

Kidney Transplant Management Service Assignment and Refinement (SAR) Webinar Meeting Summary

MACRA Episode-Based Cost Measures: Clinician Expert Workgroups
Workgroup Webinar, September 29, 2022

November 2022

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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 schedules. 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.

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. Then, Acumen convened the workgroups again for a Service Assignment and Refinement (SAR) Webinar to revisit the specifications

¹ For information on measure development in Wave 4, refer to the [Wave 4 Measure Development Process](https://www.cms.gov/files/document/wave-4-measure-development-process-macra.pdf) document (<https://www.cms.gov/files/document/wave-4-measure-development-process-macra.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) (<https://www.cms.gov/files/document/wave-5-public-comment-summary-report.pdf>).

recommended during the initial meeting and refine the measures prior to national field testing. For Wave 5, all workgroup meetings will be held virtually. The workgroups will convene for a third meeting to continue measure specification and refinement discussions after a national field test, which is currently slated for early 2023.

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This meeting summary document outlines the purpose, discussion, and recommendations from the Kidney Transplant Management SAR 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 Kidney Transplant Management SAR Webinar on September 29, 2022, were the following:

- (i) Provide input to specify a cost measure for potential use in MIPS that can accurately assess clinicians in terms of cost efficiency
- (ii) Consider the results of empirical analyses and the Person and Family Partner (PFP) findings
- (iii) Provide input on how to define the patient cohort, account for sub-populations to ensure that the measure allows for meaningful clinical comparisons, and identify clinically related services

The meeting was held online via webinar and attended by 12 of the 14 workgroup members. The webinar was facilitated by Acumen moderators, Eugene Lin and Kevin Erickson. The Kidney Transplant Management workgroup chair was Krista Lentine, who also facilitated meeting discussions. Keisha Payton was the PFP 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.³

All interested parties beyond the workgroup members had access to a public dial-in number to observe the meeting as part of Acumen's continued effort to increase the transparency of the measure development process.

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 developed based on well-documented input. Based on National Quality Forum 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.

³ 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>).

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 refinements to draft specifications and identifying clinically related services, respectively. The final subsection provides an overview of the next steps for the measure development process.

2.1 Person and Family Partner (PFP) Findings and Discussion

We conducted surveys with 5 PFPs to gather input that would inform cost measure development for Kidney Transplant Management. During the webinar, one PFP shared these findings and fielded questions from the workgroup members.

While post-transplant nephrology was identified as the primary point of care, PFPs also reported pharmacy consults, nutrition, primary care, endocrinology, and dermatology as other common components of their care. The frequency of services decreased over time after the kidney transplant but would vary depending on the complications PFPs experienced.

Some PFPs reported reasonable post-transplant medication routines, while others mentioned difficulties in medication management. One PFP noted the significant difficulty in assessing infusions following a post-transplant-related complication. Needing authorizations for medication changes and costly prescriptions may cause delays and limited access to medications.

PFPs cited complications following their transplant, including heart attacks/strokes, long-lasting wounds, and urinary tract infections requiring hospitalization as well as related services to treat those complications (e.g., cardiology, hematology, and social work). They mentioned that complications can have a broad impact on services. For example, a PFP shared that the measurement device for dialysis was no longer accurate following a stroke event, resulting in the purchasing of a new device.

PFPs mostly experienced high-quality care coordination but one PFP reported that the care coordination fell off quickly. One factor that facilitated care coordination was to have all clinicians in one system with a single electronic health record (EHR) system. PFPs shared that the responsibility for care coordination mostly fell to the patient and family caregivers. PFPs cited that some barriers to quality care included transportation and access to adequate treatments.

2.2 Refinements to Draft Specifications

Acumen reviewed the draft specifications and decision points from the previous workgroup webinar and discussed pending topics to refine measure specifications prior to national field testing. Section 2.2.1 provides a summary of the discussion on refining trigger services and diagnoses. Section 2.2.2 provides a summary of the discussion on how to account for certain sub-populations of interest.

2.2.1 Defining the Episode Group

Acumen reviewed the methodology for constructing an episode-based cost measure, with a focus on “triggering an episode.” In the draft measure specifications, episodes are triggered when the same clinician group, identified by their Taxpayer Identification Number (TIN), bills Medicare one trigger claim (billing for any outpatient evaluation & management or kidney education code) and one confirming claim (billing any trigger service, or transplant medication, laboratory test, or antibody treatment) within 180 days (but not on the same day). One member reiterated the need for implementing a minimum period between the trigger and confirming claims if the confirming claim is a laboratory test. The member noted that codes for laboratory tests ordered as part of the initial visit may be billed up to a month later and, therefore, could trigger an episode with only one encounter. Acumen noted that if a rule were to be implemented, it would have to apply to all services in the trigger logic (i.e., not just lab services as confirming claims).

