a poor visual outcome.[20][21] Because of this, an AMD cost measure could create a worrying incentive for retina specialists to forgo what could be beneficial additional treatment if they know it could adversely impact their cost score. Faced with the decision of whether to increase the frequency of a patient's treatment or not, the physician should not have to choose between poorer clinical outcomes and poorer MIPS cost scores, since poor clinical outcomes are not measured by CMS claims data. Even if the physician is not actively restricting treatment frequency to improve his or her cost scores, a patient who cannot attend regular appointments for a variety of reasons, such as hospitalization for another condition or lack of reliable transportation, would appear to be "low cost" due to non-compliance with recommended treatment intervals.

Other cost measures are formulated to prevent that disincentive by tying them to existing quality measures. However, for AMD, there are currently no outcome-based MIPS quality measures and only one topped-out process measure: #14 Age-Related Macular Degeneration (AMD): Dilated Macular Examination, left in the program. CMS has repeatedly removed retina quality measures over the objections of ASRS and other stakeholders. ASRS has worked to develop additional quality measures, but struggled to craft measures for diseases such as AMD that lack clear clinical endpoints. Without any corresponding AMD quality measure in MIPS, there would be no way to ensure that there were no adverse quality consequences of the cost measure.

Given that the MACRA statute specifically ties quality and cost together, developing any measure with a disincentive to provide care should be antithetical to the program's purpose.

New Treatment Options on the Horizon

While the cost of the existing drugs and the potential for undertreatment are key factors that would make developing an AMD episode measure challenging at any time, the current landscape of products new to the market or in the pipeline makes now a particularly

[20] Ciulla TA, Hussain RM, Pollack JS, Williams D. Visual Acuity Outcomes and Anti-Vascular Endothelial Growth Factor Therapy Intensity in Neovascular Age-Related Macular Degeneration: A Real-World Analysis of 49,485 Eyes. Ophthalmology Retina. 2020 January 4(1) p19-30.

[21] Kiss S, Campbell J, Almony A, Shi V, Serbin M, LaPrise A, Wykoff CC. Management and Outcomes for Neovascular Age-Related Macular Degeneration: Analysis of Unites State Electronic Health Records. Ophthalmology. 2020 September 127(9) p1179-1188.

inopportune time to develop a measure. In just the past six months, the FDA has approved a new implantable port delivery device that allows for constitutive delivery of Lucentis; a new dual-mechanism molecule, faricimab (Vabysmo), that targets both the VEGF and Ang-2 pathways; and a biosimilar to Lucentis (Byooviz). Additional Lucentis biosimilars are expected later this year, as is an Avastin formulated specifically for ocular use which will likely be available in 2023. In the near future, there will likely be biosimilars for Eylea, as well as possible innovations in single-dose gene therapy and possible treatment for geographic atrophy associated with dry AMD. Any or all of these innovations are expected to contribute to a significant shift in the current treatment paradigm within the next 3-5 years.

With so much expected to change in the management and treatment of AMD in a way we cannot accurately predict, it would be difficult to craft a meaningful cost measure at this time. Since the cost measure development process, review, rulemaking and comment period takes several years, by the time the measure would be in the MIPS program it would likely be obsolete. ASRS recommends CMS and Acumen prioritize other measure concepts at this time.

RETINAL DETACHMENT REPAIR

Retinal detachment repair is a more discrete care episode with better-defined endpoints and may appear to be a topic that is more appropriate for developing a cost measure. However, we are concerned that the procedure is relatively low volume and a surgeon with an average surgical case load may not meet the minimum threshold of 20 eligible Part B patients in a performance year. In 2019 and 2020, the most frequently billed retinal detachment repair code (67108) was billed in Medicare Part B 16,523 and 14,871 times respectively. Even allowing for the COVID-19 pandemic, which likely did not alter incidence of these emergency procedures, these are not high-volume codes and would only correspond to fewer than 20 cases per physician.

It is statistically invalid to compare costs between physicians with relatively few cases. We estimate that there are approximately 1500 retina specialists who perform retinal detachment repair in the United States, so this means that the average retina specialist performs about 15 cases in Medicare beneficiaries a year. With enrollment in Medicare Advantage only expected to grow in the coming years, this dearth of cases eligible for measurement will not likely change. In addition, the peak age of incidence of retinal detachment is 55-59 years, outside the Medicare-aged population.[22]

There may certainly be some differences in cost between different retina specialists, but the primary difference would relate to whether the surgery was performed in a hospital outpatient department and an ambulatory surgery center (ASC). Controlling for that variation, similar to the way it was handled for the cataract surgery measure, would make it difficult to distinguish between lower versus higher cost retina specialists. The procedure does not rely heavily on imaging and 82% of the time in 2019 it was billed without any other codes. There may be some variation in the anesthesia provided, however, that decision is largely at the discretion of the HOPD or ASC and not within the retina specialist's control.

[22] Van de Put MAJ, Hooymans JMM, Los LI. The Incidence of Rhegmatogenous Retinal Detachment in the Netherlands. Ophthalmology. 2018 July 125(7) p1127.

Due to the lack of eligible surgical cases, ASRS recommends retinal detachment repair be removed from consideration for the current wave and future measure development.

RESPONSES TO SURVEY QUESTIONS

- Question 1: For AMD, what is the most appropriate patient population (e.g., all AMD versus only wet AMD) and episode window for this condition?

  Please see our response above. ASRS does not support the development of an AMD measure. Quality is not measurable from claims data for either AMD as a whole or the wet AMD subgroup. While wet AMD is inherently more resource-intensive to treat than dry AMD, factors other than a patient's particular diagnosis or disease state and the episode window would make the development of a measure nearly impossible. The cost of the drugs that are not within the physician's control, the lack of corresponding quality measures to prevent undertreatment, and new and evolving treatments would continue to play an outsized influence even if the measure could isolate a homogeneous patient population for comparison.

- Question 2: Would anti-vascular endothelial growth factor (VEGF) intervention be appropriate for identifying whether a clinician is managing a patient's AMD chronic condition? What other interventions may indicate that a clinician is managing a patient's AMD?

  As noted above, dry and wet AMD are two different diseases with vastly different treatment protocols. We oppose the development of any measure related to AMD, including one that would group both dry and wet AMD together. There are no other ways currently to identify a physician managing wet AMD other than providing anti-VEGF injections. It could be difficult to identify the physician managing a patient's dry AMD because they may have other ocular co-morbidities, such as cataract or glaucoma, that would be managed by another ophthalmologist. Likely, the dry AMD diagnosis would appear in claims for the other ophthalmologists, and potentially erroneously assign the cost of dry AMD care to that physician. This programmatic challenge is yet another reason to avoid developing a measure for AMD.

- Question 3: Can we infer AMD clinical outcomes from claims data? How can a measure avoid penalizing clinicians who treat patients for whom the more expensive injection is the only clinical option or more frequent injections are needed (e.g., requiring a higher case volume per clinician)?

  There is no way to infer clinical outcomes from claims data, and as mentioned above, there is no available outcome measure for AMD to ensure that quality would not erode as a consequence of the cost measure. Claims data does not in any way capture the basic indicators of quality of care, which include change in visual acuity, and findings on the ophthalmologic exam and/or findings on ancillary testing. Furthermore, the decision on which drug to use for a particular patient is appropriately based on the retina specialist's interpretation of these indicators, and a discussion with the patient. Therefore, there can be no simple guidelines for when a particular drug is most appropriate.

- Question 4: For retinal detachment, how should the measure account for differences across patients based on pre-existing conditions that may impact the likelihood of treatment success?

How can the measure be constructed to be as broad as possible for measure impact and viability (e.g., risk adjusting or sub-grouping certain patient cohorts rather than excluding)?

As noted above, the overall low incidence of cases would make it difficult to develop this measure. However, the current lack of granular ICD-10 coding to describe the type and severity of a particular case would likely preclude sub-grouping patients into specific cohorts. Claims data would not accurately capture potential co-morbidities or other risk factors that may contribute to the differences in cost, such as the potential for future retinal detachments.

- Question 5: Besides AMD and retinal detachment, are there other concepts in this clinical area (e.g., glaucoma care) that would be strong candidates for development considering the prioritization criteria and essential features of cost measures? The goal would be to capture the care provided by different types of ophthalmologists for which there is sufficient opportunity for improvement.

  Not at this time.

1.1.18 Comment Number 18

- **Date:** 03/30/2022
- **Submitter Name, Credentials, and Organization:** Tricia Marine Barrett, MHSA, Bayer
- **Comment Text:** Bayer US ("Bayer") thanks the Agency for the opportunity to submit comments in response to the Centers for Medicare and Medicaid Services' (CMS) call for public comment for the upcoming cycle of episode-based cost measure development ("Wave 5"). We recognize that developing cost measures that are clinically meaningful for MIPS eligible clinicians will be critical to ensure that the MIPS program effectively incentivizes the delivery of high-quality care to improve patient outcomes. Further, developing such measures will support the ongoing development and implementation of MIPS Value Pathways (MVPs).

  Related to the Chronic Kidney Disease/End Stage Renal Disease (CKD/ESRD) cost measures, Bayer recommends that CMS seek input from patients, providers, and stakeholder groups to understand the patient perspective and the needs of transplant patients, including post-transplant care, as well as burden of costs.

  Soliciting additional feedback may also support the identification of potential unintended consequences, which should be addressed before finalizing the measure for inclusion in the MIPS program.

  In this letter we support:

  - **CMS's interest in addressing care across the continuum for people with kidney conditions**. The costs associated with kidney transplant management, including post-transplant care, underscore the need for better care, and measures to guide that care, for patients with less advanced stages of kidney disease. This may prevent progression to later-stage disease, which is associated with more complications to manage and worse patient- and caregiver- outcomes.

Bayer is a global enterprise with core competencies in the life science fields of health care and agriculture with nearly 25,000 employees in 300 sites across the United States. Our products and services are designed to benefit people and improve their quality of life. At the same time, we aim to create value through innovation and are committed to the principles of sustainable development and to our social and ethical responsibilities as a corporate citizen.

Our summary recommendations in response to these items are below.

KIDNEY TRANSPLANT MANAGEMENT

Question 1: The CKD/ESRD measures currently under development target the ongoing outpatient management of these conditions, with an emphasis on comprehensive assessment. The CKD/ESRD measures do not include kidney transplant recipients. How could a transplant measure best be developed to align with the CKD/ESRD measures and jointly assess the high costs of kidney care?

Bayer supports CMS's decision to explore options for capturing people who received a kidney transplant in MIPS cost measures. Developing a cost measure focused on kidney transplant management to complement the CKD/ESRD measures would provide a more holistic picture of kidney care, including post-transplant care.

Although kidney transplants are regarded as one of the best treatment options for ESRD, transplant recipients are at an increased risk of rehospitalization within the first year. In one large cohort study conducted with over 1,400 kidney transplant patients, 19.4% of patients had hospital readmission at 30-days post-transplant and 26.8% faced readmission at 90-days post-transplant. Thirty-day readmissions with the highest mean cost were associated with surgical complications, rejection, and infections.[23] An analysis using the US Renal Data System (USRDS), which includes data from over 40,000 kidney transplant recipients from 2005-2014, found that post-transplant hospital admissions represent 20% of all Medicare payments for transplantation, and that 50% of these readmissions can be preventable.[24] Studies suggest that transitions of care during the post-transplant period such as time between follow-up visits, provider communication, and patient education may play a role in hospital readmissions and overall quality of care.[25] A cost measure that addresses care for transplant recipients may incentivize the delivery of high-quality cost-effective post-transplant care and care coordination, which can improve post-transplant care outcomes. Furthermore, without understanding the costs of care for transplant recipients, the benefits of treating CKD in earlier stages to prevent ESRD may be overshadowed by the cost of those treatments.

Question 2: Stakeholder input received to date has emphasized the importance of assessing the costs for kidney transplant recipients. Other kidney payment models, such as the ESRD Treatment Choices Alternative Payment Model, have emphasized the importance of assessing transplant-related care and reducing disparities among Medicare beneficiaries with

[23] Famure O, et al. What Are the Burden, Causes, and Costs of Early Hospital Readmissions After Kidney Transplantation?. Progress in Transplantation. 2021 Jun;31(2):160-7.

[24] Hogan J et al. Assessing predictors of early and late hospital readmission after kidney transplantation. Transplantation direct. 2019 Aug;5(8).

[25] Harhay, M et al. Early rehospitalization after kidney transplantation: assessing preventability and prognosis. American Journal of Transplantation. 2013 Dec;13(12):3164-72.

kidney disease. Are there potential unintended consequences of including or excluding the transplant recipient population in kidney cost measures? How can the kidney care measures promote high-value care and health equity?

- Bayer agrees that assessing transplant-related care for Medicare beneficiaries is a necessary step for making improvements to reduce disparities overall among those with kidney disease across the continuum, and to improve outcomes for these patients and their caregivers.
- CKD/ESRD disproportionally affects patients of lower socioeconomic status and racial/ethnic minority groups. For example, Black Americans comprise of approximately 13% of the US population; however, there are more than 30% of Black Americans with ESRD in the US.[26] A literature review found that higher neighborhood income was associated with decreased mortality and an increased likelihood of placement on the renal transplant waiting list. This effect was greater among Black individuals versus white individuals.[27]

  Excluding the transplant population from kidney cost measures may not allow for a comprehensive assessment of treatment and outcomes for the full spectrum of people who are managing kidney conditions. Including kidney transplant recipients in a MIPS cost measure may also encourage clinicians to focus on improving patient care coordination and identifying and addressing health disparities, which may improve management, outcomes, and reduce costs associated with unnecessary emergency room visits and readmissions.

  Pairing cost measures with quality measures in MIPS will reduce the potential for stinting of care to reduce costs. MIPS Value Pathways (MVPs) group quality measures, improvement activities, and cost measures for comprehensive, yet streamlined reporting. They are intended to improve the engagement and evaluation of MIPS eligible clinicians, especially specialists, by grouping measures and activities relevant to a specialist or condition. Capturing kidney transplant management through a MIPS episode-based cost measure will also support future MIPS Value Pathway (MVP) development and implementation. Excluding kidney transplant patients from the suite of MIPS cost measures may make any kidney disease MVP less relevant for those clinicians involved in the care management of people who have received these services.

1.1.19 Comment Number 19

- **Date:** 03/31/2022
- **Submitter Name, Credentials, and Organization:** Matthew Popovich, PhD, American Society of Anesthesiologists
- **Comment Text:** On behalf of the 55,000 members of the American Society of Anesthesiologists® (ASA), I am pleased to offer feedback and comments on the Centers for Medicare and Medicaid Services' (CMS) MACRA Episode-Based Cost Measures: Wave 5

[26] Norton JM, et al. Social determinants of racial disparities in CKD. Journal of the American Society of Nephrology. 2016 Sep 1;27(9):2576-95.

