Chronic Kidney Disease / End-Stage Renal Disease (CKD/ESRD) Post-Field Test Refinement (PFTR) Webinar Meeting Summary

MACRA Episode-Based Cost Measures: Clinician Expert Workgroups
Workgroup Webinar, March 6, 2023
April 2023

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 Wave 5, we obtained input on candidate clinical areas and episode groups through a public comment period from February 18, 2022, to April 1, 2022.[2] This approach provided flexibility for a wider range of interested parties to participate around their schedule. The prioritization criteria used to identify strong candidate episode groups and concepts were developed based on input from our technical expert panel (TEP), Person and Family Engagement (PFE), Clinical Subcommittees (CS), and Clinician Expert Workgroups ("workgroups"). The following Wave 5 episode groups were finalized based on the prioritization criteria, public comments received, and discussions with CMS: (i) Kidney Transplant Management, (ii) Rheumatoid Arthritis, and (iii) Prostate Cancer. In addition to Wave 5 of cost measure development, which is currently underway, Acumen is developing cost measures for Chronic Kidney Disease (CKD) and End-Stage Renal Disease (ESRD).

[1] For information on measure development in Wave 5, refer to the Wave 5 Measure Development Process document (https://www.cms.gov/files/document/2023-cmft-ebcm-process.pdf).
[2] For a summary of comments we received during the public comment period, refer to the Wave 5 Measure Development Public Comment Summary Report (https://www.cms.gov/files/document/wave-5-public-comment-summary-report.pdf).

We held a nomination period for workgroup members between June 3, 2022, and July 1, 2022. The workgroups are composed of clinicians with expertise directly relevant to the selected episode groups. Workgroups (of about 15-20 members) were finalized in July 2022, and they provided detailed input on the development of the selected episode groups during their first workgroup webinars from July 26 to 28, 2022. Acumen convened the workgroups again for a Service Assignment and Refinement (SAR) Webinar to revisit the specifications recommended during the workgroup webinar and refine the measures prior to national field testing. After the national field test from January 17, 2023, to February 14, 2023, Acumen convened the workgroups for a Post-Field Test Refinement (PFTR) Webinar to continue measure specification and refinement discussions in March 2023.[3] For Wave 5, all workgroup meetings were held virtually.

CKD/ESRD PFTR Webinar, March 6, 2023

This meeting summary document outlines the purpose, discussion, and recommendations from the CKD/ESRD PFTR Webinar. Section 1 provides an overview of the webinar goals and process. Section 2 summarizes the discussion and recommendations from the workgroup. Section 3 is an appendix that describes the materials and information provided to workgroup members prior to and at the beginning of the webinar as preparation for discussion on detailed measure specifications.

1. Overview

The goals of the CKD/ESRD PFTR Webinar on March 6, 2023, were the following:

(i) Review feedback on the measures from the national field test
(ii) Provide input to specify the cost measures for potential use in MIPS that can accurately distinguish between good and poor performance among clinicians in terms of cost efficiency
(iii) Consider results of empirical analyses and the Person and Family Partner (PFP) findings
(iv) Provide input on risk adjusting for crash starts, modifying the minimum trigger gap window, and categories of services to assign to the episode group

The meeting was held online via webinar and attended by 9 of the 16 workgroup members. The webinar was facilitated by Acumen moderators, Kevin Erickson and Eugene Lin. The CKD/ESRD workgroup chair was Alexander Liang, who also facilitated meeting discussions. Derek Forfang and Michael Mittelman were the PFPs that attended the webinar to discuss and address questions regarding the PFP findings. The MACRA Episode-Based Cost Measure Workgroup Composition List contains the full list of members, including names, professional roles, employers, and clinical specialties; it's available on the MACRA Feedback Page.[4]

Prior to the webinar, workgroup members were provided with information and materials to inform their meeting discussions (see Section 3). After the webinar, workgroup members were sent a recording of the webinar and polled on their preferences to ensure the measures are

[3] The approach was slightly different for the CKD and ESRD measures. The CKD/ESRD workgroup convened for their workgroup webinars on September 23 and October 4, 2021. After the CKD and ESRD measures were part of the 2023 field test, the workgroup convened once more for the PFTR Webinar. More information on the original workgroup webinars from 2021 is available here: https://www.cms.gov/files/document/summary-ckdesrd-workgroup-webinar.pdf.