To trigger an episode, both the trigger and confirming claims must have at least one qualifying International Classification of Diseases, 10th Revision (ICD-10) diagnosis code to indicate that the patient is receiving kidney transplant-related care. The workgroup previously agreed on the following categories of ICD-10 codes:

- Kidney transplant status: Z940, Z4822
- Complication of kidney transplant: T8611, T8612, T8613, T8610, T8619
- Hypertensive chronic kidney disease: I120, I1311, I132
- Chronic kidney disease: all ICD-10 codes under N18 and N19
- Immunodeficiency due to drugs: D84.421

During the webinar, some members suggested adding ICD-10 code Z79.899 (Other long term [current] drug therapy) to the list. The workgroup advised Acumen to explore additional ICD-10 codes used for immunosuppression care and monitoring to ensure the list of diagnosis codes is inclusive.

Acumen listed specific medications to consider as confirming claims. Acumen noted that, in order to facilitate similarity with measures for Chronic Kidney Disease and End-Stage Renal Disease (CKD/ESRD), medications will only be used as confirming claims. Within the voting results from the first workgroup webinar, the workgroup voted to retain many transplant medications in the draft measure specifications as confirmation services within the trigger logic, but a unanimous consensus wasn’t reached for all medications. In the comment section of the poll, some members provided rationales for removing basiliximab, muromonab-cd3, and daclizumab from the list of confirming services.

During the webinar, members recommended adding corticosteroids and intravenous immunoglobulin (IVIg) to confirmation services in addition to the medications in the draft measure specifications. Some members suggested adding bortezomib and alemtuzumab. The workgroup recommended removing basiliximab and muromonab-cd3 from the list of confirming services. Members noted that basiliximab is used exclusively for induction therapy and, therefore, wouldn’t be relevant if episodes aren’t intended to be triggered within 90 days of a transplant; muromonab-cd3 is rarely used in current practice.

The workgroup also discussed whether a medication included as a confirming service would need to pair with a diagnosis code. In the current specifications, both trigger and confirming claims are paired with at least one qualifying ICD-10 code to trigger an episode. However,

members noted that the pairing may not be necessary if medications included as confirming services are clearly indicated for kidney transplant management.

Key Takeaways from Discussion and/or Polls for Defining the Episode Group:

- Members had split opinions on whether to implement a minimum period between the trigger and confirming claims if the minimum period would be implemented to all services in the trigger logic. Acumen won't implement a minimum period between the trigger and confirming claims based on internal clinical input.
- Members recommended adding the following ICD-10 codes to the list of diagnosis codes:
 - Z7969 Long term (current) use of other immunomodulators and immunosuppressants
 - Z79621 Long term (current) use of calcineurin inhibitor
 - Z79623 Long term (current) use of mammalian target of rapamycin (mTOR) inhibitor
- Members didn't reach a consensus on the following ICD-10 codes; however, based on internal clinical input, Acumen will include the following ICD-10 codes in the list of diagnosis codes:
 - Z79624 Long term (current) use of inhibitors of nucleotide synthesis
 - T451 Poisoning by, adverse effect of and underdosing of antineoplastic and immunosuppressive drugs
- Members recommended adding the following medications as confirming services within the trigger logic:
 - Rituximab
 - Bortezomib
 - Eculizumab
 - Corticosteroids
 - IVIg
- Members recommended removing basiliximab and muromonab-cd3 from the list of confirming services.
- Members didn't reach a consensus on whether to pair a medication included as a confirming service with a diagnosis code. For most medications, more than half of the members voted to pair the medication with a diagnosis code. Acumen will continue the current approach of pairing trigger and confirming claims with at least one qualifying ICD-10 code to trigger an episode.

2.2.2 Accounting for Patient Heterogeneity

Acumen reviewed the following methods used to account for patient heterogeneity and allow for meaningful clinical comparisons: (i) risk adjustment⁴, (ii) sub-grouping⁵, (iii) exclusion⁶, and (iv) monitoring⁷.

All episode-based cost measures use risk adjustment to account for clinical complexity. The default model is the CMS-Hierarchical Condition Category (HCC) model. This model has 87 variables for comorbidities based on the beneficiary's claims history, as well as indicators for age and Medicare enrollment status; cost measures also include additional measure-specific risk adjustors as recommended by the workgroup.