[27] Nicholas SB, Kalantar-Zadeh K, Norris KC. Socioeconomic disparities in chronic kidney disease. *Adv Chronic Kidney Dis*. 2015;22(1):6-15. doi:10.1053/j.ackd.2014.07.002

Measure Development. We thank CMS for the opportunity for physician anesthesiologists to provide feedback, particularly on the proposed "Anesthesia Care" episode-based cost measure (Section 4.1.1 in the Call for Public Comment). Within the Merit-based Incentive Payment System (MIPS), anesthesiologists rarely receive attribution in the cost performance category through existing measures. Although some anesthesiologists and their groups enjoy facility-based scoring, we nonetheless are encouraged by CMS seeking to develop an anesthesiology cost measure that can accurately reflect the care an anesthesiologist provides, whether in a perioperative setting or in providing pain medicine services.

An individual physician anesthesiologist is often one member of a larger team of health care professionals providing services to a patient. Depending on the needs of the patient and the skills, experience, and training of the other medical professionals involved, the physician anesthesiologist may play a different role with different patients. These varying roles can impact the resources or costs that can be attributed to the Eligible Clinician or their group. Any measure or method developed to estimate costs attributed to an anesthesiologist or their group should be nuanced enough to differentiate among the varying roles that a physician anesthesiologist may play as a member of a larger team.

Physician anesthesiologists represent one of the few specialties that contribute to nearly all surgical and procedural patient care. Anesthesiologists provide care coordination and are instrumental in improving quality and delivering more cost-effective care. Anesthesiologists provide patient care in many settings, including but not limited to, inpatient, outpatient, office-based, and non-operating room anesthetizing locations. Many anesthesiologists have subspecialty expertise in, among others, ambulatory care, critical care medicine, obstetrics, and pain medicine. The spectrum of roles that anesthesiologists play includes:

Providing anesthesia care during surgery

Traditional practice: This includes assessment of a patient's condition prior to anesthesia/surgery, preoperative management of current medications, review of diagnostic studies, determination of available anesthetic options, creating a plan with the patient and obtaining consent, intraoperative management of anesthesia, monitoring and maintenance of physiologic functions, and immediate postoperative care.

Providing and coordinating comprehensive care during the perioperative period

Advanced, more comprehensive practice: This includes the above "traditional practice" actions but with deeper engagement in preoperative preparation including optimization services to address medical conditions that may include patient nutrition, tobacco use, diabetes control, and other comorbidities that often take place weeks ahead of planned surgery; postoperative management of pain with interventional procedures or pharmacologic therapy during hospitalization and after hospital discharge; and fluid management. The ASA Perioperative Surgical Home (PSH) service delivery model reflects this enhanced, comprehensive level of care.

Providing Critical Care

Critical care of patients with medical or surgical conditions/disease: Anesthesiologist intensivists function as consultants to admitting physicians or, in many facilities, as the admitting attending physician themselves. Anesthesiologists are uniquely qualified to

coordinate the care of patients in this setting because of their extensive training and experience in clinical physiology, pharmacology, and resuscitation.

Providing Pain Medicine Services

Acute (post-surgery): This includes multimodal pain management, prescribing oral or injected opioid and nonnarcotic analgesics, and/or providing interventional pain management utilizing epidural or peripheral nerve block techniques. The goal is to minimize the use of addictive opioids, alleviate patient discomfort, and optimize recovery.

Chronic pain management: This includes care of patients with the full spectrum of painful disorders including musculoskeletal disease, painful nerve conditions, or traumatic pain. Similarly, approaches include pharmacologic therapy, especially management and prevention of opioid dependency and interventional procedures.

While we appreciate CMS' important objectives of more accurately tracking and driving down health care costs, we believe the proposed "Anesthesia Care" questions fail to fully capture the complexity of anesthesia and anesthesiologists' roles on the care team by placing the specialty in a silo separated from its counterparts on the surgical team. Because anesthesiologists often work in tandem with surgeons and other specialty clinicians, it is exceedingly difficult to carve out anesthesia-specific costs fully and accurately within a given case. For this reason, ASA believes CMS should identify existing measures, including those addressing surgical episodes of care, to find appropriate attribution for anesthesia care, including a percentage of the costs to anesthesia care professionals. Other specialties in the team-based surgical setting are not as readily divided into individual cost cohorts. Anesthesia should not be an exception.

Like CMS, ASA has struggled with identifying an appropriate method for applicable cost measures. In the typical practice environment for physician anesthesiologists, purchasing and acquisition decisions and the availability of choices of equipment and supplies are most often not within the control or discretion of the anesthesiologist. For chronic pain management services, most of the costs are associated with or significantly influenced by the facility where the interventional pain procedure occurs, whether in an office, ambulatory surgery center, or within a hospital. Any cost measure related to anesthesia care should take into consideration facility charges, including variations across facilities for surgical and procedural care. As such, ASA believes it would be most appropriate that consideration of these resources and their accountability be shared with the surgeon and the facility.

In this call for public comment, CMS is attempting to frame a cost measure based upon Medicare Part B claims instead of looking more broadly at how anesthesiologists and other medical professionals decrease health care costs and spending within the larger system. ASA recommends CMS look beyond Medicare Part B spending and examine the most prevalent and deep-rooted drivers of cost, many of which are occurring outside of hospitals and other facilities. For anesthesiologists, cost savings are often tied to Medicare Part A, reduced lengths of hospital stay, prevention of surgical site infections, improved quality of life, and a return to function that patients hopefully experience following their surgery.

ASA also recognizes that cost savings can occur when CMS and other stakeholders make a concerted effort in addressing and mitigating demographic disparities and better understanding how social determinants of health (SDOH) affect population health, access,

and appropriate treatment options. As demonstrated in the comprehensive care that physician anesthesiologists provide and coordinate as part of Perioperative Surgical Home (PSH), successful interventions to address SDOH throughout the surgical journey for patients are possible. The PSH service delivery model is patient-centered and thus provides the infrastructure to implement protocols that enhance recovery and improve patient outcomes in ways that also decrease cost (decrease length of stay, readmissions, discharge disposition to home versus skilled nursing facilities, etc.). Another key element in reducing costs and health care disparities is ensuring patients have access to anesthesiologists, other physicians, and clinicians who will work closely with them to understand their diagnoses and determine how best to achieve positive health outcomes. As perioperative physicians, anesthesiologists play an essential role in implementing patient-specific anesthesia plans, identifying patient goals, and leading care coordination efforts that positively affect individual patient care and reduce costs.

We appreciate CMS and Acumen holding office hours and their desire for ASA and other stakeholders to collaborate on anesthesia and interventional pain management cost measures.

Our comments provide a high-level assessment of potential opportunities for cost measure development. We therefore have not identified specific CPT codes or specific points as to when an episode should begin and end. We welcome continued engagement with CMS on anesthesia care cost measures and expect that our expertise will be appreciated through future Wave 5 technical expert panels. We urge CMS and its vendors to prioritize transparency by public posting of measure calculations and testing data. This level of transparency is also necessary when providing actionable feedback reports to individuals and their groups. The ability for a health care professional to drill down to the specific costs within a surgical episode is an essential benefit to understanding their overall cost. This methodological information would enable a greater understanding of the measures and allow practices to evaluate best practices in cost savings.

Below we have provided direct comments to Section 4.11's questions on the proposed "Anesthesia Care" measure:

Question 1

ASA does not believe that anesthesia-related complications should be the basis of a cost measure as complications will not accurately reflect differences in cost or quality of care. Complications from anesthesia, including the ones mentioned in the question, are rare enough for such cases to be considered outliers. These complications, such as difficult intubation or untreated hypothermia, are not necessarily indicative of poor practices, either. Unfortunately, a patient may experience complications even if their anesthesiologist delivered quality care and took all needed precautions.

We are also concerned that intraoperative and postoperative complications are not easily identified by claims data. CMS has indicated, both in past cost measure design and through this call for comments, that a cost measure requires a triggering event, includes a combination of diagnostic and billing codes, and has a well-defined end point. Under current regulations, anesthesiologists and their groups do not receive a separate payment for operating preoperative clinics that are aimed at improving patient outcomes and preventing complications. During the surgical procedure, an anesthesiologist may use a variety of operating room resources and perform many clinical actions that are not separately billable,

even for complications that may arise in the delivery of anesthesia. When complications occur in the postanesthesia care unit (PACU) that require the anesthesiologist to return to the PACU, anesthesiologists may include their time spent directly addressing those complications in their reported anesthesia time. We caution that patient diagnoses identified during the surgical procedure or in the PACU, especially if it is a complication, may not be consistently captured in claims data.

ASA has considered whether treatment for different post-surgical complications could be a starting point for a cost measure. Such complications that are associated with anesthesia include postoperative nausea and vomiting, corneal abrasion, airway trauma, dental injury, and unplanned reintubation. However, it is unclear how CMS would capture these complications outside of the hospital or within a 30-day postoperative period. Diagnoses for those complications might be captured by an ophthalmological consult or a patient visit to otolaryngologist, dentist, or other health care professional. For other complications, such as kidney injury, pneumothorax, respiratory failure, return to operating room, or other acute episodes that require more urgent attention, the diagnosis and cost accrued may fork into multiple different paths for patient care.

An alternative to measuring complications could be measuring adherence to best practices in preventing or mitigating the risk of complications. A quality "gating" practice would aim to capture the ways physicians and other clinicians are currently containing costs that could complement facility-wide objectives around cost savings. In practice, this would mean measuring if anesthesiologists and other anesthesia professionals meet quality measure performance requirements designed to mitigate patient risk and, at the same time, determine whether cost containment strategies can be achieved. As an example, anesthesiologists contribute to reduced surgical site infections by administering prophylactic antibiotics, ensuring normothermia, and managing the patient's glucose levels. Those quality measures could be an indicator for how the expected cost of treatment, including length of stay and risk of complication, could be assessed. A quality measure bundle, as described above, could also supplement other features of "quality" anesthesia care such as multimodal pain management. For multimodal pain management , anesthesiologists ensure appropriate patient selection for the surgical setting and postanesthetic care, the use of multimodal analgesia, and anesthesia type to provide quality care, reduce costs, and reduce unnecessary opioid prescribing.

We remind CMS that lower cost does not necessarily equate to better care. Although the movement of procedures to ambulatory surgery centers has resulted in cost savings for the system (and time savings for patients), patient selection for who should have their procedure completed in an ambulatory setting is a significant concern for anesthesiologists. A patient who is transferred to a higher level of care from an ambulatory setting because of a complication will most likely incur a higher cost to Medicare than if the procedure had been completed in a hospital setting to begin with. Complications and other related metrics like transfer to a higher level of care or readmission rates are certainly worth tracking from a quality perspective, but these factors are ill-suited for a cost measure.

Question 2

As mentioned in our introduction, we do not believe a broad anesthesia measure for all types of procedures would accurately reflect the cost of anesthesia care. Not only would such a measure depart from previous CMS cost measure development methodology, but the

measure would result in uneven comparisons between anesthesiologists, their groups, and surgical settings. Instead, we prefer a more targeted approach that is complementary of existing measures but also inclusive of future cost measure requirements. CMS and its contractors have developed more than 20 cost measures that reflect some of the most costly procedures and chronic conditions for Medicare beneficiaries. For the surgical episode cost performance measures, anesthesia should be a contributing, and not a standalone, cost to the patient. We believe CMS should first explore amending current surgical-related cost measures to appropriately incorporate the role of anesthesiologists.

Since the first year of MACRA, ASA has provided consistent feedback to CMS in support of cross-specialty cost measures, MIPS Value Pathways, and improvement activities. Early in the Quality Payment Program, we were excited about the role that patient relationship codes could have in fostering better attribution of anesthesia care within a surgical episode of care. These codes were designed to better define the length and rigor of a clinician's services rendered in a given case and determine how other clinicians contributed to the case. The relationship codes for each category could be tested to help determine the attribution of anesthesia and other services within surgical cost measures. Rather than choosing either a broad or narrow approach, using these relationship codes will allow CMS to test a current cost measure that will more accurately pinpoint costs and relationships between clinicians on each case.

If the intended goal of CMS in developing an anesthesia cost measure is to ensure anesthesiologists have a cost measure available for MIPS and MVPs, then a complementary goal should be focused on encouraging anesthesiologists to use their cost performance data to support their role within an alternative payment model (APM). An APM takes a more holistic approach to the patient journey and identifies where cost savings can occur. In a Total Knee Arthroplasty, the patient will move their way through preoperative visits, the surgical procedure, discharge planning and disposition, and follow-up care. If a complication occurs, the patient may incur additional costs for readmission or an unplanned emergency department visit. Although many physicians and other clinicians may deliver patient care in this surgical pathway, for anesthesiologists, the cost is not primarily driven from administering anesthesia but rather intangible costs that are not captured by billing or diagnosis codes. Such actions include prehabilitation of the patient in a preoperative setting, reducing opportunities for surgical site infections, and partnering with other specialists for care coordination. Quantifying these aspects of anesthesia care will be challenging since most cost savings are to Medicare Part A instead of Medicare Part B.

CMS should also consider the anesthesia cost measure from a patient perspective. Patients may not understand how anesthesia costs are incurred but patients certainly understand why anesthesia care is important to their well-being during a surgical procedure. Among their top concerns, patients do not wish to feel any pain or have postoperative nausea and vomiting. Patients wish to have no memory of their procedure and to return to their normal function as soon as possible. It is doubtful that a patient would choose certain anesthesiologists or a group based upon an anesthesia-specific cost measure where the general patient's default understanding is likely to support the idea that more cost equals better care. By including anesthesia within surgical episodes, or at the very least identifying complementary anesthesia costs with relation to established cost measures, CMS can assist

patients in understanding the totality of surgical care cost instead of relying on the patient to determine what features of specialty care their treatment will require.

ASA requests more information on reasoning or case examples to explain the effort to target anesthesia costs apart from other surgical costs. If CMS wishes to see a standalone anesthesia cost measure, we recommend that CMS build off current cost measures and understand where anesthesia costs are accrued. We do not recommend creating a broader anesthesia cost measure for all anesthesia cases. We welcome the opportunity to collaborate with CMS to identify cost measure solutions for any types of cases that CMS believes might more intuitively be decoupled from surgical costs.

Question 3

In 2019, the Department of Health and Human Services (HHS) convened an interagency task force to identify pain management best practices that may serve to highlight some of the challenges in developing cost measures for interventional pain management. The report emphasized that an effective pain treatment plan requires proper patient evaluation to "establish a diagnosis, with measurable outcomes that focus on improvements, including quality of life, improved functionality, and activities of daily living." These treatment plans may span a significant amount of time and require a step-by-step evaluation to understand if pain strategies are effective or not.

A measure that accurately reflects or models interventional pain management (IPM) costs may not be currently feasible, as pain is subjective and the timeframe of a case as well as a patient's long-term needs are difficult to predict. As further described in the HHS task force document, effective treatment requires an individualized, patient-centered approach that may include multiple medical disciplines. For acute pain, treatment options often include a multimodal approach that includes not just those that are identified via CPT codes (such as nerve blocks, physical therapy, etc.) but also medications and other targeted strategies for pain management.