[4] CMS, "MACRA Episode-Based Cost Measures Wave 5 Clinician Expert Workgroup Composition (Membership) List" (https://www.cms.gov/files/document/wave-5-workgroup-comp-list-922.pdf).

developed based on well-documented input. Based on similar meeting discussion practices, the threshold for support was >60% consensus among poll responses. This document summarizes the workgroup members' input from both the discussion as well as the polls.

This meeting was convened by Acumen as part of the measure development process to gather expert clinical input; as such, these are preliminary discussions and materials, which don't represent any final decisions about the measure specifications or MIPS.

2. Summary of Sessions and Discussion

This section is organized based on meeting sessions and describes workgroup member discussions and recommendations. The first subsection summarizes the PFP findings discussed during the webinar. The remaining subsections describe workgroup member discussions and recommendations on risk adjustment for crash starts, the measure's minimum trigger gap window, and service assignment category alignment with the Kidney Transplant Management measure, respectively. The final subsection provides an overview of next steps for the measure development process.

2.1 Person and Family Partner (PFP) Findings and Discussion

We received 24 comments from the Person and Family Engagement (PFE) Field Testing Survey regarding the CKD and ESRD measures. Several topics were raised in these comments, such as crash starts, diagnosis stages, and the challenges of having comorbidities that are common in CKD and ESRD. During the webinar, 2 PFPs shared these findings and fielded questions from workgroup members.

Regarding crash starts, PFPs commented how this is a key area that the patient community struggles a lot with, as crashes happen quite frequently. Crash starts generally refer to patients who unexpectedly crash into dialysis, or aren't prepared by their nephrologists for the initiation of dialysis at the start of their ESRD episode. Due to the lack of preparation, it's expected that costs would be higher than an average ESRD episode. The workgroup members pointed out how important it is for patients to understand the stages of kidney failure better in order for the patients to transition more easily. They also said care coordination plays a huge role in regard to the transition process. Lastly, PFPs noted that services for mental health are important for patients with CKD, particularly during and after their transition to dialysis and ESRD, since that's often when patients have the most challenging experiences.

Diagnosis stage and disease progression was also a common theme in the PFE input. Most commenters were diagnosed before stages 4 or 5. The PFPs emphasized certain comments that highlighted how patients would have an easier time starting their dialysis if they knew about their diagnosis earlier in their disease progression. Relatedly, PFE commenters also found it much more difficult to manage other conditions and comorbidities as the CKD stages progress. Based on this, there was a suggestion to consider whether or not to include earlier stages of CKD in the patient cohort for the measure (i.e., not just stages 4 and 5). However, workgroup members already reached consensus that the scope of the CKD measure will only include stages 4 and 5, given that including earlier stages in the patient cohort would likely introduce substantial clinical heterogeneity.

PFE survey commenters also emphasized the importance of and challenges associated with managing comorbidities for patients with CKD. Some comorbidities they mentioned, such as atrial fibrillation, coronary artery disease, stroke, hypertension, diabetes, cancer, and mental health conditions, are currently risk-adjusted for in both the CKD and ESRD measures. PFPs

also noted some other conditions, such as other kidney-related conditions, hypoglycemia, erectile dysfunction, and infertility.

There was also a brief discussion about the importance of mental health services for patients with CKD and ESRD, and the group briefly considered the idea of explicitly including mental health services in service assignment for the measures. However, consensus wasn't reached on this topic. Some members mentioned a concern about inadvertently disincentivizing the use of these services if they're included in the measure.

2.2 Risk Adjustment for Crash Starts

During the previous CKD/ESRD workgroup meeting in 2021, the workgroup discussed the concept of crash starts and whether and how to address them in the measures. Specifically, the workgroup raised 2 issues concerning crash starts. First, there were questions about whether nephrologists should be held accountable for those costs that happen following a crash into dialysis. Second, there was discussion about how to identify situations where costs would spike as a result of crash starts in the claims data. Acumen revisited these topics again during the PFTR Webinar to gather workgroup input on how to define and specify crash starts for the purpose of potential risk adjustment within the ESRD measure.