Acumen presented results from the July 2022 workgroup webinar poll. The workgroup previously reached a consensus to risk adjust for additional indicators of patient complexity, including the number of years post-transplant, number of prior transplants, evidence of BK virus nephropathy, and evidence of cytomegalovirus (CMV) viremia. The workgroup voted to add risk adjustors, including ones for frailty, prior heart failure hospitalization, and episodes ending in renal failure, to align with other kidney care cost measures currently under development. One member asked how risk adjustment would be done for patients with evidence of BK virus nephropathy. Acumen clarified that the evidence of BK virus nephropathy in the 12-months prior to the episode would be used as a risk adjustor.

During the webinar, members verbally agreed to exclude patients with evidence of atypical hemolytic uremic syndrome (HUS) prior to the episode from the measure as costs could be extremely variable for this small set of patients. The workgroup expressed interest in discussing how to incorporate United Network for Organ Sharing (UNOS) data into the measure if Acumen can secure that data. UNOS data would provide more information on the characteristics of transplanted organs, donors, and recipients since 1987.

Key Takeaways from Discussion and/or Polls for Accounting for Patient Heterogeneity:

- Members recommended to exclude patients with evidence of atypical HUS prior to the episode from the measure.
- Members recommended to risk adjust for patients with lupus nephritis and glomerulonephritis.
- The workgroup expressed interest in further discussing how to incorporate UNOS data into the measure once Acumen secures UNOS data.

⁴ Risk adjusting 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 compare observed episode spending to an expected episode spending (predicted by a risk adjustment model).

⁵ 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.

⁶ 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.

⁷ Monitoring is a method in which we gather additional data to see how best to account for factors resistant to the other methods specified above.

2.3 Identifying Clinically Related Services

The purpose of service assignment is to identify services occurring during the episode that are clinically related to the attributed clinician's role in managing patient care. These assigned services should be inclusive enough to identify a measurable performance difference between clinicians but not introduce excessive noise.

Acumen reviewed input shared from the July 2022 webinar regarding service assignment and analysis results to help inform the discussions. Most members voted to apply the same broad service assignment rules from the CKD/ESRD measure. However, using these service assignment rules only captures around 26% of the total cost occurring during preliminary episodes. Acumen noted that the CKD/ESRD workgroup specified to not include many services relevant and specific to kidney transplant management to avoid discouraging the use of those services.

Acumen asked for feedback on whether and how to add the following service assignment categories to the measure:

- Transplant rejection
- Opportunistic infection
- Complications related to immunosuppression
- Complications of transplant surgery
- Complications of kidney biopsy
- Diabetes-related services
- Primary care services
- Surveillance testing
- Nutrition therapy

Acumen also shared a list of high-cost services by claim setting for workgroup members to consider.

During the webinar, members were split about whether to include certain high-cost service categories in the measure. Several members expressed concern about excluding high-cost services where it was unclear whether the services were wasteful. They acknowledged that even though there's no evidence of the benefit of many high-cost services, many clinicians still use them. There was concern that including certain high-cost services in the measure could incentivize clinicians to avoid using expensive services that prove to be beneficial in the future; however, workgroup members acknowledged that there's minimal evidence showing that expensive surveillance regimes are clinically beneficial.

Much of this discussion centered on surveillance testing. The workgroup didn't reach a consensus on whether to include surveillance testing as assigned services. Members noted that surveillance testing could be expensive. Complicating this concern was that it's difficult to use administrative claims data to discern the purpose of testing (i.e., for active surveillance or for detecting rejection due to suboptimal care). For example, members of the workgroup noted that in many instances it wouldn't be possible to discern from claims data whether a kidney biopsy was performed as a part of routine surveillance or to evaluate for the cause of kidney injury. Additionally, because there's minimal scientific evidence or consensus on ideal surveillance practices or on the frequency of surveillance, several members argued that all tests should be assigned to the measure. Other members reiterated the concern that including those costs might discourage the provision of care that's expensive in the short term but might result in

better patient outcomes in the long term. A similar point was raised for diabetes-related services, specifically insulin pumps. One member noted that insulin pumps are costly in the short term but could have prolonged benefits for glucose control.