When considering that chronic pain treatment relies on patient reported outcomes and other methods that are just beginning to be standardized, identifying "poorly managed" patients would often include additional costs that may not be easily adjusted to establish common performance and cost benchmarks. To assess cost, CMS would also need to address diagnostic processes and therapeutic actions that often cannot be determined until the patient is evaluated after an intervention. For chronic pain, patient treatment often takes place over a longer period of time and includes different escalation approaches that meet patient needs and treatment objectives. For chronic pain patients, treatment may include any combination of options from medications, restorative therapies, interventions such as surgical procedures, behavioral modifications, and more integrative health strategies. Anesthesiologists and pain medicine physicians begin with a tiered approach to pain management and escalate to more aggressive treatments based upon patient assessments and feedback. In general, use of complementary and alternative treatments will raise costs but is actually a sign of well-managed care rather than poorly managed care.

ASA considered the different approaches that anesthesiologists and pain medicine physicians might take besides injections. Neuromodulation devices would be next in line for treatment options – not as an initial expense to trigger a cost measure but rather as a follow-up cost. A cost measure would have to consider what percentage of stimulators are explanted

due to inadequate treatment or, say, infection in the first year as opposed to battery replacement every five years. Such a scenario might reflect value to the patient and to the health care system. Another example of poorly managed care versus well managed care with regard to both cost and best practice would be the combined administration of oral and intrathecal opioids in a patient with a surgically implanted pain pump. Except in rare cases, such as with cancer or end of life care, this dual route administration increases the risk of complications with little improved patient benefit and at a higher cost of care. Should CMS look into neuromodulation devices, consideration would have to be given to physicians who have poor patient selection for these devices versus those who have a more targeted implant ratio.

While patients with pain benefit from multidisciplinary, team-based care, interventional procedures use advanced diagnostic imaging and focused injections or procedures to treat and manage chronic pain. These procedures are very invasive and difficult and constitute the practice of medicine. Due to the complexities in diagnosing and treating chronic pain and the inherent risks associated with interventional measures, it is imperative that these difficult procedures only be performed by physicians.

Nurse anesthesia training and licensure or other non-physician educational courses are insufficient to meet competencies for the independent practice of Pain Medicine. The licensure, training and clinical experience of non-physicians is insufficient to provide the medical expertise required for the evaluation, diagnosis, and management of complex pain, especially advanced invasive interventional procedures. ASA strongly opposes the independent practice of pain medicine by non-physician providers. Advanced practice nurses may work together with and under the supervision of Pain Medicine physicians. In preserving our patients' best interests, ASA maintains an ongoing commitment to the delivery of safe, multidisciplinary, physician-led pain care.

Question 4

ASA does not believe a cost measure for either chronic or acute pain management would be appropriate at this time, as treatment for pain is often centered around a patient-specific approach and subjective perceptions of pain from patients. However, there are paths CMS can pursue that may make future efforts on cost measures more feasible. CMS should clearly delineate acute pain management from chronic pain management before pursuing such cost measures. There is a lack of clarity on how key terms are being used in this question based on the examples given. For example, facet injections are used for chronic pain management, not acute pain management. Acute pain management should not be included in a measure for interventional pain management.

But a larger question may be how CMS and its contractors can appropriately delineate when acute pain evolves into a chronic medical problem and when chronic pain may lead to acute pain flares. If the first few "Waves" of cost measure development are an indicator for future methodological structures, CMS must be especially cautious with how an episode begins, when it ends, and if the episode will trigger any additional cost measures. An example of this may be a patient with low back pain who, after several months of treatment, begins to experience pain in a separate location.

CMS should also consider features of cost that are not easily captured by claims data but rather patient-focused metrics. Chronic pain management is based, in large part, among a

subjective assessment of the patient on their level of pain and their treatment expectations. For chronic pain, CMS should consider access to pain care as a central feature for determining cost and cost benchmarks. Anesthesiologists and other physicians specializing in pain medicine understand that access to physicians, treatment options, and other avenues of medical support can improve patient outcomes over time. In short, CMS should identify how best to measure and assess costs in determining whether a patient can receive timely care in a cost-effective way. Coupled with social determinants of health, where a patient chooses to have their procedure or chronic pain managed, in an office, ASC, or hospital, will likely influence the cost of their procedure. Access to pain medicine physicians in those locations also influences the cost to Medicare beneficiaries.

Yes. The American Society of Anesthesiologists is interested in nominating physicians to work on Wave 5.

1.1.20 Comment Number 20

- **Date:** 03/31/2022
- **Submitter Name, Credentials, and Organization:** Karen Johnson, PhD, American Urological Association
- **Comment Text:** The American Urological Association appreciates the opportunity to provide comment on the candidate concept related to oncological care. Our comments focus primarily on issues and suggestions related to prostate cancer. Our advisors differentiated between five categories of prostate cancer: low-risk localized, intermediate-risk localized, high-risk localized, locoregional, and metastatic. They also suggest linking administrative claims data with tumor registry data to ascertain extent of disease (stage). If this is not possible, they believe claims data can be used, to some extent, to impute extent of disease.

  For localized prostate cancer, typically, the higher the risk, the higher the cost associated with diagnosis and treatment. While it is difficult to distinguish between the three risk groups, identifying higher risk disease is possible. That said, reliance on post-diagnosis hospitalization would be tricky because in the PSA screening era, it could be that post-biopsy hospitalization is more commonly related to post-biopsy sepsis (an iatrogenic condition) than a cancer-related issue. One possibility would be to look for sequenced outpatient E+M codes for the same ICDs by different providers (e.g. urologist, radiation oncologist, medical oncologist).

  Compared to localized prostate cancer, metastatic disease is associated with the highest cost, although it may be easier to differentiate algorithmically. Specifically, for metastatic prostate cancer, concomitant ICD-10 for primary prostate cancer and secondary metastatic sites (especially bony metastases) would be a proxy for metastatic prostate cancer. These diagnoses, coupled with imaging studies (bone scan, CT scan, PET scan) obtained within 2-3 months of a new prostate cancer diagnosis (or, more specifically, a prostate biopsy) would be an indicator of more high-risk features of that particular diagnosis. Note, however, that this would not discriminate between appropriateness in obtaining those imaging studies (cross sectional imaging is not recommended by AUA guidelines for low-risk disease).

  Our advisors also noted the importance of determining whether the focus of measurement would be incident prostate cancer, prevalent prostate cancer, or both. The natural history of prostate cancer is lengthy (>10 years), and as such, men are frequently at different phases

of management, which require different levels of intensity of treatment. Given the heterogeneous nature of management of prevalent prostate cancer, one might consider focusing initially on management of incident (new) disease.

Our advisors acknowledged that any logic used to classify prostate cancer patients will be imperfect, and there will be some degree of misclassification. They believe, however, that for such misclassification to become material, there would have to be systematic differences in misclassification among providers, which would be unlikely.

Finally, our advisors suggested the following services that may differentiate different stages of prostate cancer:

- Low risk localized:
  - E+M codes from urologist, radiation oncologists, medical oncologists
  - Prostate biopsy, with no imaging (rarely prostatectomy or radiation therapy, although there are plenty of scenarios when surgery or radiation are indicated (e.g., young patients, strong family history, etc.)
- Intermediate/high risk localized:
  - Same as low risk, but with imaging (CT abdomen, pelvis or both; MRI pelvis/prostate; bone scan; PET scan)
- Localized disease – Incident Prostate cancer diagnosis +
  - External beam radiotherapy/Proton therapy +/- up to 3y of concurrent ADT
    - Could adjust for duration of concurrent ADT (none, up to 6mo, 6mo-3y) as a proxy for disease risk
  - Brachytherapy +/- external beam radiotherapy +/- ADT
  - Radical prostatectomy
  - Repeat biopsy within 18 months (to identify men on active surveillance)
- Locoregional disease – Incident prostate cancer diagnosis +
  - External beam radiotherapy/Proton therapy + 2-3y of concurrent ADT
  - Brachytherapy + external beam radiotherapy + 2-3y of concurrent ADT
  - Radical prostatectomy +/- external beam radiotherapy + 2-3y of concurrent ADT
- Metastatic disease – Incident prostate cancer diagnosis +
  - ADT
  - ADT+
    - Abiraterone
    - Apalutamide
    - Docetaxel
    - Enzalutamide

We believe that measure development should focus on those cancers that most significantly impact public health and that carry the most significant costs. These include breast, colorectal, lung, and prostate cancers. While a unifying framework could be proposed to unify measures associated with each of these common and impactful solid tumors, the clinical nuances associated with each cancer would require separate measures. Stated differently, these disease states are sufficiently different from each other (particularly lung vs. prostate) that our advisors believe it would be methodologically impossible to develop a broad cost measure for cancer that would be appropriate for these different disease states.

While drug costs dominate costs of care among patients with metastatic disease, they do not dominate costs of care among patients with localized (or locoregional) disease. Overuse of imaging around the time of diagnosis is one of the biggest drivers of cost (other than drug costs), although this is not the case throughout the disease course.

Specific clinical services related to the management of prostate cancer where one would expect to see variation in clinical practice include:

- Use of imaging
  - Pre-diagnosis (MRI)
  - Post-diagnosis (MRI, CT, Bone scan, PET-CT)
- Use of genomic testing post-diagnosis
- Use of active surveillance in the management of low-risk and low-intermediate risk prostate cancer
- Use of hypofractionated external-beam radiation therapy
- Use of proton therapy
- Use of short-term or long-term ADT
- Readmission/ED visit after prostatectomy
- Surgery for treatment of incontinence, ED after prostatectomy
- Admission/ED visit after radiation therapy
- Surgery for treatment of incontinence, ED after radiation therapy
- Admission/ED visit while on systemic therapy for metastatic prostate cancer
- Use of palliative care/hospice
- ICU admission in last 30 days of life
- Systemic therapy in last 14 days of life

More generally, the following reflect potential opportunities for improvement in prostate cancer care:

- Variation in diagnostic workup
- Variation in treatment modalities and options
- Variation in regional/geographic practice patterns

- High rates of inappropriate use or resources (i.e. overutilization)

Overall , this list of trigger codes seems well positioned to discriminate between localized versus metastatic prostate cancer. This is a much cleaner distinguishing feature, statistically speaking, and may be the best option (vs. trying to differentiate localized strata). However, if there is a desire to distinguish between the varying localized prostate cancer risk groups described in response to Question 1, common forms of prostate cancer treatment and imaging work-up (e.g., radical prostatectomy codes, prostate radiation codes, CT, bone scan, PET scan, etc.) would need to be included. In addition, the C61 code would need to be combined with timing of diagnosis to determine whether an individual patient has incident or prevalent disease.

Please see the bulleted list included under Question 3 for ideas for quality indicators (there are existing measures for some, but not all, of these concepts).

We believe the Clinician Expert Workgroup should include the following:

- Those who diagnose prostate cancer and those who treat it in inpatient and/or outpatient settings (includes (e.g. urologists, radiation oncologists, and medical oncologists)
- Those with relevant medical coding knowledge
- Patients and/or patient stakeholder representatives
- Pharmacists
- Palliative care professionals
- Long-term care and hospice professionals

The AUA would be delighted to nominate qualified candidates from our membership.

1.1.21 Comment Number 21

- **Date:** 04/01/2022
- **Submitter Name, Credentials, and Organization:** Karen Hagerty, MD, American Society of Clinical Oncology and Association for Clinical Oncology
- **Comment Text:** We are submitting comments on behalf of the American Society of Clinical Oncology and Association for Clinical Oncology (ASCO) to provide early technical guidance on the consideration and development of MACRA episode-based cost measures within the upcoming Wave 5 measure development cycle. ASCO is a national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans, including Medicare beneficiaries.

  In its Call for Public Comment, the Centers for Medicare & Medicaid Services (CMS) and Acumen, LLC seek feedback on two cancer related measures, Diagnostic Radiology Procedures: Screening Mammography and Oncological Care: Cancer, among others. As the Diagnostic Radiology Procedures measure will focus primarily on radiologists, ASCO is focusing its comments on the Oncological Care measure.

Medical Oncologists currently lack an applicable cost measure within the Merit-based Incentive Payment System (MIPS) and are often excluded from the nonspecific Total Per Capita Cost measure. After this initial round of public input, CMS will narrow the originally proposed eight clinical areas to four areas to finalize for cost measure development. ASCO agrees with CMS and Acumen that broad stakeholder input is critical to the development of cost measures, and we share the following responses to CMS and Acumen's questions with the understanding that further stakeholder engagement will be necessary when determining the appropriateness of any new cost measure.

Selection of the Oncological Care Cost Measure for Further Development

The heterogeneity of cancer disease and treatment presents significant challenges in the development and deployment of an oncological care cost measure.

Development of an oncological care cost measure will require a complex prediction and risk- adjustment methodology that accounts for the heterogeneity of cancer disease, comorbidities, and social determinants of health. Medicare claims data, from which a cost measure would be calculated, lacks many of the clinical and other factors that drive differences in utilization and cost, notably cancer histology, molecular characteristics, disease stage, and goals of therapy.[28]

For these reasons, CMS must be cautious in selecting the Oncological Care cost measure for further development and be prepared for substantial engagement with medical, billing, and measure development experts.

Quality measures, focused on clinical guideline and pathway concordance, offer an alternative to cost measures.

Whereas MIPS cost measures are limited to the administrative claims data from which they are derived, MIPS quality measures can benefit from clinical and other data that better predict appropriate utilization of anti-cancer and supportive therapies. Measures which consider concordance with published clinical guidelines serve to support both quality care and appropriate utilization of costly therapies.[29] Selection of preferred treatments within clinical pathways—high quality clinical pathways consider comparative efficacy, potential side-effects, and cost— considers a wide range of clinical and patient factors not available within Medicare claims data.[30]

Oncological Care: How should this measure account for differences in costs due to cancer severity using administrative claims data?

Acumen must consider administrative claims data beyond ICD-10 codes to account for differences in cost due to cancer severity.

In prefacing this question, Acumen provides an example of risk adjustment within the Diabetes cost measure, differentiating between Type 1 and Type 2 diabetes through use of

[28] https://ascopubs.org/doi/full/10.1200/JOP.2016.015834

[29] E.g., MIPS Quality ID #450 (NQF 1858): Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy

[30] https://ascopubs.org/doi/full/10.1200/JOP.2015.009134

ICD-10 codes. In contrast, most malignant cancers lack specificity within the ICD-10 code set to account for disease severity. For example, an early-stage breast cancer patient who is responding positively to hormonal therapy will be assigned the same ICD-10 code (e.g., C50.511 – malignant neoplasm of the lower-outer quadrant, right female breast) as a late-stage breast cancer patient whose disease has recently progressed and who requires multiple chemotherapy and immunotherapy treatments.

While we have included a few suggestions below as to how the presence of certain ICD-10 codes may be used to assist in risk adjustment, other factors should be considered specific to cancer disease.

Multiple primary cancers, secondary malignancies, and history of prior cancer each require unique approaches in development of a cost measure.

