Chronic Kidney Disease/End-Stage Renal Disease (CKD/ESRD) Workgroup Meeting Summary

MACRA Episode-Based Cost Measures: Clinician Expert Workgroup
Workgroup Webinar, September 23 and October 4, 2021
November 2021

Contents

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 of 2015 (MACRA). Acumen's measure development approach involves convening clinician expert panels to provide input in cycles of development ("Waves").[1] In addition to Wave 4 of cost measure development, which is currently underway, Acumen is developing cost measures for chronic kidney disease (CKD) and end-stage renal disease (ESRD).

We held a nomination period for a clinician expert workgroup, or "workgroup", between June 28, 2021, and July 12, 2021. Acumen selected 16 members based on experience and expertise directly relevant to the CKD/ESRD measures. Additionally, Acumen recruited two Person and Family Partners (PFPs) who have experience living with CKD and/or ESRD, to represent the patient and family perspective on topics related to measure development. The workgroup met once on September 23 for 4 hours and once on October 4 for 1.5 hours.

Based on input from these meetings, CMS will extend the timeline for measure development activities to allow for time to address the workgroup's interest in including the costs of care for kidney transplant recipients. As such, the CKD/ESRD measures are expected to be field tested in early 2023 rather than January 2022. CMS is exploring the potential to develop a cost measure focused on kidney transplant management alongside the CKD/ESRD measures to have a holistic set of kidney care measures.

[1] For information on measure development in Waves 1-3, refer to the 2020 Episode-Based Cost Measures Field Testing Wave 3 Measure Development Process document (https://www.cms.gov/files/document/macra-cmft-ebcm-process-2020.pdf).

CKD/ESRD Workgroup Webinar, September 23 and October 4, 2021

The CKD/ESRD workgroup met on September 23, 2021, and on October 4, 2021 via webinar. The first meeting was attended by 15 of the 16 members, and the second meeting was attended by 14 of 16 workgroup members.[2] The webinars were facilitated by two Acumen moderators, Kevin Erickson and Eugene Lin, and the workgroup chair, Alexander Liang. Two PFPs, Derek Forfang and Michael Mittelman, discussed their experiences living with CKD and ESRD, and they summarized their input via a survey and meeting prior to the webinar. Finally, the first meeting was also attended by members of the public via a listen-only line, to ensure transparency of the measure development process.

This document summarizes the discussions from the 4-hour virtual meeting and from the 90-minute follow-up webinar. Section 1 addresses the goals of the webinars, background of MACRA cost measures, and the PFP findings. Section 2 discusses the sets of diagnosis and service codes on claims used to define a patient-clinician relationship for each measure, including the targeted beneficiary population. Section 3 discusses defining sub-populations to handle heterogeneity of the episode groups, including the terminating conditions for each measure. Section 4 discusses assigning services to the measures. Finally, Section 5 summarizes next steps in the measure development process. These meetings were convened by Acumen as part of the measure development process to gather expert clinical input; as such, these are preliminary discussions and materials, which do not represent any final decisions about the measure specifications or MIPS.

1. Person and Family Partner (PFP) Findings and Discussion

Prior to the webinar, the PFPs had filled out a survey, summarizing aspects of the care they received for CKD and/or ESRD, including the composition of their care team, services they received, complications, and indicators of quality. The PFPs also met with the Acumen team before the webinars to discuss their input.

Overall, the PFPs indicated that they received poor education on kidney health and limited coordination across care settings. They mentioned their condition was not explained well at the outset of care, and they only learned important information such as CKD staging until after their condition had deteriorated. PFPs noted that the burden of tracking and accessing care fell to patients and families. To manage their CKD, the PFPs received regular bloodwork, urine tests, and imaging. Other services that PFPs cited included nephrology consults and specialty care for comorbidity management (e.g., ultrasounds, cardiology consults, angiography, and urinalysis). The PFPs underwent dialysis at various points in their disease progression. Beyond visiting primary care and nephrology clinicians on a weekly or monthly basis for kidney care, the PFPs' care spanned several specialties such as endocrinology and podiatry for management of diabetes and other specialties (e.g., cardiology and dermatology) for other routine care. The PFPs reported that with better care coordination and education, complications such as rapid disease progression or kidney transplant failure could have been slowed or avoided. Other complications that PFPs cited as potentially avoidable based on their care team's role included graft/access clotting, fluid shifts, blindness, and leg amputation. During subsequent discussions with the wider group, the PFPs suggested that the cost measures include telehealth codes to define the patient-clinician relationship, and that they emphasize care transition between teams.