Acumen highlighted results from the sub-population analysis and other prior work that indicates unique cost patterns among episodes progressing to ESRD between the bottom and top 10% of observed cost. Among episodes in the bottom 10% of cost, there's often a cost pattern with a constant rate of spending for the CKD episode followed by an increase in spending that plateaus, then stabilizes in the ESRD episode. This likely indicates a patient who didn't crash start. In episodes in the top 10% of cost, however, there's often a large increase in costs for CKD that settles into a larger plateau once an ESRD episode starts. Workgroup members agreed that these differences and variability among these ranges, likely due to crash starts, ought to be accounted for in 2 ways: (i) retaining the risk adjustor for CKD episodes that progress to ESRD, and (ii) considering addressing crash starts directly.

The workgroup discussed various aspects of defining crash starts: hospitalizations occurring within certain time windows prior to the start of dialysis, whether or not the initiation of outpatient dialysis without a prior hospitalization can be considered a crash start, and the existing patient-clinician relationship. The group discussed that detecting the first outpatient treatment for dialysis and determining when patients are discharged are components that are simpler to detect in claims data, as compared to detecting whether or not someone received dialysis within the inpatient setting, which can be challenging due to imprecision in the claims data. The workgroup members discussed whether claims data would be sufficient to identify crash starts or if access to data from the 2728 ESRD medical evidence report forms would be necessary. However, some expressed concerns about different interpretations of data and the accuracy of the first day of dialysis reported on the 2728 ESRD medical evidence report. Workgroup members also discussed how the initiation of dialysis with a central venous catheter (as opposed to an arteriovenous fistula or graft) could be used as an indication of a crash start. This indicator is available in monthly dialysis claims and could be used to define crash starts with or without the addition of information about prior hospitalizations.

<u>Key Takeaways from Discussion and/or Polls for Crash Starts</u>:

- Members recommended adding a risk adjustor for the presence of crash starts for new ESRD episodes.

- Members generally agreed that the definition of crash starts for this risk adjustor should be based on dialysis initiated with a catheter, preceded by a hospitalization.
- Members suggested that this risk adjustor shouldn't apply in cases where the same clinician was caring for the patient in CKD before the crash start to ESRD, if feasible to implement technically.

2.3 Minimum Trigger Gap Window

Members discussed increasing the minimum trigger gap window between a trigger claim and a confirming claim from the 1-day minimum. For reference, the measure construction logic for the CKD and ESRD measures states that an episode is triggered if a confirming claim occurs between 1 and 180 days after a trigger claim. A workgroup member in a prior meeting brought up the rationale that clinicians who only see a patient once could be attributed the ongoing measure. For example, under the default framework, if a clinician has a patient visit on day 1, and then a test done in day 2, this would be considered 2 separate encounters and would trigger an episode. The workgroup member was interested in reviewing testing results based on increased minimum trigger gaps to evaluate the impacts. From the results that Acumen produced and shared during the workgroup meeting, increasing the minimum trigger gap would likely have minimal effect on the overall number of episodes triggered. This topic was also discussed with the Kidney Transplant Management workgroup, given that changes to this specification would likely impact that measure.

The workgroup considered these results and discussed the possibility of considering a larger minimum than the current 1-day minimum. Evaluating the options of 2, 7, and 14 days that were tested in Acumen's analysis, one member said they were unsure if those days would make much of a difference, and that 2 and 7 days in particular would be unusual for bringing a patient back for care. Overall, most members agreed that increasing the minimum gap between trigger and confirming claims would likely have minimal effect.

Key Takeaways from Discussion and/or Polls for Minimum Trigger Gap Window:

- Members recommended retaining the current default minimum trigger gap window of 1 day.

2.4 Identifying Clinically Related Services

Acumen described the purpose of service assignment so that members could continue discussing which services associated with the attributed clinician's role in managing the patient's care should be included in the cost measure. The intent of the 3 kidney measures is to ensure a consistent and coherent set of measures across renal disease progression and care, while also recognizing the unique features of each phase/condition. The Kidney Transplant Management measure currently includes a larger set of services than the CKD and ESRD measures; some services are relevant to all the measures but currently only included within the Kidney Transplant Management measure. Some workgroup members expressed differing opinions on aligning the CKD and ESRD measures with the Kidney Transplant Management measure; however, most members were in favor of aligning all service assignment rules overall across the 3 measures for clinical coherence.