A small percentage of cancer patients are afflicted with more than one primary cancer simultaneously (e.g., a patient with both lung and colon cancers). These cases require patient-specific care plans that may include multiple localized surgeries and radiation therapy treatments, along with systemic chemotherapy and/or immunotherapy and supportive care drugs. The necessary composition and timing of each treatment is so unique that a patient's utilization and cost will not conform to national averages among patients with only one cancer type. The most appropriate approach would be to exclude patients with two primary cancers from any cost measure.

In contrast, secondary malignancies (ICD-10 codes C77.0 to C79.9) arise from the advancement and metastases of a cancer from its primary origin. Physicians use secondary malignancy codes to specify that a cancer has spread to distant lymph nodes, organs, and other sites. The presence of a secondary malignancy code is one instance where ICD-10 codes can be used to distinguish disease severity in cancer patients.

History of cancer (ICD-10 codes Z85.00 to Z85.9) may be used to denote a primary malignancy that has been successfully treated yet the aftereffects of which require management, or for patients who are survivors of a prior cancer and are now being managed for a second primary cancer. History of cancer codes should not themselves trigger an episode but can be used to account for differences in severity given the unique considerations that must be given to patients who may have prior exposure to radiation treatment and cardiotoxic or neurotoxic chemotherapy.

Use of certain drug treatments indicate meaningful differences in cancer severity.

As previously mentioned, cancer episodes range in severity and expected costs are not accounted for in the ICD-10 value set. There are, however, a few cases where developers within the CMS Oncology Care Model and Medicaid measurement programs have used the presence of certain drug treatments within the episode as a proxy for differences in cancer severity.[31] [32]These adjustments are done cautiously, as using actual utilization to predict

[31] https://innovation.cms.gov/files/x/ocm-pp3beyond-pymmeth.pdf

[32] E.g., Ohio Medicaid's Breast medical oncology episode: https://medicaid.ohio.gov/static/Providers/PaymentInnovation/DEF/BC-ONC.pdf

expected utilization is generally discouraged. However, in each of the following examples, it has been necessary to ensure appropriate risk adjustment:

- Breast Cancers:
  - Low-risk breast cancer episodes receiving only long-term oral endocrine therapy (e.g., anastrozole, exemestane, letrozole, or tamoxifen).
  - HER-2 positive breast cancer episodes receiving targeted therapy (trastuzumab, ado-trastuzumab emtansine, fam-trastuzumab deruxtecan, pertuzumab, and/or margetuximab).
  - High-risk breast cancer episodes receiving other chemotherapies and/or immunotherapies.
- Bladder Cancers:
  - Low-risk bladder cancer episodes receiving only Bacillus Calmette-Guerin (BCG) or mitomycin.
  - High-risk bladder cancer episodes receiving other chemotherapies and/or immunotherapies.
- Prostate Cancers:
  - Low-risk, castrate-sensitive prostate cancer episodes receiving only first-line androgen deprivation and/or anti-androgen therapies.
  - High-risk, castrate-resistant prostate cancer episodes receiving other chemotherapies and/or immunotherapies.

In each of the above cases, there are significant differences in severity and utilization, in addition to differences in treating medical specialties—e.g., low-risk bladder and prostate cancers are often treated by urologists, whereas high-risk cancers are treated by hematologists/oncologists.

Social determinants of health codes should be utilized in risk-adjustment.

In recent years, CMS has promoted recording and reporting of social determinants of health (SDOH) codes (ICD-10 codes Z55.0 to Z65.9).[33] SDOH play a meaningful role in care planning and management within cancer episodes. Cancer patients with significant SDOH concerns may require additional management by navigators, social workers, dieticians, and other specialists, as well as modifications to treatment plans to account for employment, family, housing, economic and/or transportation concerns. For example, a patient with a lack of reliable transportation may require a treatment plan that decreases the frequency of visits to the cancer center.

In order to encourage use of SDOH codes and appropriately account for differences in severity and treatment and support needs of patients with SDOH concerns, CMS should use these ICD- 10 codes in risk adjustment of cost episodes.

Oncological Care: Are there other types of cancer preferable for measure development? Should we consider a broad cancer measure that stratifies patients by type of cancer and stage?

[33] https://www.cms.gov/files/document/zcodes-infographic.pdf

Breast cancers, colon cancers, lung cancers, prostate cancers, and non-Hodgkin's lymphomas should be considered in cost measure development.

CMS has so far included breast, colon, lung, pancreas, and prostate cancers within the proposed cost measure. ASCO recommends removal of pancreatic cancers given their often-late diagnosis, short duration, and high-intensity treatment.[34] The addition of non-Hodgkin's lymphoma would assist in creating a broad measure covering the majority of hematologists/oncologists.

Risk adjustment factors should be calculated per cancer type.

While numerous cancer types may be aggregated in final measure results, they should not be treated as a single disease for purposes of risk adjustment. Each cancer type is unique in both its aggregate utilization and cost, but also in the impact of other risk adjustment factors mentioned in the proposed episode design and ASCO's included comments. Performing regression analysis on each cancer type will reveal a more accurate risk adjustment method than attempting to aggregate all cancer types into a single episode design.

ICD-10 codes lack the critical specificity of cancer stage and goals of therapy.

As previously mentioned, ICD-10 codes do not stratify patients by stage of cancer at diagnosis or subsequent progression of disease. Similarly, ICD-10 codes fail to account for goals of anticancer therapy—goals of therapy (also referred to as treatment intent) are often classified as either cure, control, or palliation, each with differing expected utilization and total costs.

The lack of specificity within the ICD-10 code set can either preclude development of cancer cost measures due to lack of specificity or require other factors, such as those mentioned in ASCO's comments, to account for differences in severity. Disease-specific algorithms may be necessary to account for the lack of staging information within the ICD-10 code set.[35]

Oncological Care: Given that drug costs dominate costs of care across types of cancer, what are other opportunities for cost improvement? That is, what types of services are clinically related to the treatment and management of cancer that could distinguish variation in care?

Drug costs should be excluded from the cost episode.

As mentioned in the question, drug costs dominate total cost of care in most types of cancer. The predominant factor in whether to include drug costs within the episode is that physicians do not set the price of drugs used for cancer treatment and often do not have low-cost alternatives with similar efficacy available to them. The rise of precision medicine in cancer treatment has resulted in treatments that are less interchangeable based on patient genomics and other factors. For this reason, the cost of chemotherapy and immunotherapy agents should be excluded from the episode's predicted and actual costs.

While chemotherapy and immunotherapy costs should be excluded from the cost measure episode, there are other drug costs related to supportive care that may be considered for inclusion. While they share the same limitation in that physicians do not set the price of

[34] https://dx.doi.org/10.14740%2Fwjon1166

[35] https://ascopubs.org/doi/full/10.1200/CCI.18.00156

drugs, supportive care agents more often have appropriate alternatives available (e.g., denosumab vs. bisphosphonates for patients without renal impairment).

CMS should use caution in including Part D drugs within an episode design.

Treatment for cancer may involve Part B injectable drug therapies and/or Part B oral drug therapies. The inclusion of Part D drugs within an episode's predicted and actual costs must account for two distinct scenarios:

1. In some cases, the inclusion of Part D drugs may result in episodes that may not have otherwise been triggered. For example, a low-risk breast cancer patient with Part D may trigger an episode with only the oral drug treatment; whereas, if the patient did not have Part D coverage, the episode would not have been triggered.
2. In other cases, the inclusion of Part D drugs may add significant costs to an already triggered episode. For example, a prostate cancer patient with Part D could trigger an episode with costs inclusive of an injectable gonadotropin-releasing hormone, plus a high-cost oral enzalutamide treatment. A similar patient without Part D would trigger an episode with only the cost of the injectable drug.

If CMS wishes to include Part D drug costs within an episode, they should account for differences in patients receiving one or both of Part B versus Part D drug treatments, and how these factors differ between cancer types.

Episodes should consider the presence of surgery, radiation therapy, and transplantation services when predicting episode costs.

Surgical resection of tumors, targeted radiation therapy, and stem cell transplantation each represent meaningful costs within cancer care. However, they lead to complications in episode design and cost prediction. For example, CMS and Acumen propose an episode window that is triggered by one of a set of drug and biologic administration codes and lasts for the duration of drug administration or a defined time thereafter. Because drug administration triggers an episode, a breast cancer patient who receives neoadjuvant chemotherapy (i.e., first drug administration prior to the day of surgery), would have the surgical expenses captured within the episode. Conversely, a breast cancer patient who receives only adjuvant chemotherapy (i.e., first drug administration after the day of surgery), would not have the surgical expenses captured within the episode, as they took place prior to the episode trigger. Similar situations exist for receipt of radiation therapy.

Within the Oncology Care Model, CMS accounted for surgeries, radiation therapy, and transplantation services in its prediction model for episode costs.[36] Unfortunately, they did so by using a single coefficient for all cancer types, leading to underpredicting surgical and radiation costs for otherwise lower cost cancer types and overpredicting surgical and radiation costs for otherwise higher cost cancer types. For this and other reasons, some of which we allude to above, we strongly urge CMS to perform regression analysis on each cancer type independently.

[36] https://innovation.cms.gov/files/x/ocm-pp3beyond-pymmeth.pdf

Increased care management services utilization often reflects improvements in care and should not be discouraged by use of cost measures.

In recent years, CMS has increased Medicare beneficiaries' access to care management services, such as chronic care management, complex chronic care management, principal care management, transitional care management, and advance care planning. These services, now reimbursable within Medicare's fee schedules, complement new models in the delivery of patient-centered, comprehensive cancer care envisioned by the National Academy of Medicine[37] and codified within the Oncology Medical Home standards.[38]

As the coverage of these services, along with their billing codes, are only recently reimbursable, their utilization in billing is still lower than eventually expected.[39] Utilization is further complicated by Medicare barring use of some of these codes for beneficiaries within the Oncology Care Model.[40] ASCO believes that additional education on the coverage of these services within Medicare, as well as the end of the Oncology Care Model, will lead to increased utilization of these services and their billing codes for Medicare beneficiaries.

The creation of an oncology cost measure should not discourage use of these services deemed beneficial in management of Medicare beneficiaries with cancer. Appropriate risk adjustment based on comorbidities, reported SDOH, and other recommended factors will help to mitigate the risk of cost measures leading to stinting of necessary care. Cost measures can also be complemented by quality measures that encourage use of appropriate care or discourage use of inappropriate care.

Oncological Care: Trigger Codes

The preliminary specifications for the Oncological Care measure includes 19 CPT/HCPCS codes for delivery of chemotherapy using multiple administration routes and techniques, included with each of the proposed cancer types. There are examples, however, where unrelated CPT/HCPCS codes are included in the preliminary specifications:

- Breast Cancer: 0581T – Cryotherapy ablation. This code is unrelated to other triggers included in the cancer type and would result in episodes not comparable to others within the measure. Further, as a Category III CPT code, this code reflects an emerging technology for which a permanent code has yet to be established. For these reasons, 0581T should be removed as an episode trigger.
- Prostate Cancer: 55700 – Biopsy of prostate gland. This code is unrelated to other triggers included in the cancer type and would result in episodes not comparable to others within the measure. Further, biopsies would most appropriately be included in procedural episodes and attributed to surgeons and/or pathologists. For these reasons, 55700 should be removed as an episode trigger.

[37] National Academy of Medicine. Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis.

[38] https://doi.org/10.1200/op.21.00167

[39] https://www.asco.org/sites/new-www.asco.org/files/2021-QCS-ACP-ABS25-FINAL.pdf

[40] https://innovation.cms.gov/files/transcripts/ocm-faq-app-trans.pdf

Participation in Wave 5 Development

CMS should engage experts in cancer care delivery and medical coding in development of an oncological care measure.

The design of an oncological care measure should reflect the numerous complexities in the delivery of cancer care and the presence of diagnosis and service codes within administrative claims data. It is important that CMS and Acumen engage clinical experts in cancer care delivery and medical coding experts in all aspects of measure development, along with future opportunities for public review and comment.

While ASCO has reservations on selection of the oncology care measure for further development, if the measure is selected for Wave 5, we offer our clinical and medical coding expertise for representation in the Clinician Expert Workgroup and other workgroups.

1.1.22 Comment Number 22

- **Date:** 04/01/2022
- **Submitter Name, Credentials, and Organization:** Carolyn Millett, American Academy of Physical Medicine & Rehabilitation
- **Comment Text:** On behalf of the more than 9,000 physiatrists of the American Academy of Physical Medicine and Rehabilitation (AAPM&R), we appreciate the opportunity to provide feedback on the Episode-Based Cost Measures Wave 5 Call for Public Comment. AAPM&R is the national medical specialty organization representing physicians who are specialists in physical medicine and rehabilitation (PM&R). PM&R physicians, also known as physiatrists, treat a wide variety of medical conditions affecting the brain, spinal cord, nerves, bones, joints, ligaments, muscles, and tendons. PM&R physicians evaluate and treat injuries, illnesses, and disability and are experts in designing comprehensive, patient-centered treatment plans. Physiatrists utilize cutting-edge, as well as time-tested treatments to maximize function and quality of life.

  AAPM&R has reviewed the clinical areas and measure concepts outlined in the call for public comment. Below, we describe our feedback regarding the Anesthesia Care measure concept focusing on interventional pain management as well as the Post-Acute Care measure concept. Physiatrists have significant expertise in both post-acute care and interventional pain management. If CMS and Acumen choose to move forward with building cost measures in either of these areas, we urge you to include physiatrists on the measure development workgroups.

  Anesthesia Care – Interventional Pain Management

  The call for public comment notes that focusing on interventional pain management would "have a much smaller beneficiary coverage and apply to a smaller subset of clinicians." We agree. We would also note that the subset of clinicians impacted by this measure would likely have significant overlap with the clinician group that the wave 4 low back pain cost measure applies to. We believe an interventional pain management cost measure would require an exclusion for low back pain to avoid clinicians being attributed to both measures for the same care. Low back pain is likely to be one of the more common conditions for which interventional pain management is required, which suggests that it may not be a high priority measure to pursue.

Post-Acute Care

AAPM&R is concerned about the lack of heterogeneity in Post-Acute Care (PAC) cost measure concepts currently proposed. In the context of a single diagnosis there is massive variability between patients and their needs which would significantly impact total cost. For example, patients with acute stroke diagnoses may be discharged home without any therapy or additional help, or may require extensive acute rehab, or anything in between. The cost variance is broad. Stroke patients admitted to IRF, SNF or LTACH would each have different costs of care associated with those different settings. Even more significant would be the difference in cost for a patient who is discharged to home. The setting in which a patient receives their care is primarily dependent on that patient's condition.

To truly measure differences in care we would have to drill down and compare patients with very similar diagnoses such as a patient with dense right hemiparesis with expressive aphasia and cognitive deficits who requires a totally different level and type of care from a patient with only mild right hemiparesis which resolves in two days so that the patient can return home with a home or outpatient program. AAPM&R strongly recommends that CMS and Acumen consider the extent to which risk adjustment and sub-grouping would need to be employed to make a post-acute care cost measure accurate and meaningful. Further, if cost is assessed in the post-acute care setting, AAPMR suggests tying the cost to correlated functional measures.