Key Takeaways from Discussion and/or Polls for Identifying Clinically Related Services:⁸

- Members recommended including the following transplant-related drugs as assigned services:
 - Everolimus
 - Immune globulin (HIZENTRA)
 - Immune globulin (Privigen)
 - Immune globulin (GAMMAGARD LIQUID)
 - Immune globulin (GAMUNEX-C / GAMMAKED)
 - Other IVIg products
 - Methylprednisolone
 - Mycophenolate mofetil
 - Mycophenolic acid
 - Prednisolone oral
 - Prednisone
- Members recommended including the following categories of infections as assigned services:
 - Urinary tract infection
 - Pneumonia
 - Viral infections
 - Sepsis
 - Other infections (e.g., other respiratory infections)
- Members recommended including kidney biopsy in service assignment, as it's a complication of procedures/treatment.
- Members recommended including hyperglycemia/hypoglycemia and other diabetes-related complications in service assignment (they're diabetes-related services); members had split opinions on whether to include insulins, non-insulin diabetes medications, and diabetic wound care in the measure.
- Members recommended including hypertension management and lipid management in service assignment (they're primary care services); members had split opinions on whether to include immunizations in the measure.
- Members recommended including the following surveillance testing as assigned services:
 - Drug assays for rejection medications (e.g., tacrolimus, sirolimus, cyclosporin)
 - Cytomegalovirus (CMV) blood polymerase chain reaction (PCR), BK virus blood or urine PCR
 - Biopsy (all indications)
 - Molecular testing for rejection
 - Cell-free deoxyribonucleic acid (DNA) testing

⁸Acumen will use the following principles to determine whether to include services with split opinions from the workgroup in regard to service assignment: (i) service assignment rules in the draft specifications are intended to be inclusive to allow data collection from field testing, (ii) most workgroup members previously voted to apply the same broad service assignment rules from the CKD/ESRD measures currently under development; therefore, services in the CKD/ESRD measure would be included to facilitate alignment, (iii) if there was a split opinion on services built upon other categories of services that reached a consensus among workgroup members, Acumen will include these services in the upcoming field testing, and (iv) for other cases, Acumen will make decisions on whether to include the service based on input from the internal clinical team.

- Human leukocyte antigen (HLA) antibody testing
 - Urinalysis
 - Urine culture
 - Urine protein and creatinine
 - Serum creatinine
 - Serum electrolytes
 - Liver function tests
 - Uric acid
 - Lipid profile
 - Hemoglobin A1C
- Members recommended including nutrition therapy in service assignment.
- Members recommended including cytologic malignancy as transplant-related malignancy, but they were split on whether to include melanoma.
- Members recommended including the following conditions and symptoms in service assignment:
 - Cytopenia
 - Volume overload/volume depletion
 - Nausea/vomiting
 - Chest pain
 - Shortness of breath
 - Fatigue
 - Dizziness
- Members recommended including the following categories of inpatient services in service assignment:
 - Esophagitis, gastroenteritis, and miscellaneous digestive disorders
 - Major gastrointestinal (GI) disorders and peritoneal infections
 - Postoperative and post-traumatic infections
 - Major hematological and immunological disorders
 - Infectious and parasitic disease with operating room procedures
 - Kidney and ureter procedures for non-neoplasm
 - Peritoneal adhesiolysis
 - Major bladder procedures
- Members had split opinions on whether to include the following categories of inpatient services in service assignment:
 - GI hemorrhage
 - Nonbacterial infection of the nervous system
 - Disorders of pancreas except malignancy
 - Circulatory system procedures
- Acumen will factor in the following considerations to determine whether to include services with split opinions from the workgroup in service assignment:
 - Service assignment rules in the draft specifications are intended to be inclusive to allow data collection from field testing.
 - Most workgroup members previously voted to apply the same broad service assignment rules from the CKD/ESRD measure currently under development.
 - If split opinions are for services that are clearly related to other services for which workgroup members reached a consensus, Acumen will include these services for completeness.
 - If split opinions are presumed to result from poll questions that do not have enough specificity, Acumen will make decisions on whether to include the service based on input from their internal clinician team.

2.4 Next Steps

In the last session, Acumen provided an overview of the next steps. After the meeting, Acumen distributed the SAR Webinar Poll to gather input from members on the discussions held during the webinar. Acumen will operationalize input for the measure specifications based on SAR Webinar Poll results and follow up with workgroup members with more information about the next steps in the measure development process.

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, and 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 were sent prior to the meeting and outlined the topics and process used for the webinar, including embedded empirical analysis results
- A Chronic Condition Cost Measure Framework Overview, which provided an at-a-glance summary of the chronic condition measure framework and lists the initial set of draft codes used in triggering for the meeting analyses, as well as HCCs used in the base risk adjustment model
- 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 preliminary set of sub-populations informed by public comments received 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 Wave 5 measure development public comments, discussions with CMS, and the input the workgroup provided during the July 2022 Workgroup Webinar.

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 brief recap of the Quality Payment Program and episode-based cost measures for MIPS
- A recap on the different sources of information for the workgroup to consider in addition to their clinical expertise, including analyses and data, a literature review, and findings from the PFPs

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.