Workgroup members considered a field testing comment expressing concern about the inconsistency of drug pricing; however, considering the measures' use of standardized prices, workgroup members ultimately agreed with continuing to assign Part D drug costs. All 3 kidney measures currently include Part D costs within their service assignment, and this includes drugs such as antihypertensives, anemia drugs, and bone-mineral drugs, although the draft Kidney Transplant Management measure currently groups more Part D costs relative to the CKD and ESRD measures.

Acumen identified categories of services that are included in Kidney Transplant Management, but not the CKD/ESRD measures, in order to facilitate the workgroup's discussions on whether to align more detailed service assignment rules across the 3 kidney measures. The workgroup considered the inclusion of services related to lipid management, nutrition, and diabetes care in the CKD/ESRD measures, as well as anti-rejection drugs and glycemic control drugs. One member expressed concern about costly prescription drugs, such as sodium-glucose cotransporter-2 (SGLT-2) inhibitors, which may have substantial clinical benefits but over a longer time horizon; some noted that including the costs in the CKD and ESRD measures may discourage its use. Other categories of services not consistently included across the 3 draft kidney measures include services related to infections and cardiovascular and pulmonary complications. Using urinary tract infections (UTIs) as a way to distinguish transplant and CKD/ESRD was suggested, with the rationale that they're more common and preventable in transplant management. Another member posed whether Kidney Transplant Management should assign different cardiovascular and pulmonary complications than the CKD/ESRD measures.

Key Takeaways from Discussion and/or Polls for Identifying Clinically Related Services for CKD/ESRD:

- Members recommended including services for lipid management.
- The following categories of services will remain distinct between CKD/ESRD and Kidney Transplant Management measures based on workgroup member input (i.e., not assigned for CKD/ESRD):
    - UTIs
    - Insulin
    - Hypoglycemics
    - SGLT-2 inhibitors[5]
    - Valvular disorders
- Members didn't reach consensus on whether to include service categories related to peritoneal adhesiolysis (ESRD only), peritonitis, or arrhythmias, and Acumen will evaluate these services in context of overall clinical coherence of the measures.

2.5 Next Steps

In the last session, Acumen provided a wrap-up of the discussion and an overview of the next steps. After the meeting, Acumen distributed the PFTR Webinar Poll to gather input from members on the discussions held during the webinar, as well as a follow-up poll to gain further clarity on service assignment recommendations. Acumen will operationalize input for the measure specifications based on PFTR Webinar discussion and poll results and will follow up with workgroup members with more information about the final steps in the measure development process.

[5] While voting indicated some members were in favor of including SGLT-2 inhibitors, these medications will also not be included in the CKD/ESRD measures, both to maintain consistency with their recommendations on other diabetes-related medications and in consideration of the higher cost and longer time horizon for clinical benefits.

3. Appendix: Overview of Workgroup Member Preparation and Shared Materials

3.1 Introduction

Section 3.2 provides an overview of materials shared with the workgroup members prior to the workgroup webinar. Section 3.3 provides a recap of concepts of the measure development process presented by Acumen.

3.2 Overview of Meeting Materials

Prior to the meeting, workgroup members were provided with the following information to inform their discussions and votes:

- Agenda and Slide Deck, which was sent prior to the meeting and outlined the topics and process used for the webinar, including embedded empirical analysis results
- Investigation workbooks sent prior to the meeting, which presented detailed findings from empirical analyses:
    - A Sub-Population Analysis, which provided data on the frequency and cost associated with a set of sub-populations informed by public comments received, prior workgroup discussions, and deliberations among the Acumen clinical team
    - Service Utilization over Time Analysis, which lists the top 200 most frequent services for each claim setting across episodes for the draft version of the measure along with various metrics regarding those services (e.g., share of episodes with that service, average cost of the service per episode, share of attributed clinicians who furnished the service).

The materials shared were based on analyses run on draft measure specifications that the Acumen clinical team created, based on input from the previous meetings, field testing feedback, and discussions with CMS.

3.3 Overview of Cost Measure Development

At the beginning of the meeting, Acumen presented an introductory session on the following topics:

- The activities done to date for the development of episode-based cost measures, including the Wave 5 measure development public comment period
- The goals of the meeting and timeline of activities for Wave 5
- A recap of applicable background and context related to the cost measure, framework items, and information from the previous meetings