Finally, we would like to highlight some concerns about post-acute care cost being measured at the clinician level. While the individual physician has some role to impact cost, we would argue that when it comes to post-acute care, the decisions that impact cost most significantly are in the hands of the facility. Most physicians will have limited ability to directly impact such things as nursing training and staffing ratios, availability of consulting or support services such as stat lab, diagnostics, etc. These variables, that are out of a physician's control could have a significantly higher likelihood of impacting total cost for post-acute care patients. With so many factors out of the physicians' control, we believe it is inappropriate to tie post-acute care cost to the physician. We direct CMS and Acumen to review the AMA House of Delegates resolution D-385.958 Patient Satisfaction Surveys and Quality Parameters as Criteria for Physician Payment, which urges that "physician payment determination, when incorporating quality parameters, only consider measures that are under the direct control of the physician."

1.1.23 Comment Number 23

- **Date:** 04/01/2022
- **Submitter Name, Credentials, and Organization:** Yajuan Lu, Johnson and Johnson
- **Comment Text:** Cancer diagnosis has dramatically outpaced current disease classification; the reliance on billing and coding to accurately describe a patient is insufficient in its current state. The ICD-10 diagnosis codes will need to expand to more accurately reflect a cancer patient's current disease state for population analysis of similar patients. Cancer has moved from an anatomical, to a histological, to a molecular and now to a genetic classification of disease. This genetic characterization of disease is inherently connected to disease acuity and projected costs. There is a tendency to expect that the complexity of cancer care can be collapsed into distinct subcategories of cancer, such as the 24 subtypes identified in CMMI's

Oncology Care Model (OCM). This approach can have disastrous unintended consequences for providers and patients due to oversimplification of projected costs for adjacent seeming but fundamentally different diagnoses. Certain diagnoses are especially challenging as OCM benchmarks for total cost of care can fall below the cost of drugs alone for the six-month episode. As a result, cancer therapy choice may be changed without a balance to the value in outcomes for the patient. This was the case for multiple myeloma, as well as other cancer subtypes with high demands for innovation above the standard of care at during the benchmarking period.

The direction of innovation is trending to treatments where are increasingly personalized to a patient's unique genomic profile. When aggregated against other patients, the similarities are often less and less when examining care being delivered for a certain tumor type. This innovation is occurring more rapidly than our current system of classification can currently accommodate. Precision medicine requires a methodology for precision coding, to be updated frequently to reflect these innovations. CMS should refrain from implementing any cost measure that results in clinicians unable to select appropriate therapies for Medicare beneficiaries. As it currently stands, we are not confident that the ICD-10 system alone is sufficient to capture cancer acuity. This is partially a coding challenge, but also a challenge within cancer taxonomy and classification that has marked deficiencies in standardized approaches to characterizing disease acuity. New taxonomies and coding approaches are necessary to do this without undue pressure on clinicians to select therapies that may not be most appropriate for patients; CMS should refrain from implementing any cost measure that bears this risk.

It is important to also understand the location of cancer care being delivered, especially with respect to prostate cancer. Initially, most prostate cancer patients are treated in the urology setting with only those with progressive disease moving to oncology care setting. Surveillance, surgery, radiation along with additional therapies are common in the urological care setting. So, differentiating between urology and oncology care locations may prove beneficial to understanding costs. Additionally, adequate measurement of surveillance is an important consideration as it is likely to skew lower costs than those patients receiving therapeutic interventions. Cost measures along with quality measures addressing outcomes need to be considered in tandem for this reason. Please also consider our response to question two.

It is important to recognize that in oncology, as treatments have innovated, the specificity has also grown to target specific genomic profiles of many cancers. By having a much more detailed classification of cancer, we may account for the difference across oncology specialties. Simple episode-based measurement may fail to yield meaningful outcomes for patients and providers. Cancer care is complex and incorporating patient reported outcomes should be equally considered. We strongly encourage CMS to carefully consider the definition of the care episode, as well as the propensity for many durable therapies to have value that carries well beyond the measurement period of the care episode. For example, with the emergence of cell and gene therapies which commute a substantially higher value through a single treatment than legacy therapies, value is carried across multiple performance periods, but a single upfront cost is necessary to achieve lasting value. While durable therapies are an emerging consideration, the concept of downstream savings associated with upfront cost is not a feature unique to cell and gene therapies, but a common feature of many

advanced treatment regimens in cancer care. CMS is strongly encouraged to consider the inappropriateness to incent providers to focus on lower value therapies simply to fulfill the mechanics of short-term cost measures. This is detrimental to both patient care and the efficiency of our healthcare system.

As with all measurement, the architecture of the approach for cost measures should be designed to fit the goals of the program. CMS's goal for care delivery at the clinician level in cancer care should be to optimize the efficiency of care delivered to achieve value. Value is defined as cost per unit of quality over time. Value should not be conflated or reduced to simple cost.

In order for cost measures to translate to value, they must be paired with outcome measures over an appropriate measurement period that covers the durability of the treatment provided. This is not reflected in the current cost measures within MIPS, nor in the available outcome measures for cancer care. There are no outcome measures of treatment response rate, progression free survival or overall survival in CMS's quality programs. CMS has not commissioned the development of cancer patient goal articulation and attainment that includes meaningful patient quality of life considerations outside of health and safety, although those goal setting measures have important analogues in the home and community-based services setting.

One of the central theses of value-based payment is that overutilization is perversely incented through a fee for service model. Overutilization of direct therapy is not the crux of value optimization in cancer treatment. We are concerned that providers who select therapies that can deeply impact patient quality of life on these types of outcomes will not be measured according to the value these therapies confer because they are not paired with meaningful outcomes measures. Rather, MIPS cost measures are structured to reduce the problem of cancer care to a short episodic cost containment problem.

Were the current MIPS cost measure approach to be replicated in cancer, it would be especially problematic for cancer care delivery. This is because there is no clinical equilibrium in cancer care and innovation in treatment is at its highest.

The MIPS cancer cost measures should be subdivided by areas of care that are known to be most susceptible to clinical variation and provider choice. Cost measures should not be leveraged in areas of known relatively fixed cost which varies only according to disease acuity. The reason for this is that each practice's panel of patients cannot be considered a representative sample of disease acuity from a national pool; rather, some cancer providers specialize in treating patients with higher disease acuity. These providers will be penalized under a genericized approach to cost measurement without the necessary complexity to account for acuity. This was a known problem with the oncology care model (OCM).

CMS should perform a rigorous analysis by cancer subtype of costs that are fixed according to acuity and those that are more under the control of the provider. For example, treatment costs may be relatively fixed for a given cancer subtype, but have variation in peripheral costs such as side effect management, hospital visits, ER utilization, etc. These peripheral components are within the realm of control of the clinician during the cost measure episode where direct treatment costs may not have their full value realized within the performance episode. Direct treatment costs should therefore have different considerations and represent a different category of cost measure. We encourage CMS and

their MIDS contractors to subdivide cancer cost measures at the genetic level of precision medicine delivery and to account for the acuity of disease.

Prostate cancer is a highly prevalent cancer type within the Medicare population and accounts for a significant portion of Medicare spending on cancer care. There are demonstrated prostate cancer health care disparities for vulnerable populations . For these reasons, prostate cancer should continue to be a focus for quality measurement and improvement in the MIPS program, including the focus of future development of MIPS Value Pathways.

While we agree that urologists are frequently treating patients with prostate cancer, we would emphasize the importance of prioritizing this population for quality measurement and accountability under the MVP framework. Such a framework should be patient-centered, and inclusive of considerations for patients treated by both oncologists and urologists.

As demonstrated under the OCM, total episode payments were reduced for lung, lymphoma, high-risk breast, and colorectal cancers. Total episode payment was reduced for high-intensity prostate cancer, but without statistical significance, and total episode payments increased for low-intensity prostate cancer . CMS should consider prioritizing these types of cancers based on lessons learned from the OCM. Reductions in total episode payments were concentrated in higher-risk episodes for the same four cancer types. CMS should consider prioritizing high-risk cancer episodes over low-risk episodes.

A broad oncology episode-based cost measure will be challenging to develop, as diagnostic and treatment methods vary significantly between different types of cancer, and within different stages of cancer for the same diagnosis. Cancer-specific measures and MVPs, and measures focused on advanced vs. early-stage diagnoses may be more appropriate than broad measures focused on cancer care generally.

Exploration of measurement beyond direct treatment costs may be beneficial in addressing cost variation. Oncology clinicians that may do well in palliative care consultation, may demonstrate lower costs when compared to other clinicians who choose to add additional therapies. Alignment of therapeutic choices and patient goals may help align cost improvement and patient outcomes. Having documented patient goals for their health and beyond health and safety would more closely align care being delivered.

As many have experienced with the Oncology Care Model, when cancer care providers are hyper focused on cost of care, care stinting may and does occur. Cancer treatments that may have lower direct costs often have higher toxicities which then lead to poorer outcomes and costs associated with side effect management. Patients ultimately suffer as a result. Additionally, by focusing directly on costs we fail to understand the full value many innovative therapies can deliver. Therapies that extend the life of cancer patients may lead to higher costs which in turn may cast cancer providers as above the norm and completely miss the important outcome of patients living with cancer as a chronic condition.

As stated in a November 2021 JAMA editorial, "…the inclusion of drug spending in an APM bundle is problematic. Drug costs are increasing steeply as a share of the total cost of cancer care. Including drug spending in a bundle implies that oncologists have discretionary spending power in drug prescribing, which may not be true given the dynamic innovation in cancer treatment. Oncologists will substitute less costly regimens when there is clinical

equipoise, such as with biosimilar agents and bone-strengthening agents, but for new agents there are often no viable alternatives. Physicians will be unwilling to make guideline-discordant substitutions that compromise safety or efficacy purely for cost."

CMS should consider excluding drug costs until such time that appropriate outcomes measures are added to capture the value of care being delivered. This is with the exception of non-chemotherapy drugs (e.g., supportive care drugs) where practices have demonstrated value-based selection.

CMS should consider lessons learned from the OCM when developing episode group measures. As demonstrated in the model, cost containment incentives in the model did not significantly address drug spending, and CMS should consider strategies to omit these costs from episode-based measures:

- Reductions in total episode payments were concentrated in high-risk episodes for four cancer episode types (lung cancer, lymphoma, colorectal cancer, and high-risk breast cancer episodes)
- Overall, OCM had no impact on Part B chemotherapy spending or on most other Part B components
- OCM had no impact on Part D payments

Advocation for a longer than 6-month episode of care measurement period may be closer aligned to overall cost savings and achievement of value. In previous models, cancer patients who experienced delayed subsequent therapeutic needs, due to positive outcomes or PFS with a therapy, were often seen as high-cost outliers due to use of innovator therapies that may have longer term outcomes. Cancer patients who tolerate and maintain their current disease status tend to have higher costs than patients who cycle on/off therapy with little change in outcomes beyond 6-month.

Oncology clinicians should be measured on survivorship and other longer-term outcomes given a specific cancer sub-type where survival or longer-term outcomes has been demonstrated. Continuous maintenance therapy in cancer care may lower overall healthcare costs but under TCOC modeling, oncology clinicians may stop therapy due to episode benchmarking.

Patient-centered quality measures (PRO-PMs) assess patients' perception of the process of goal setting with their care team and evaluate whether care goals, including those outside of health and safety, were met during or after treatment. Goal setting is a critical component of the Institute of Medicine care plan included under the OCM. Concordance between patient and provider goals for care, particularly for advanced or metastatic cancer, may differ. Ensuring that measures evaluating cost of cancer care are balanced by patient-centered measures assessing whether patients' and caregivers' goals for care were met will be a better determinant of value than cost containment by itself.

Immunization-related quality measures are used to a limited degree at the PAC-level. For example, the Home Health Quality Reporting program includes Influenza Immunization Received for Current Flu Season (Home Health). Although this program directly targets home health agencies (as opposed to clinicians), agencies pass down accountability to their provider networks and may work with providers to improve immunization rates. Therefore,

some providers are already indirectly exposed to incentives to improve immunization rates in the home health setting.

Other PAC-level programs do not currently have these kinds of immunization related measures. For example, the Skilled Nursing Facility (SNF) Quality Reporting Program and Long-term Care Hospital Quality Reporting Program only include immunization-related quality measures that assess whether personnel have received certain vaccines There is an opportunity to further incorporate immunization-related quality measures in these programs.

There may be an opportunity to expand use of the AIS-E measure, which is currently specified and used at the health-plan level, by adapting and using it across the PAC quality reporting programs mentioned above as well as provider- and ACO-targeted quality reporting programs such as MIPS and MSSP. This would align adult immunization quality measure reporting and support improvements in adult immunization delivery.

Patient-centered quality measures (PRO-PMs) assess patients' perception of the process of goal setting with their care team and measure whether care goals were met during or after treatment. Ensuring that measures evaluating cost of RA are balanced by patient-centered measures assessing whether patients' and caregivers' goals for care were met will be a better determinant of value than cost containment by itself.

Patient-centered quality measures (PRO-PMs) assess patients' perception of the process of goal setting with their care team and measure whether care goals were met during or after treatment. Ensuring that measures evaluating cost of AMD and other ophthalmological care are balanced by patient-centered measures assessing whether patients' and caregivers' goals for care were met, will be a better determinant of value than cost containment by itself.

Opprotunity for Improvement:

- Supportive care treatment selection, including adoption of biosimilars when appropriate
- OCM, which included cost reduction incentives, led to a shift to lower cost supportive care drugs to mitigate side effects of chemotherapy, including drugs used to prevent neutropenia and cancer-related bone fractures.
- End-of-life treatment management (e.g., chemotherapy utilization in end-of-life) and utilization (ICU and hospice utilization) where there is potential variation (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7752516/#:~:text=Chastek%20et%20al%20%5B6%5D%20showed,2009%20data)%20%5B7%5D.)
- Managing triage and improving practice communication and access during active treatment to prevent avoidable emergency department and hospital utilization
- In addition to the opportunities highlighted in the Call for Public Comment document (e.g., supporting care transitions, reducing transfers to emergency departments and hospitals, and reducing pressure ulcers and falls), improved adult immunization rates represent another opportunity to improve cost effectiveness in post-acute care (PAC). For example, people who live in long-term care facilities are at higher risk of acquiring communicable diseases such as influenza , pneumonia , COVID-19 , and RSV among others. In a 2001 study, authors found that the mean cost per case of influenza-like illness in long-term care facilities was

$1,341 +/- $2,063 ($2,141 +/- $3,294 in 2022 dollars). Holding PAC clinicians accountable for the cost of defined PAC episodes may incentivize clinicians to improve adult immunization rates as a means of reducing potentially avoidable utilization and cost.

- Novel treatment options (e.g., cell and gene therapy) have a long-time horizon for better clinical outcomes and durability, but higher up-front costs. Extending the timeline for data collection (i.e., more than a year) and measurement of outcomes associated with novel treatments would more accurately reflect the long-term benefits of novel treatments.

1.1.24 Comment Number 24

- **Date:** 04/01/2022
- **Submitter Name, Credentials, and Organization:** Craig Johnson, PT, MBA, Therapy Partners, Inc.
- **Comment Text:** Risk adjustment using CSM approved methods is appropriate.