[2] CMS, "MACRA Episode-Based Cost Measures: Chronic Kidney Disease/End-Stage Renal Disease (CKD/ESRD) Clinician Expert Workgroup Composition (Membership) List [PDF] (https://www.cms.gov/files/document/ckdesrd-clinician-expert-workgroup-compositon-list.pdf)

They PFPs also stressed the importance of patient outcomes and empowerment in quality kidney care.

2. Defining the Episode Group

In this session, Acumen reviewed the chronic condition cost measure framework, the intended scope of the draft CKD/ESRD measures, and the list of service and diagnosis codes used to construct episodes of care, before discussing these specifications in depth. To trigger an episode of care, the chronic framework requires that a clinician group, as identified by their Tax Identification Number (TIN), bill 2 claims with particular Current Procedural Terminology / Healthcare Common Procedure Coding System (CPT/HCPCS) codes within a pre-defined period of time (typically 180 days). Both of these claims must have an International Classification of Diseases, 10th revision (ICD-10) diagnosis code indicating the chronic condition. Triggered episodes are automatically attributed to the TIN that bills these two claims. Acumen's draft CKD/ESRD measures target advanced CKD (stages 4 and 5) and maintenance dialysis, respectively. Each draft measure includes a narrow set of diagnoses that accompany the following service codes:

- Outpatient evaluation and management (E&M) codes that include clinician visits in the outpatient setting, clinician's office, nursing facility, or assisted living facility that are intended to identify primary care (used in both the CKD and ESRD measures)
- Kidney education, group or individual (CKD only)
- Lab tests related to kidney function (CKD only, confirming only)
- Monthly capitation payment codes (ESRD only)
- Dialysis education codes (ESRD only)

2.1 Discussion of Measure Scope and ICD-10 Diagnosis Codes

Members discussed the appropriate patient population to include in a cost measure for ongoing management of CKD and ESRD and which codes could be used to capture that scope. Some members suggested including stages 3a and 3b, especially if the measure is attributed to primary care providers who are more likely to care for CKD patients at earlier stages. Other members suggested including only stage 3b. Additionally, some members suggested that a broader scope could promote more care coordination if attributed clinicians are responsible for costs over a longer period of time. However, other members pushed back on this broader proposed scope due to the clinical heterogeneity it would introduce to the CKD episode group, which is difficult to account for using claims alone.

Other members raised concerns about coding ambiguities around CKD staging, acknowledging that Medicare claims do not contain test results on kidney function. Some members stated that earlier stages of CKD may not be as precisely coded, while others indicated the limitations imposed by not having access to data on albuminuria.

Workgroup members also discussed the targeted specialties of the draft cost measures. Acumen showed data demonstrating that most of the draft measures were attributed to nephrologists, with primary care providers comprising the bulk of the remainder. A small number of ESRD episodes were attributed to vascular surgeons, presumably due to instances involving complex vascular access maintenance. Some members expressed concern that vascular surgeons were attributed, while others thought this was appropriate. Some members thought that primary care providers should only be attributed earlier stages of CKD and not ESRD.

Finally, the workgroup discussed whether patients who received a kidney transplant should be included in the measures. In general, members agreed that when a patient on maintenance dialysis receives a transplant, the patient should be excluded. Multiple members flagged that excluding kidney transplant recipients may disincentivize providers from referring late- or end-stage kidney patients to transplant, as transplant-ready patients often have the lowest cost. Multiple workgroup members supported including recipients of a kidney transplant in some form of a cost measure, whether in these CKD/ESRD measures or in a cost measure specifically targeting kidney transplant management. Some members suggested incorporating transplants with more advanced CKD (stages 4 and 5) into the CKD measure. One suggestion was to include transplants if a sufficient amount of time had elapsed after the transplant (e.g., 3 years). Members indicated that expanding this population would align the measure with the kidney care community's emphasis on post-transplant care. Finally, multiple members agreed that the quality of the kidney, which is not observable in claims, is a very strong predictor of rejection and other transplant-related complications. Acumen noted that it might be possible to capture data from the United Network for Organ Sharing (UNOS) and the Organ Procurement and Transplantation Network (OPTN) to risk adjust for these differences. This could be done through a transplant management cost measure in future Waves of development, or through additional research and development for including the transplant population in the CKD/ESRD measures.