  PAC and acute patients are not the same type of patient and methodologies of attribution should not be mixed in the cost measure.

  Rehabilitative services by PT, OT, SLP should be included in the cost measure.

  Early diagnosis and early conservative, non-pharmacological interventions will improve care management in the Medicare population. Once early RA is diagnosed, a course of guided exercise and patient education by a physical therapist, that is not proscribing medication can reduce the incidence of joint replacements in the Medicare population.

  A trigger diagnosis of early stage RA, prior to the need for prescriptions will provide the opportune window for effectiveness of conservative treatment.

1.1.25 Comment Number 25

- **Date:** 04/01/2022
- **Submitter Name, Credentials, and Organization:** Jacob Goodman, American Academy of Ophthalmology
- **Comment Text:** We appreciate the opportunity for public comment. As the leading societies in ophthalmology (American Academy of Ophthalmology with 27,000 members, American Society of Retina Specialists, The Retina Society, The Macula Society and the American Glaucoma Society), we understand the need for another episode-based cost measure. We would like to work together to identify an appropriate episode measure.

  We would respectfully request that CMS treat the development of a cost measure the same as the development of a quality measure in terms of careful and considered involvement of the relevant medical specialties, analyses of the current practice patterns, gap in care, determination of factors that are within and not within the control of the physician and potential consequences on the quality of patient care, testing of validity, reliability and fairness, etc. The development of the episode-based cost measure is an example of this collaboration in which ophthalmologists participated and provided input, and the ultimate outcome was an equitable measure that did not result in a negative impact on patient care.

Unfortunately, for the reasons elaborated below, AMD, Retinal Detachment and Glaucoma conditions are not conducive for creating equitable episode of care cost measures. Such measures would provide negative incentives relative to the appropriate patient management needed for optimal long-term patient outcomes.

Question 1: For AMD, what is the most appropriate patient population (e.g., all AMD versus only wet AMD) andepisode window for this condition?

Neither patient population is amenable to an episode-based cost measure under current drug pricing and CMS and MAC reimbursement policies. Ten to 20% of non-neovascular (dry) AMD patients develop severe vision loss, but this is out of the physician's control as currently there are no FDA-approved treatments beyond the use of over the-counter AREDS 2 antioxidants. For neovascular (wet) AMD, the initial vision loss is the greatest predictor of visual outcome, regardless of the drugs used. The cost of the drug has no bearing on the quality of treatment and should not drive clinical decisionmaking for the best interests of the patient; the selection of treatment should be based on the individual patient's needs, stage of disease and prior treatment response. And higher costs are correlated to more frequent injections-a strategy that is aligned with clinical trial protocols and results in better visual outcomes. Because the initial presentation (i.e., subretinal blood with fluid vs. only subretinal fluid) is out of the physician's control, this would again be an inappropriate episode to follow. Moreover, once treatment begins, the visual acuity improvement is variable and is based on the presence of atrophy, subretinal fibrosis, , and other factors for which there is no treatment.

Also, the landscape for anti-VEGF treatment is changing rapidly, and the cost differentials are likely to drastically shrink with the advent of biosimilars and the diminished access or complete loss of access to repackaged bevacizumab, possibly/expected in the next year.

Question 2: Would anti-vascular endothelial growth factor (VEGF) intervention be appropriate for identifyingwhether a clinician is managing a patient's AMD chronic condition? What other interventions may indicate that a clinician is managing a patient's AMD?

No. Dry AMD is also managed with office visits and imaging, without anti-VEGF injections. If a clinician reports an AMD diagnosis on a claim for an office visit, it would be reasonable to assume that the AMD is being managed at that visit. ICD-10 codes can distinguish between dry and wet AMD, if accurately coded.

Question 3: Can we infer AMD clinical outcomes from claims data? How can a measure avoid penalizing clinicians who treat patients for whom the more expensive injection is the only clinical option or more frequent injections are needed (e.g., requiring a higher case volume per clinician)?

No. Claims data is wholly inadequate for inferring clinical outcomes or administering an episode-based cost measure for treatment of wet AMD. There are factors outside the physician's control that may preclude utilization of the less expensive repackaged bevacizumab, e.g., risk of endophthalmitis, risk of cardiovascular events, risk of inflammation, prior lack of success with repackaged bevacizumab, access to repackaged bevacizumab, patient refusal to be treated with compounded or repackaged medications when FDA approved products are available, etc.

Question 4: For retinal detachment, how should the measure account for differences across patients based onpre-existing conditions that may impact the likelihood of treatment success? How can the measure be constructed to be as broad as possible for measure impact and viability (e.g., risk adjusting or sub-grouping certain patientcohorts rather than excluding)?

This is not at all a simple question to answer. Answering it fairly and accurately would require a multidisciplinary approach and substantial investment of resources, similar to the Acumen-led process for other episode-based cost measures. This would be nearly impossible to achieve regardless of whether you use single-operation success rate or visual acuity as your measure (the best two measures for monitoring outcomes). For single operation success rate, there would need to be a finite window for determining success. This would incentivize greater use of silicone oil than necessary because the retina typically remains "attached" under silicone oil, with the true test of the repair occurring once the oil is removed many months later, possibly after the measurement window. Moreover, this would reduce the use of the pneumatic retinopexy surgery, which can be effective in many patients, but has a lower success rate compared with operative repair (with the resultant effect of increasing costs to the system).

For a visual acuity outcome, macula on vs. off at the time of presentation by far makes the biggest difference in outcome, followed by other variables that are out of the physician's control, including the following: disease chronicity (hard to determine as symptom start and initial visit can be very different), number of retinal tears, location of retinal tears, presence or absence of vitreous hemorrhage, family history of retinal detachment, etc. Research papers have tried to quantify these risk factors for worse prognosis and were unable to reliably or repeatably do so. Assessing this from claims-based data would be fruitless because none of these variables are accounted for in such data bases. There is relatively little granularity in ICD-10 coding related to retinal detachment. Even if accounted for, they would not provide a full explanation of expected differences in patient outcomes. Another reason for the lack of feasibility of this proposed measure is the low volume of cases performed, so the average volume per ophthalmologist would be less than 15 Medcare FFS cases per year.

Question 5: Besides AMD and retinal detachment, are there other concepts in this clinical area (e.g., glaucoma care) that would be strong candidates for development considering the prioritization criteria and essential features of cost measures? The goal would be to capture the care provided by different types of ophthalmologists for which there is sufficient opportunity for improvement

Glaucoma is a common ophthalmologiocal disorder, treated by a significant percentage of ophthalmologists, and, in most cases, managed with topical medications of varying costs. All of these factors might make it seem a suitable candidate for a cost measure. However, access to drug cost data (Part D) is a prerequisite to developing such a cost measure. When developing the cataract episode cost measure, it was apparent that prescription drug cost data was not available. Even if Part D data were available, it would likely be inadequate to accurately stratify care by drugs prescribed and disease severity.

Further, and more importantly, the convoluted structure of drug pricing, including PBMs, distributors, rebates, etc., makes it impossible for a physician to have any significant impact on costs. The same drug may be high cost for one patient and low cost for another, depending

on the behind-the-scenes payment arrangements that the physician is not privy to. Even for a single patient, a single prescription drug may go from high to low cost or vice versa due to changing payment arrangements that are beyond the physician's knowledge or control. The point of control here is not at the physician level. The role and responsibility for addressing runaway drug prices lie with the Administration and Congress.

The complexities of drug pricing make development of a fair cost measure for glaucoma based on factors under the physician's control largely impossible. We would suggest that CMS act upon the following steps if they are considering developing any type of measure in a condition that is managed with drugs.

1. Do the modeling with Acumen and/or a similar experienced consultant and ophthalmologists on the panel that would normally be done in developing a cost measure. Test it retrospectively with claims data, fine tune it, and field test it prospectively as CMS would normally do.
2. Instead of proceeding to implemention as a cost measure, identify practices below the expected cost targets determined in step 1.
3. Collect information from the low-cost practices to find out how and why they are able to prescribe lower-cost drugs than expected. This would require interviews by a consultant. This cannot be done with claims data alone. Ophthalmologists need to be involved because they understand all of the intricacies and how this impacts patientcare.
4. Assess whether the things that make those practices low cost are truly under the physician's control. Does the practice do any extra work to achieve that? Is it generalizable to most or all practices? Ophthalmologists need to be involved because they understand practice patterns and working with payers. These are the questions that need to be answered.
    a. Are the physicians aware of which drugs are low cost at any given time? If so, how do they know?
    b. Is their patient population different than higher-cost practices?
    c. Do they refer out all or a higher percentage of difficult to control patients than higher cost practices?
    d. Are their criteria for proceeding to surgery different?
    e. Do they have a different payer mix?
    f. Does practice drug cost performance differ by payer? If so, why?
    g. Do the local carriers/PBMs have different pricing schemes?
    h. Do costs for individual drugs fluctuate less than for other practices?

    The answers to these questions might highlight where the real problems are.

    If step 4 does not identify physician-controllable, generalizable cost levers, then there is no point in proceeding to development as cost measure. Only those factors under the physician's control should affect the cost measure score. Do the identified physician-controllable cost levers have enough impact to create meaningful savings for the program? If those physician factors result in trivial savings, are only practical for large health systems, or would require

additional staff to implement in small practices, then there is no evidence base to impose these as cost measures applicable to large groups of ophthalmologists.

1.1.26 Comment Number 26

- **Date:** 04/01/2022
- **Submitter Name, Credentials, and Organization:** Judy Burleson, MHSA, American College of Radiology
- **Comment Text:** The American College of Radiology (ACR), representing more than 40,000 diagnostic radiologists, radiation oncologists, medical physicists, interventional radiologists, and nuclear medicine physicians, appreciates the opportunity to submit comments for consideration regardingmeasure concepts and development for future MACRA episode-based cost measures.

  The ACR supports Acumen's approach for a transparent and stakeholder-informed process indeveloping cost measures for non-patient facing clinicians and welcomes discussions on how toapproach episode-based measurement. The current cost measures within Merit-based Incentives Payment System (MIPS) are not typically attributed to radiology groups because the current measures structure often assess imaging costs but not radiological care. Care provided by radiologists does not usually fit into a traditional episode framework, and there is no existing measurement of care coordination between radiology teams and other specialties. Given these challenges, we emphasize that Acumen must consider opportunities for developing cost measures that link to existing quality measure topics, such as breast cancer screening and incidental imaging findings.

  The ACR suggests developing a breast cancer screening episode-based measure encompassing screening mammography through cancer diagnosis or return to annual screening. This episode is almost entirely under the radiologist's direct control, making it easily attributable to a radiology group. The episode cost window for this measure would span one year.

  Additionally, there are well-established quality metrics that breast imaging physicians use to audit the quality of their practice. Previously included in MIPS as Qualified Clinical Data Registry (QCDR) measures, cancer detection rate, recall rate, and true/false positive rates would be a fair balance to a breast cancer screening (BCS) cost measure. The ACR would advocate reintroducing these to MIPS, linked to a BCS cost measure. This suite of measures, including a cost measure, could provide a comprehensive view on the quality and efficiency of diagnostic care in this area to the benefit of patients and could potentially be a candidate for a CMS' MIPS Value Pathway (MVP).

  Management and care coordination of imaging incidental findings, incorporating both prevention of unnecessary or repeat testing and assurance that evidence-based follow-up recommendations are completed, are concepts worthwhile to explore as cost measures for radiology. Across an incidental finding episode, prevention of low-value follow-up testing, or a "null event" may be assessed as part of the full episode, similar to a low back pain episode-based cost measure for orthopedics, where surgery was avoided and costs attributed would be limited to evaluation and management codes. For example, an abdominal CT incidental-finding episode may begin with the CT exam, carry through any downstream management or referrals to specialists, and compare costs of the episode when radiologist recommendations

stated "no follow-up necessary" to cases where radiologist guidance was not explicit. Overdiagnosis of benign incidental findings places patients at risk for anxiety and unnecessary harm from diagnostic procedures and treatment. A standardized approach to managing incidental findings is desirable to reduce practice variation, decrease costs, limit the potential for harm from unnecessary therapies (biopsies or surgeries) and alleviate unnecessary patient and physician anxiety. Additionally, MIPS quality measures focused on incidental finding-appropriate recommendations currently exist, providing an opportunity for balance with cost measure(s) for this concept.

As previously stated, a significant challenge that radiologists confront is a lack of opportunity to be recognized for care coordination and the inability to be rewarded for team-based care led by radiologists. We hope that the potential areas of future cost measure development that we have outlined may increase radiologists' opportunities to participate in value-based care.

1.1.27 Comment Number 27

- **Date:** 04/01/2022
- **Submitter Name, Credentials, and Organization:** Kate Gilliard, JD, American Physical Therapy Association
- **Comment Text:** On behalf of our more than 100,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association appreciates the opportunity to submit comments regarding the MACRA Episode-Based Cost Measures: Wave 5 Measure Development. APTA is dedicated to building a community that advances the physical therapy profession to improve the health of society. As experts in rehabilitation, prehabilitation, and habilitation, physical therapists play a unique role in society in prevention, wellness, fitness, health promotion, and management of disease and disability for individuals across the age span, helping individuals improve overall health and prevent the need for avoidable health care services. Physical therapists' roles include education, direct intervention, research, advocacy, and collaborative consultation. These roles are essential to the profession's vision of transforming society by optimizing movement to improve the human experience.

  APTA provides comments below on cost measure development generally and on specific cost measures proposed:

  CMS indicated that in considering cost measure development, one factor is whether a certain procedure or condition is likely to have sufficient variation across clinicians in cost performance (opportunity for improvement). APTA proposes that the variation may not be between clinicians of the same practice or discipline; instead it is between clinicians from different disciplines who are involved in the episode of care.

  Physical therapists play a significant role in many patient populations. There is often great variability in the functional capacity, reserves, and performance of patients who are part of any of the populations identified for a measure. It is important to consider access to physical therapy, evaluation by a physical therapist, and the presence of a physical therapist plan of care when looking at many of these measures. Patients who are functionally compromised prior to a procedure or secondary to a procedure might represent a different cohort of patients with different cost-of-care profiles. One of the significant differentiators

may be whether these patients received appropriate evidence-based physical therapy as part of their care.

Although physical therapists may not often be the attributing clinician, their role may be significant in impacting cost of care for a measure.

Related to the Wave 5 proposed measures, physical therapists play a significant role in two of the measures.

Post-Acute Care

Patients in a post-acute care setting are often there primarily for rehabilitation. Therapy may, in fact, have a significant influence over the plan of care, length of stay, and recommended services at discharge. The variation in care, cost, and outcomes may be impacted by access to therapy, the intensity of therapy, and the quality of therapy. To control costs, some providers may limit access to services including physical therapy. This may reduce the direct cost of care during a post-acute stay, but the overall impact is a longer length of stay, readmission, increased risk of post-procedure complications, and/or adverse events such as falls.