Key Takeaways from Discussion and/or Polls for Scope and Diagnosis Codes:

- Workgroup members provided mixed input on broadening the CKD scope to include earlier stages; ultimately, they reached consensus to maintain the initial target scope of stages 4/5. The workgroup also agreed on the narrow scope of the ESRD measure targeted at maintenance dialysis.
- The workgroup was strongly in favor of assessing costs for the late-stage kidney transplant recipient population due to both the importance of this care pathway to quality, and the risk and cost that subsequent renal failure poses to the patient.

2.2 Discussion of Service Codes to Define a Patient-Clinician Relationship

Acumen presented the list of CPT/HCPCS service codes that, when billed with an accompanying diagnosis for CKD or ESRD, "trigger" an episode of care. This list of services is narrow compared to the services that are included in the cost measures once a patient-clinician relationship is detected. To trigger an episode, two claims must appear within a pre-fixed window. This "trigger window" is the maximum number of days between two encounters with the same TIN that define a patient-clinician relationship; for example, the current chronic condition measures (Asthma / Chronic Obstructive Pulmonary Disease [COPD] and Diabetes) use a 180-day trigger window. Acumen explained the benefits and drawbacks of having a shorter or longer trigger window, noting that a 180-day trigger window captures around 95% of all draft CKD trigger events and over 99% of all draft ESRD trigger events. One member noted that the appropriate trigger window for CKD likely differs by severity, as sicker patients will see their providers more often.

After this discussion of the framework, the workgroup opened up for discussion of the service codes used to define a patient-clinician relationship. Workgroup members discussed whether laboratory services should trigger an episode. Some members suggested that laboratory services were not necessarily indicative of the establishment of a relationship or indicative of the presence of CKD. Other members suggested that lab services could be included but should be restricted to only those specific to nephrologists. Members supported the inclusion of telehealth codes in the outpatient E&M list. Some members suggested considering additional service categories to the trigger and confirming codes lists. Medical nutrition therapy (MNT) was widely

agreed to be an important component of kidney education and cohesive outpatient management of CKD/ESRD patients. Other types of care (vascular access and interventional radiology (IR)) were briefly suggested but would not focus on care management for CKD or ESRD.

Key Takeaways from Discussion and/or Polls for Trigger and Confirming Services

- The workgroup generally supported the outpatient E&M list. Members agreed to include medical nutrition therapy codes as trigger and confirming codes
- Members voted to remove some of the proposed laboratory confirming service codes

3. Addressing Sub-Populations for Meaningful Clinical Comparison

Members discussed how to account for heterogeneity within the patient cohorts. Sub-populations refer to patient cohorts defined by the presence of pre-existing conditions or other clinical and functional characteristics. Acumen reviewed the following methods to handle heterogeneity that can be incorporated in the measure specifications:

(i) Stratifying the patient population into mutually exclusive and exhaustive sub-groups to define more homogenous patient cohorts[3]
(ii) Defining covariates in the risk adjustment model[4]
(iii) Identifying measure exclusions[5]
(iv) Monitoring certain sub-populations for further testing[6]

Prior to the webinar, Acumen ran analyses summarizing frequencies and observed cost of various sub-populations in the measures, including those suggested by the workgroup members in a pre-webinar survey.

3.1 Suggested Sub-Populations and Risk Adjustors

The workgroup identified several patient features that can predict severity and should be considered for sub-grouping or risk adjustment. Members asked whether albuminuria levels were available to stratify patients. Acumen confirmed that these laboratory results are not currently available on Medicare claims. Multiple workgroup members suggested functional and social factors such as frailty, socioeconomic status, and homelessness. Members discussed whether specific risk adjustors were sufficient to capture the heterogeneity of patients. For instance, some members expressed concern that heart failure could be further divided into systolic and diastolic dysfunction despite a singular “heart failure” risk adjustor variable in the

[3] Sub-grouping is a method that’s intended for when we want to compare episodes only with other similar episodes within the same sub-group. This approach is used when sub-groups are very different from one another, and each sub-group requires its own risk adjustment model. Since each sub-group will have its own risk adjustment model, the size of each sub-group should be sufficiently large.
[4] Risk adjustment is a method to account for the case-mix of patients and other non-clinical characteristics that influence complexity. It’s meant to be used for sub-populations that make up a large share of patients who have a characteristic that’s outside of the attributed clinician’s reasonable influence. Risk-adjusted cost measures adjust observed episode spending to an expected episode spending (predicted by a risk adjustment model).
[5] Excluding is a method in which we exclude certain patients or episodes to address issues with patient heterogeneity. This approach should be used when the sub-population affects a small, unique set of patients in which risk adjustment wouldn’t be sufficient to account for their differences in expected cost.
[6] Monitoring for further testing is an option for flagging certain sub-populations that the workgroup may revisit later during measure development upon review of further data. This approach is best used when the workgroup requests additional data or information on a sub-population to discuss the appropriate method for meaningful clinical comparison.

standard CMS-Hierarchical Condition Categories (HCC) model. Members also suggested the importance of risk adjusting for prior COVID-19, lupus nephritis, and cirrhosis. One member stressed that quality care in the inpatient setting can influence downstream costs, potentially confounding the impact on cost of the attributed outpatient provider. Some members expressed skepticism that the comorbidities included in the CMS-HCC risk adjustment model could precisely predict severity for the CKD and ESRD populations.

Key Takeaways from Discussion and/or Polls for Suggested Sub-populations:

- With the exception of stratifying by albuminuria levels, which is impossible using claims data alone, the workgroup members suggested several sub-populations that Acumen will monitor and test in the CKD/ESRD measures:
    - lupus nephritis
    - cirrhosis
    - homelessness and socioeconomic status
    - patients with amputations
    - CKD patients who progress to ESRD during the episode
    - heart failure
    - frailty
- In the poll, the workgroup was in favor of risk adjusting for progression to dialysis from CKD, frailty, amputations, and prior heart failure hospitalization
- Workgroup members generally supported risk adjusting for "crash starts" but did not reach a 60% consensus on the method to do so:
    - Risk adjust for the first 120 days of dialysis
    - Risk adjust for the first 120 days only if the provider is new to caring for the patient
    - Risk adjust for a hospitalization prior to the start of dialysis (typically 120 days)

3.2 Terminating Conditions and Other Adjustments

Like other MIPS cost measures, the draft CKD/ESRD measures excluded episodes of care that end in death or have evidence of hospice care. Because this excludes about 20% of episodes from each measure, many members raised concerns about their exclusion. Members also stated that mortality and hospice care are important features of the CKD/ESRD population and thus should be included in the measures. Acumen outlined some of the challenges with including episodes that end in death, specifically that end-of-life can be disproportionately expensive. Members were generally supportive of Acumen testing methods that include episodes of care that include hospice and that end in death while avoiding prorating short, expensive episodes to an entire year.

The draft measures also terminate episodes in both measures at first evidence of kidney transplant, and CKD episodes terminate at the first evidence of dialysis due to the change in cost profile and care pathway implied by these changes. Acumen shared data showing ballooning costs during these periods of transplantation and progression. The workgroup discussed and ultimately supported the possibility of risk adjusting for the transition to ESRD. Additionally, there was some discussion of "crash starts", or patients who initiate dialysis in an inpatient setting; the workgroup expressed support for adjusting for this in the ESRD measure only if the provider did not have a previous relationship with the patient.

The workgroup discussed extending the lookback period used to detect a patient's service and diagnosis history beyond the 120-day period that is typically used for risk adjustment and sub-population construction. In particular, members suggested using a 1- or 2-year period in order to capture a full clinical picture of the patient. Traditionally, Acumen uses a 120-day lookback period because it balances between being comprehensive in capturing patients' comorbid

conditions and including as many patients as possible. Requiring that patients have a longer diagnosis history (and thus a longer period of continuous Medicare Parts A/B enrollment) could reduce the size of the patient population. Members were interested in exploring whether Acumen could require 120 days of Medicare A/B enrollment but use a longer diagnosis history if available.

Key Takeaways from Discussion and/or Polls for Terminating Conditions and Other Adjustments:

- Members expressed an interest in including and accounting for death, including end-of-life care, and extending the 120-day lookback period for risk adjustment

4. Assigning Services to the Episode Group

Service assignment was discussed in the two webinars. Acumen described the purpose of service assignment as assigning costs that the attributed clinician could reasonably influence. These assigned services should be inclusive enough to identify a measurable performance difference between clinicians without introducing excessive noise.

In the pre-webinar survey, members had suggested the following service categories for consideration:

- Palliative care
- Patient education and counseling
- Home health
- Home-based primary care
- Hospitalizations, especially related to heart failure
- Kidney transplant, cardiology, and gastrointestinal evaluations
- Imaging, especially renal ultrasound and vein mapping
- Kidney biopsies
- Dialysis access

During the follow-up webinar, Acumen presented several service categories, including transplant costs, dialysis access, hospitalizations and emergency visits, kidney-related complications, outpatient services, fall complications, and post-acute care.