Rheumatoid Arthritis

For patients with rheumatoid arthritis, a physical therapist is often a key team member in addressing active issues, establishing a plan for risk management and prevention, and collaborating with the rheumatologist and other physicians regarding the plan of care. Additionally, physical therapists also often are involved with patients pre- and post-transplant as well as in oncology to ensure optimal functional readiness and successful recovery.

APTA strongly suggests that CMS and Acumen consider the significant role physical therapists play throughout an episode of care in prehabilitation, rehabilitation, and disease state management. Physical therapists continue to be challenged by a lack of cost measures that capture the cost and impact of physical therapy, and APTA looks forward to the opportunity to explore how developing cost measures can be used to evaluate the impact of physical therapy.

1.1.28 Comment Number 28

- **Date:** 04/01/2022
- **Submitter Name, Credentials, and Organization:** Tracy Johansson, MS, American College of Rheumatology
- **Comment Text:** It is pertinent to use newly diagnosed Rheumatoid arthritis as the patient cohort because patients with later stages of disease may already have high costs associated due to cumulative disease burden, comorbidities like CAD or osteoarthritis resulting in expensive interventions like joint replacements, use of multiple biologics or higher disease activity. If a broader cohort is used, it would require nuanced risk adjustment or may inadvertently result in assigning unachievable measures to providers. There are opportunities for improvement at later stages of disease, but these are also associated with exponentially higher costs in patients with multi-system involvement from Rheumatoid Arthritis. It may be worth considering distinct cost measures for newly diagnosed patients versus those with established disease.

In addition, there is significant asymmetry in healthcare utilization across populations, including patients with social risk factors, such as exposure to systemic racism due to non-white race. This asymmetry requires that efforts to reduce excess utilization and costs do not also inadvertently result in worsened healthcare disparities. We recommend considering assessing costs stratified by race, ethnicity and/or other social determinants of health in order to avoid incentivizing care reductions or worse access to care for individuals with social risk factors.

Severity of disease is assessed with various measurement tools used in Rheumatology. These tools are not routinely used in Primary Care practices at this time and have not shown sufficient correlation with clinical data to adequately account for the variation in clinical severity. Using biologics or other prescriptions may not directly correlate with disease activity and may not be able to give an accurate assessment for the measure, especially in patients who have existing diagnoses of RA. Prescription or biologic use can be weakly linked to severity in newly diagnosed patients but is also impacted by many factors that are not under the clinician's control. In contrast, the presence of extra-articular manifestations and comorbidities is associated with severity and duration of disease and could be used to account for differences in the costs. However, these tend to be rarer findings (such as vasculitis) and/or may be impacted by a range of factors outside a rheumatologist's influence; some may represent the impact of poor quality of care (for example, undertreatment). As it is challenging to accurately capture how long a clinician has been caring for a particular patient and also adequately account for underlying disease severity using claims data (as noted above), even using these techniques might not correct for underlying differences in case mix. We recommend CMS thoughtfully develop and implement cost measures for patients with rheumatoid arthritis to avoid unintended consequences, such as reduced access to critical medications needed to control disease activity.

Importantly, a brief review of the workbook (2022-02 Preliminary-specs-wave-5) provided for public comment found several errors and omissions in the codes listed for Rheumatoid arthritis. For example, the workbook includes trigger codes for several non-Rheumatoid Arthritis conditions and should be reviewed carefully by leaders in Rheumatology before furthering measure development.

The ACR is actively engaged in quality measure development, health equity and inappropriate use of medications. We have unsuccessfully submitted a Rheumatology APM and successfully submitted MVPs to CMS for consideration in QPP. We are eager to work collaboratively with CMS to improve the quality and value of rheumatological care.

The ACR has developed a list of ICD-10 diagnosis codes that identify rheumatoid arthritis and are used in RA-specific quality measures within the MIPS program. We suggest the trigger codes be cross-referenced with that list of codes. For example, we do not include M064, codes for enteropathic arthropathies or codes for juvenile arthritis in our RA code set.

As previously noted, the ACR is eager to work collaboratively with CMS to improve the quality and value of rheumatologic care. The organization has been successfully developing quality measures for years and runs a Qualified Clinical Data Registry (the RISE Registry) that tracks performance on both MIPS and QCDR quality measures managed by the ACR, including a risk-adjusted RA disease activity outcome measure. The ACR also offers access

to clinical data on hundreds of thousands of RA patients through the RISE registry and to measure development experts in the field of rheumatology through the ACR's volunteer base. The expertise and data from the ACR would be valuable assets in developing a measure that appropriately evaluates the cost of caring for RA patients.

Please include ACR staff on further communications about this work.

1.1.29 Comment Number 29

- **Date:** 04/01/2022
- **Submitter Name, Credentials, and Organization:** Adrienne Jordan, Jackson Oncology Associates
- **Comment Text:** Oral chemotherapy. Breast, renal and prostate malignancies are often treated with oral chemotherapy.

  Treatment of side effects and comorbidities.

  It is reasonable to assume that a multispecialty practice, or a practice that has more than one TIN, would circumvent attribution by not treating the beneficiary in the office setting (i.e., E&M billed under TIN xx0) and administering treatment in a separate infusion clinic under a separate TIN (i.e., TIN xx01).

  Also, it is standard practice for beneficiaries whose chemotherapy regimen is reimbursed below cost to obtain treatment in a hospital outpatient setting; thus also avoiding attribution when the E&M and chemo administration code is the trigger.

  There are many clinical factors taken into consideration when treating cancer. As such, the cancer's stage, line of treatment, and oral chemotherapy are not captured when reported via claims.

  Community oncologist.

1.1.30 Comment Number 30

- **Date:** 04/01/2022
- **Submitter Name, Credentials, and Organization:** Michael Mabry, RadNet
- **Comment Text:** RadNet, the leading national provider of outpatient diagnostic imaging services in the United States, appreciates the opportunity to provide Acumen and the Centers for Medicare & Medicaid Services (CMS) with feedback regarding the proposed Wave 5 cost measure episode for screening mammography. We have significant first-hand, real-world experience at detecting and diagnosing breast cancer which is reflected in our comments. Specifically, we have identified several methodological issues that should be addressed in order to make the measure fair and accurate, if finalized.

  About RadNet

  RadNet's goal is to provide convenient access to high-quality, cost-effective imaging care for our patients and referring clinicians through expert radiologists, state-of-the-art equipment, advanced information technology, a track-record of quality measurement and reporting, and a commitment to patient and clinician satisfaction. RadNet has a network of over 360 outpatient imaging centers across Arizona, California, Maryland, Florida,

Delaware, New Jersey, and New York. Many of RadNet's centers are located in underserved communities, thus providing at-risk populations with access to high-quality cancer screening services and imaging care. Our nearly 800 radiologists and approximately 9,500 employees perform an estimated nine million imaging procedures annually. In addition, RadNet provides radiology information technology solutions, including an ONC-certified radiology information system (RIS) through its eRAD subsidiary, teleradiology professional services, and other related products and services to customers in the diagnostic imaging industry. Finally, RadNet is a global leader in the use of artificial intelligence (AI) in the early detection and diagnosis of breast, lung, and prostate cancers through its DeepHealth AI division.

Women's imaging is a core competency of RadNet. RadNet is on track to perform 1.8 million mammograms this year which is approximately five percent (5%) of the total mammograms performed in the United States. Nearly half of the breast cancer screening patients in our program come from racially diverse backgrounds. All of our imaging centers have the latest digital breast tomosynthesis (also known as three-dimensional mammography) technology. Our mammography equipment and personnel are certified by the American College of Radiology (ACR). We also advocate for breast cancer awareness and screening.

Background

Cost is one of four performance categories in Medicare's Merit-based Incentive Payment System (MIPS) which rewards value-based care for eligible clinicians. Currently, there are 25 cost measures in MIPS: (1) two for population health and (2) 23 that are episode-based; none are specific to radiology. Therefore, we appreciate that diagnostic radiology is a clinical area for measure development. An episode-based cost measure for screening mammography has been proposed based on stakeholder feedback from Wave 4.

Breast Cancer Screening Clinical Pathway[41]

Breast cancer screening for most women starts with periodic mammography. Most women who undergo breast cancer screening have normal mammography results and are advised to return in one or two years, while 12 percent are recalled for additional imaging to visualize areas of concern identified on the screening mammogram. Additional imaging may involve special mammographic views, ultrasound, or MRI. Approximately 10 percent of women having additional imaging are identified with suspicious breast lesions requiring biopsies.

Episode-Based Cost Measure Approaches

Episodes can be based on a triggering: (1) procedure, as proposed by Acumen, with related services identified subsequently or (2) clinical endpoint (e.g., breast cancer diagnosis) with related services preceding the clinical outcome.

Procedure Triggered

[41] Nelson HD, Cantor A, Humphrey L, et al. Screening for Breast Cancer: A Systematic Review to Update the 2009 U.S. Preventive Services Task Force Recommendation [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2016 Jan. (Evidence Syntheses, No.

124.) Available from: https://www.ncbi.nlm.nih.gov/sites/books/NBK343819/

As conceptualized by Acumen, the proposed screening mammography episode would be triggered when a CPT®/HCPCS code for a screening mammogram is billed and paid by Medicare. The screening mammogram and related services provided afterwards and within a pre-determined timeframe are attributed to the clinician who billed the screening mammogram. Then, Medicare allowed charges representing the cost for services within each episode would be compiled and used to compare clinicians relative to the benchmark, points are awarded based on their performance. The potential challenge for procedure triggered episodes is how to control for variations in outcome (e.g., normal, abnormal/benign, abnormal/malignant) when compiling and benchmarking costs per episode. Another potential issue is how to take into account patient risk factors. (See our comments under "Additional Concerns.")

Clinical Endpoint Triggered

Alternatively, the episode can be activated based on a specific clinical endpoint such as Medicare payment for a procedural claim with a trigger ICD-10 diagnosis code (e.g., breast cancer). Related services preceding the trigger ICD-10 code would be identified and compiled including the initial (or proximal) screening mammogram. This approach may control for clinical variation better and does not require a specific timeframe which may be helpful given the frequency differences in breast cancer screening (one-year vs. two-years). (See our comments under Question 2.)

Comments Regarding the Proposed Screening Mammography Episode-Based Cost Measure

In contemplating the proposed screening mammography episode-based cost measure, Acumen is seeking stakeholder input on: (1) how to identify and account for differences in the patient care depending on the findings of the exam, (2) services that should be included in the episode so that the measure captures opportunities for improvement and differentiates between clinician performances. To obtain this information, Acumen poses a series of questions:

Question 1: What should be the scope of a mammography measure, given the expected differences in cost depending on the result of the scan?

RadNet: Regardless of triggering approach, either procedure or clinical, the scope of the episode should include the following services (if performed): (1) screening mammogram, (2) diagnostic mammogram, (3) breast ultrasound, (4) breast MRI, (5) needle biopsy (with or without imaging-guidance), and (6) localization (e.g., needle, wire).

Question 2: Currently, the MIPS cost measures span episode windows from 14 days to 1 year or more. What are some suitable timeframes for capturing radiologists' overall effects of their work on mammography?

RadNet: Mammography for breast cancer screening is either annually or biennially. Our real-world experience suggests time-windows between normal screenings of: (1) 12-15 months for annual and (2) 24-27 months for biennial to accommodate delays in scheduling exams. Quality measurement organizations acknowledge delays in mammography scheduling. For example, in its measure of breast cancer screening rates for women age 50-74, the National Quality Forum (NQF) specifies that a woman should have a mammogram

every 24 months with a three month grace period (or 27 months total).[42]Race and social determinants of health may result in longer delays between screenings. [Please see our comments under "Additional Concerns" for more information.] Note that, pre-determined timeframes would not be necessary under the clinical endpoint approach to episode creation.

Question 3: Should other types of screening (e.g., outpatient chest scans) be considered as candidates for development within this clinical area?

RadNet: We have no other screening measures to propose at this time.

Opportunity for Improvement: What kinds of services can reflect that the candidate episode group has sufficient opportunities for improvement?

RadNet: The screening mammography cost episode can improve care efficiency and cost by identifying the variations in the use of subsequent imaging and how total costs can be reduced through the use of: (1) less follow-up imaging or (2) imaging technology than provides a more definitive diagnosis sooner in the breast cancer diagnosis pathway.

Trigger Codes: Trigger codes define the patient cohort for the measure.

The procedure codes for breast CT (CPT® codes 0633T – 0638T) should not be considered triggers for the screening mammography cost episode if finalized because they are Category III.

Acumen: Trigger codes are the starting point for identifying the patient cohort. The following codes are the preliminary triggers for the screening mammography episode-based cost measure. The trigger codes will be refined according to stakeholder input.

Table 1: Preliminary Trigger Codes for Screening Mammography

Code Number	Description
0633T	Ct of one breast with 3d rendering
0634T	Ct of one breast with contrast and 3d rendering
0635T	Ct of one breast before and after contrast with 3d rendering
0636T	Ct of both breasts with 3d rendering
0637T	Ct of both breasts with contrast and 3d rendering
0638T	Ct of both breasts before and after contrast with 3d rendering
77061	Digital *tomosynthesis** of one breast
77062	Digital *tomosynthesis** of both breasts
77063	Screening digital *tomosynthesis** of both breasts
77065	Diagnostic mammography of one breast
77066	Diagnostic mammography of both breasts
77067	Screening mammography of both breasts
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to 77065 or 77066)

*Acumen's Wave 5 spreadsheet incorrectly lists codes 77061-77063 as "tomography."

RadNet: Of the proposed trigger codes for the screening mammography episode-based cost measure, it should be noted that codes 0633T through 0638T (breast CT) are CPT® Category

[42] NQF Measure 2372, "Breast Cancer Screening,"

III codes which are "temporary codes for emerging technology, services, procedures and service paradigms."[43] Procedures designated as Category III are not in widespread use. The Category III codes for breast CT are problematic further because there are no relative value units (RVUs) for them under the Medicare Physician Fee Schedule (MPFS) and Medicare coverage is at the discretion of the local administrative contractor; thereby, making coverage and costs highly variable. Breast CT is reimbursed under Medicare's Hospital Outpatient Payment System (HOPPS).

Quality Alignment: We solicit comments regarding alignment of quality of care with cost measures as well as comments on any indicators of quality that would be valuable to assess alongside the cost performance for the candidate episode group.

RadNet: CMS' Hospital Outpatient Quality Reporting (OQR) Program has four Outpatient Imaging Efficiency (OIE) measures, one of which is "Breast Cancer Screening Recall Rates (OP-39).[44] Recall rates by radiologist will impact the final costs in the episodes. This measure calculates the percentage of beneficiaries with mammography or digital breast tomosynthesis (DBT) screening studies that are followed by a diagnostic mammography, DBT, ultrasound, or magnetic resonance imaging (MRI) of the breast in an outpatient or office setting within 45 days. This re-specified measure aligns with the care coordination domain of the National Quality Strategy (NQS).[45] OP-39 is not a quality measure under MIPS.

Additional Concerns: Are there any other concerns that may be present with assessing the care of patients in this clinical area?

RadNet has concerns how the proposed screening mammography episode-based cost measure will be risk adjusted for social determinants of health, genetic risk factors, and variations in clinical practice.

RadNet has several methodological concerns regarding the proposed screening mammography episode- based cost measure. If these issues are left unaddressed, the fairness and accuracy of this measure could be called into question.

1. Impact of Social Determinants of Health (SDH): Social determinants of health (e.g., race, education level obtained, socioeconomic level) will impact the construction, benchmarking, and comparison of the proposed screening mammography episode-based cost measure in several ways:
    a. Compliance Rate: Not every eligible patient has a regular (12-month or 24-month) screening mammogram (so-called compliance rate). SDH impact compliance rate. Our real-world experience suggests that compliance rate varies by race (Black women have lower screening rates than Non-Hispanic White women). As a result, Black women tend to have more cancers between screenings (interval cancers) and more suspicious

[43] American Medical Association, 2022 CPT Professional Edition, page 873

[44] https://qualitynet.cms.gov/outpatient/measures/imaging-efficiency

[45] https://qualitynet.cms.gov/files/61e6c24c5277d800221ca92f?filename=OP-39_Ad-HocReevalRpt_011222.pdf

or abnormal screenings that require additional imaging. Radiologists in underserved communities may have different episodic costs than their peers.

b. "Lost to Follow-up" Rate: Not all patients with an abnormal or suspicious screening mammogram will comply with their radiologists' recommendations for follow-up imaging or other diagnostic tests (so-called "lost to follow-up"). Our real-world, first-hand experience has "lost to follow-up" in the range of 9 to 12 percent. This rate is probably higher for non-RadNet providers given our emphasis on patient tracking and compliance. "Lost to follow-up" can vary based on SDH (e.g., education obtained, socioeconomic level) and race. "Lost to follow-up" rates will skew episodic costs inversely. That is, radiologists with high "lost to follow-up" rates will likely have less costly screening mammography episodes than their peers with more compliant patients.

2. Risk Factors: Some women have genetic risk factors that make them more susceptible to breast cancer. For example, Ashkenazi Jewish women are at higher risk for breast cancer at a young age because of their pre-disposition for the BRCA gene mutation. These patients will likely have a suspicious or abnormal screening mammogram, thus requiring additional diagnostic imaging. Radiologists who see patients in these communities may have different cost episodes than their peers. Race is another risk factor with African-American women 40 percent more likely to die from breast cancer than White women.[46] [47]Also, women with disabilities were nearly 19 percent less likely to have had a mammogram in the past two years than those without disabilities (61 percent vs. 75 percent, respectively).[48]

3. Variations in Clinical Practice: It is increasingly common for a woman's clinician to order a mammogram with breast ultrasound when screening for breast cancer, particularly if she has extremely dense breasts. Some states mandate coverage of breast ultrasound and breast MRI for women with dense breasts. The proposed screening mammography episode-based cost measure may need to control for variations in clinical practice like these.

4. Attribution: Radiology is a referral-based, so-called "non-patient facing" specialty which may present some challenges to data collection and attribution. Medicare requires that all diagnostic tests, including radiology, be ordered by the beneficiary's treating physician.[49] There is an exception for a radiologist to order a diagnostic mammogram on the based on the findings of a screening mammogram.[50] This means that many of the services in the

[46] Centers for Disease Control and Prevention, "Rate of Cancer Deaths By Race and Ethnicity, Female," 2018, https://gis.cdc.gov/Cancer/USCS/#/Demographics/, accessed March 23 2022

[47] Richardson LC, Henley SJ, Miller JW, Massetti G, Thomas CC. Patterns and Trends in Age-Specific Black-White Differences in Breast Cancer Incidence and Mortality – United States, 1999–2014. MMWR Morb Mortal Wkly Rep 2016;65:1093–1098. DOI: https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a1.htm

[48] Centers for Disease Control and Prevention, "Women with Disabilities and Breast Cancer Screening," https://www.cdc.gov/ncbddd/disabilityandhealth/breast-cancer-screening.html, accessed March 23, 2022

[49] See 42CFR410.32(a)

[50] §410.32(a)(1)

screening mammography episode will have been ordered by another clinician yet attributed to the patient's radiologist. This may create some variability in the cost results which could impact MIPS scoring.

5. Data: In other parts of the MIPS program, we have experienced issues with data which have required correction and scores adjusted. With cost measure estimates determined by CMS using administrative data, we request that CMS provide a process for identifying and correcting cost information prior to final scoring.

1.1.31 Comment Number 31

- **Date:** 04/01/2022
- **Submitter Name, Credentials, and Organization:** Lane Koenig, PhD, National Association of Long Term Hospitals
- **Comment Text:** The National Association of Long-Term Hospitals (NALTH) is the only hospital trade association that is devoted exclusively to the needs of medically complex patients who require services provided by long-term acute care hospitals (LTCHs). NALTH is committed to research, education, and public policy development that further the interests of the very ill and often debilitated patient populations who receive services in LTCHs throughout the nation. On behalf of our members, composed of the nation's leading LTCHs, including free-standing, hospital-within hospital, for-profit, and non-profit LTCHs, NALTH appreciates the opportunity to respond to the Call for Public Comment on the measure development activities related to episode-based costs.

  Our response focuses on the potential measures related to Post-Acute Care (PAC). The approach outlined in the Call for Public Comment appears sensitive to the administrative challenges in measuring cost for physicians at specialty hospitals, like LTCHs. NALTH is supportive of efforts to measure and manage the cost of healthcare services in ways that:

  - Produce valid and reliable results.
  - Report results in ways that are understandable by users and actionable by administrators and providers.
  - Pair meaningfully with measures of quality of care to assess value of care.

  We hope our comments provided below are helpful as you consider how and if to pursue a PAC episode-based cost measure in Merit-based Incentive Payment System (MIPS).

  Question 1: Patients use PAC for many different reasons and with varying levels of care needs. How should the measure account for the heterogeneity of patients in PAC? We can use techniques like risk adjusting or sub-grouping by PAC setting, or based on services that are indicative of a given group of diagnoses or conditions (e.g., distinguishing patients with complex medical conditions, dementia, or those who receive rehabilitation). Are there certain types of services, diagnoses, or other data available via claims that may be useful in defining more homogeneous patient cohorts (e.g., separating the short term post-acute residents from the longer term ones)?

  Response 1:

Acumen, LLC is considering developing a post-acute care (PAC) measure that aligns with the existing Medicare Spending per Beneficiary – PAC measures (MSPB-PAC). The development of the MSPB-PAC measures was required under the Improving Post-Acute Care Transformation Act of 2014 (IMPACT Act). The Centers for Medicare & Medicaid Services (CMS) developed the MSPB-PAC for each PAC setting (HHA, SNF, inpatient rehabilitation facility (IRF), and LTCH) and each setting is assessed against its peers. For example, an LTCH's MSPB is compared to the median for all LTCHs to establish its performance on the measure. Comparing each provider to others of the same type is needed because of significant differences in the types of patients treated across settings and the cost of care.

Separate Reporting and Case-Mix Adjustment by PAC Setting.

1. LTCHs Differ from Other PAC Providers. LTCHs are acute care hospitals that provide specialized services to chronically critically ill and medically complex patients requiring extended hospital-level care. As acute care hospitals, LTCHs have staff and resources that allow them to care for patients that are too medically complex to be treated in other PAC facilities, including patients requiring administration of critical intravenous medications.

   LTCHs must have a physician on call or present 24 hours a day and 7 days a week, with patients receiving daily visits from a doctor to manage their complex medical conditions. LTCH patients often have access to onsite physician care with specialties in pulmonology, infectious disease, cardiology, nephrology, and surgery. Additionally, all patients are assigned a registered nurses (RNs) or licensed practical nurse (LPN) for the duration of their stay, and RNs must provide or supervise care for patients 24 hours a day. Frequently, these physicians and nurses have specialized training and credentials. Finally, patients in LTCHs have ready access to laboratory, radiology, and pharmacy services to help address their changing medical needs. By comparison, skilled nursing facilities (SNFs) are only required to have a physician supervise care and visit a patient once every 30 days for the first 90 days and once every60 days thereafter. Moreover, an RN is only required to be on-site for 8 hours per day.

   These different regulatory requirements create different staffing, expertise, and capabilities between LTCHs and other PAC settings. For example, LTCHs routinely provide specialized services—dialysis, central line insertion/removal, tracheostomy, decannulation, surgical services, Peg tube insertion/removal, onsite radiology and pathology—for which other PAC providers must refer to a short-term acute care hospital to receive.

2. Risk adjustment across PAC settings inadequately captures case mix differences between LTCHs and other settings. LTCH staffing levels reflect the underlying complexity of the patients these facilities treat. To be admitted to a LTCH, a patient must require a hospital—level of care. In addition, most patients typically have had at least three days of ICU care in an immediately preceding short-term hospitalization or have 96 hours of mechanical ventilation in the LTCH. In its recent design report of a value-based incentive program for use in a unified PAC prospective payment system, MedPAC's attempt to risk adjust was inadequate to account for patient differences to permit comparisons of patients

across PAC settings (MedPAC, 2022). MedPAC also found that the complexity of LTCH cases was offset by the sheer volume of home health agency (HHA) and SNF cases.

For the reasons described above, the development and use of any episode-based PAC cost measure should be grouped by PAC setting.

Challenges for Case-Mix Adjustment When Restricted to LTCH Cases

Besides peer grouping based on PAC settings, risk adjustment within LTCHs for episode-based cost measurement incurs special challenges.

1. Stratification by condition and small numbers. LTCHs may be able to generate sufficient case volumes for certain conditions like congestive heart failure (CHF), acute respiratory failure, or wound care. Many LTCHs may specialize in these conditions, so the number of measures/conditions that may be relevant to a given LTCH may be limited. To the extent that physicians' caseloads will reflect the specialization of the LTCHs that they staff, stratifying reporting by condition among LTCH-affiliated physicians is appropriate but may result in small numbers for the providers.

   However, LTCH patients are medically complex, and typically have multiple chronic conditions or organ system failures. So, though there may be a high volume of cases with CHF, many of these cases will have significant comorbidities: cases with CHF only will be an unusual group (compared to all cases with CHF) and possibly too small to report reliably; and, the permutations of CHF with other comorbidities will result in small numbers, too. Furthermore, a catch-all category of "multiple chronic conditions" will mask important variability in severity and cost profiles (e.g., CHF with respiratory failure may differ meaningfully from cases with hepatic and renal failure).

2. Insufficiency of claims data for risk adjustment. MedPAC's 2022 Report to Congress (MedPAC, 2022) noted that the median risk score of LTCH patients was 3.7 compared to2.6 for SNFs and 2.1 for IRFs. While claims can capture some of the complexity differences, researchers have documented the bias in case mix adjustment that results from using only claims-based attributes for risk-adjustment models within LTCHs (Kahnet al., 2013; Koenig, et al., 2015). Additional data from EMRs or other sources, for example, may be necessary to reliably differentiate provider-level episode costs.

We recommend that measurement incorporate stratification and risk adjustment of cases for episodes associated with LTCHs. However, the advisability of measurement and public reporting on a physician-level episode-cost measure hinges on having sufficient sample size to generate reliable provider-level measurement and sufficient information to adequately adjust for clinical severity.

Question 2: Given the similarities in facility-based care, would an attribution methodology similar to that used by the MSPB Clinician measure and acute inpatient medical condition episode-based cost measures (more on acute inpatient medical condition episode groups in the Appendix) appropriately capture the role of clinicians providing PAC services? Would any modifications be needed for different PAC settings, such as home health? If so, what approach would by clinically sound in terms of identifying responsible clinicians for those PAC settings?

Response 2: NALTH supports efforts to align measures on all dimensions, including condition definitions, provider types, and attribution methodologies. The clinician-to-facility

model of the MSPB Clinician measure is a useful starting point to evaluate the attribution for a PAC episode-cost measure. However, we want to remind CMS, that patient profile of LTCH cases is significantly different from other PAC providers, and as a result LTCH's do not provide facility-based care that is comparable to other PAC settings.

In the context of a PAC facility-based measure, a specific concern is the handling of hospitalists across the different methods of attribution.

- **Opportunity to Manage the Episode**. The attribution approach must consider the attributed clinician's opportunity to manage care. Patients in LTCHs receive care from a multitude of physicians, and due to the specialized needs of LTCH patients even though the hospitalist may bill routinely for the episode, in practice, care will be managed by one or more specialists.
- **Small numbers**. In addition to the small number of LTCHs compared to other PAC settings, the LTCHs themselves are often quite small. Facilities often contract with small physician groups which may make for challenges to achieving a minimum sample size for reliable reporting, especially when reporting on a per-condition basis.

General Question: Quality Alignment for Assessing Value. We support pairing cost measures with quality of care as this is fundamental to demonstrating value in a value-based purchasing environment. Dementia is one potential opportunity for episode-based cost measure that has several associated quality measures, including these measures currently used in MIPS: Functional Status Assessment; Associated Behavior and Psychiatric Symptoms Screening and Management; Safety Concern Screening and Follow-up; and, Education and Support of Caregivers.

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1.1.32 Comment Number 32

- **Date:** 04/05/2022
- **Submitter Name, Credentials, and Organization:** Alex Bardakh, American Medical Directors Association (AMDA) – The Society for Post-Acute and Long-Term Care Medicine
- **Comment Text:** We also want to ultimately ensure that there are incentives to place people in the right care at the right time. Here are some specific answers to the questions posed:

Question 1: Grouping by Patient Driven Payment Model category for SNF, or risk adjusted HCC score would be a step in the right direction. Would note that absent a marker for frailty, it will be an incomplete and troublesome measure as frailty does affect cost and LOS (gotta keep up the pressure on this). Separating by short and long term care patients should be able to be done via POS. If they want to partition SNF with previous or without previous long term care stay they should be able to do that by review of recent claims e.g last 6 months. Overall agree w/ aligning facility and provider incentives, as long as it based off past performance and relative improvement and not absolutes (will never get anyone to work in an impaired home…)

Question 2: Attribution methodology that's proposed seems reasonable. However home care may be difficult as multiple persons / specialties will be involved. Since PAC physicians only sign the initial cert it's not our battle really. I would tell CMS should not use the signer of the initial cert for attribution as our docs just state the need at the time of discharge and have no control over subsequent utilization. It should be attributed to the recert provider or their PCP.

Question 1: Risk stratification remains very murky and gamefied in the current PALTC construct- partly by existing VBC models such as ACOs with their push for AWVs grabbing ICD-10 codes to ramp up risk strata for their patient pools. Care setting is very important (NF vs SNF for example) as there can be two distinct patient populations with markedly different risk strata and utilization. Unfortunately, even as they are cliche and gamefied, I feel those differences need to be factored in as they are fundamental to the process of risk stratification. Perhaps we should look at using the PDPM tools (point system for NTA) to assess the risk and spend as well- as that's what they are designed to do and we should have plenty of data in the almost three years of using them.

Question 2. Attribution is probably less controversial, and plurality of service by a 'PCP' should suffice. Should be careful not to be tied to the generic MSPB, but only to MSPB-PAC. For home health, the 'PCP' signing the certification is probably the right attribution.