Acumen asked the workgroup what transplant-related services to include if transplanted patients were included in the cost measure. Members expressed mixed support for complication-related services; some advocated for including all related costs except those that come from a transplant rejection, while others were more cautious about which infections might be related and under the influence of the attributed provider. One member raised the importance of excluding costs related to transplants and complications of non-renal organs.

In light of the general interest and agreement to include end-of-life costs in the measures in order to promote care coordination and quality, the workgroup discussed the challenge of patients possibly seeking various services and treatments to stay alive, yielding higher episode costs. Acumen indicated that all episode-based cost measures have a “stop-loss” method known as winsorization that curtails the influence of outliers on a provider’s cost measure score. Workgroup members asked whether it was possible for the cost measure to implement a specific stop-loss for patients who die. One member also noted that the measures can use GV and GW modifiers on inpatient claims to identify services unrelated to the patient’s terminal condition and/or billed by a clinician other than the hospice provider.

The workgroup discussed vascular access in some depth. In a related Technical Expert Panel that Acumen convened in 2020 for development of CKD/ESRD cost measures for the Kidney Care First option of the Kidney Care Choices alternative payment model, members agreed to exclude certain vascular access costs in the CKD measure to incentivize preparation for a smooth transition to dialysis. For this measure, several members expressed support for excluding all forms of access while others advocated including some of them. For example, one member noted that maintenance procedures on grafts can be overused, which would be resource-inefficient and important to capture in the measure. Another member said that catheters can push frail patients over the edge to mortality. Members mostly agreed that complications related to dialysis access were important for providers to avoid.

The workgroup discussed whether hospitalizations should be included and which types of hospitalizations to include. Some members supported Acumen's draft list of inpatient service categories for discussion, which were broken into clinical areas like pulmonary complications or fluid overload. However, others supported eliminating all inpatient stays because the attributed provider might have limited control over those costs. Infections received similar feedback; some members supported including some infections, especially those related to dialysis access. One member expressed concern that clinicians might not be able to influence these infections, even access-related ones.

Key Takeaways from Discussion and/or Polls for Assigning Services to the Episode Group:

- Members discussed the implications of including transplant-related and end-of-life care in the episode groups, but they did not vote to include either set of services in the poll.
- The workgroup voted to exclude the following categories of services in the measures:
    - dialysis access (except tunneled dialysis catheters in the CKD measure)
    - dialysis access maintenance
    - certain hospitalizations, such as those related to gastrointestinal bleeding, mental health and substance abuse, and diabetic foot wounds, among others
    - acute infections unrelated to dialysis access or diabetes
    - outpatient cardiac services like catheters and pacemakers
    - high-cost services related to HIV, parathyroidectomy, cancer, end-of-life, and non-kidney-related infusions
    - services for trauma and falls
    - physical and occupational therapy
    - certain Part D drugs, such as immunosuppressants for transplants, cardiac drugs, and diabetes drugs
- Members voted to include the following categories of services in the measures:
    - complications from dialysis access in the ESRD measure
    - certain hospitalizations, such as those related to fluid overload, heart failure, anemia, and hypertensive emergency, among others
    - outpatient E&M claims with diagnoses for hypertension, volume overload, electrolyte abnormalities, bone and mineral disease complications, and anemia
    - routine lab tests
    - rehabilitation following kidney-related hospitalizations
    - certain Part D drugs, such as anti-hypertensives, anemia drugs, and bone-mineral drugs

5. Next Steps

In the last session, Acumen provided a wrap-up of the discussion and an overview of the next steps. After each webinar, Acumen distributed a poll to gather input from members on the

discussions. The polls were open for one week and were structures to summarize discussion to reflect where there appeared to be verbal consensus. The surveys included comment boxes to provide additional thoughts. Based on National Quality Forum practices, the threshold for support was greater than 60% consensus among poll responses.

Acumen will operationalize input for the measure specifications based on the poll results and will follow up with workgroup members with more information about the next steps in the measure development process.

Please contact **Acumen MACRA Clinical Committee Support** at macra-clinical-committee-support@acumenllc.com if you have any questions. If you're interested in receiving updates about MACRA Episode-Based Cost Measures, please complete this Mailing List Sign-Up Form to be added to our mailing list.