Sepsis Workgroup In-Person Meeting Summary

MACRA Episode-Based Cost Measures: Measure-Specific Workgroups
In-Person Workgroup Meeting, August 23, 2019
September 2019

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 (MACRA) of 2015. Acumen's measure development approach involves convening clinician expert panels to provide input in cycles of development ("waves").[1] The four Clinical Subcommittees (CS) that convened in May-June 2019 for Wave 3 were focused on the following clinical areas: Chronic Condition and Disease Management, Dermatologic Disease Management, General and Colorectal Surgery, and Hospital Medicine.[2] These CS provided input on selecting episode groups for development in Wave 3 and the composition of smaller, targeted workgroups to build out the measure. Acumen convened the following workgroups[3] (each composed of approximately 15 members) in mid-August 2019 for in-person meetings: Diabetes, Asthma/Chronic Obstructive Pulmonary Disease (COPD), Melanoma Resection, Sepsis, and Colon Resection.

Sepsis Workgroup Meeting, August 23, 2019

This meeting summary document outlines the purpose, discussion, and recommendations from the Sepsis workgroup in-person meeting. Section 1 provides an overview of the meeting goals and process. Section 2 summarizes the discussion and recommendations from the workgroup.

---

[1] For information on measure development in Waves 1 and 2 (2017 and 2018), refer to Episode-Based Cost Measure Field Testing Measure Development Process document (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2018-measure-development-process.pdf)

[2] Members for these Clinical Subcommittees were recruited through a public nomination period from March 11 to April 12, 2019.

[3] Members for these workgroups were recruited from within the CS as well as a standing pool of nominees between June and July, 2019.

Section 3 is an appendix that describes the materials and information provided to workgroup members prior to and at the beginning of the meeting as preparation for discussion on detailed measure specifications.

1. Overview

The goals of the Sepsis workgroup meeting that convened on August 23, 2019, were to provide detailed recommendations on the following:

(i) Episode group trigger codes and scope
(ii) How to account for sub-populations to ensure that the measure allows for meaningful clinical comparisons (either as episode group sub-groups, variables to include in the risk adjustment model, measure-specific exclusions, or sub-populations to monitor for future testing and consideration)
(iii) Episode window length
(iv) Categories of services that are associated with the clinician's role in managing care for the condition and that should be assigned to the episode group (i.e., included as costs in the cost measure)

The meeting was held in Washington, DC, and attended by all 20 workgroup members (17 attended in person and 3 via webinar). The meeting was facilitated by an Acumen moderator, Nirmal Choradia. The Sepsis workgroup chair was Jennifer Bracey, who also facilitated meeting discussions, and the Hospital Medicine CS co-chairs were Rob Zipper and Carolyn Fruci. The MACRA Episode-Based Cost Measure Workgroup Composition List contains the full list of members, including names, professional roles, employers, and clinical specialties.[4]

Stakeholders 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 meeting, workgroup members were provided with information and materials to inform their meeting discussions (see Section 3). During and after the meeting, workgroup members were polled on their preferences, to ensure the measures are developed based on well-documented stakeholder input. Mirroring National Quality Forum practices, the threshold for recommendations was >60% consensus. 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 an initial step 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.

2. Summary of Sessions and Discussion

This section is organized based on meeting sessions and describes workgroup member discussions and recommendations on each topic: defining episode group scope and trigger codes, addressing patient cohort sub-populations to ensure meaningful clinical comparison, and assigning clinically-related services to the episode group.

---

[4] For a list of Sepsis workgroup members in Wave 3, please download the MACRA Episode-Based Cost Measures Measure-Specific Workgroup Composition (Membership) List available on the MACRA Feedback Page (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2019-workgroup-comp-list.pdf)

2.1 Defining the Episode Group

In this session, Acumen reviewed the framework for defining an episode group. Section 2.1.1 provides a summary of the initial discussion on measure scope for a Sepsis cost measure, and Section 2.1.2 provides a summary of the discussion of trigger codes for the episode group.

2.1.1 Discussion of Measure Scope

The workgroup discussed three initial suggested scope definition options for the Sepsis measure: (i) a narrow definition which includes episodes triggered only by Medicare Severity-Diagnosis Related Groups (MS-DRGs) 870-872, (ii) a broad definition which includes episodes triggered by MS-DRGs 870-872, *or* episodes triggered by other infectious MS-DRGs if also accompanied by a sepsis or organ dysfunction diagnosis code, and (iii) any infection definition which includes episodes triggered by MS-DRGs 870-872, *or* episodes triggered by any of the other infectious MS-DRGs from the broad definition.

For the narrow definition, workgroup members remarked that some patients are coded with sepsis but are not septic. As a potential solution to this issue, members recommended using a broader definition instead of only the sepsis MS-DRGs. This definition would align with the Bundled Payments for Care Improvement (BPCI) Advanced Model for MS-DRGs 870-872. Members also mentioned that the narrow definition could miss some septic patients not coded as such and could include patients who were coded as septic without having sepsis. This would include both problems with up-coding and miscoding. The workgroup discussed the overarching concerns of up-coding and miscoding, including the possibility that some providers consistently up-code their patients, which could make them look less costly as less sick patients would be included in their cost measure (i.e., not all providers will be on the same footing). Workgroup members also mentioned that using diagnoses in addition to MS-DRGs would be valuable.

For the broad definition, some members mentioned that including organ dysfunction diagnoses is a hallmark of newer definitions of sepsis (as described in publications by Derek C. Angus), and since the set of diagnoses used in the broad definition was adapted from a previously claims-validated methodology for identifying sepsis (i.e., from the Angus publications), including organ dysfunction diagnoses may be better at capturing sepsis than a diagnosis of sepsis with an infectious MS-DRG alone. However, workgroup members also commented on the challenges of including patients with an organ dysfunction diagnosis among the cases of non-sepsis infectious MS-DRGs because dysfunction is not always related to sepsis, and because of this, they discussed focusing on only the use of diagnosis codes indicating sepsis and not organ dysfunction.

Workgroup members also discussed the third option of having a wide measure scope with all infection sources so they can direct more targeted efforts across different types of infections, which some members noted could be feasible and valuable if the approach accurately accounted for both infection type and severity of presentation via sub-groups. However, members also expressed concern that while the approach is technically feasible and valuable, it may suffer from clinical face validity concerns.

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

- Workgroup members narrowed the decision in an initial poll to the two options for the broad definition (i.e., one with only sepsis diagnosis codes, and one with sepsis or organ dysfunction diagnosis codes).
- The workgroup ultimately voted for an adjusted broad definition that did not include the organ dysfunction diagnoses, with episodes triggered by:
    - A sepsis MS-DRG (i.e., 870-872); or

- A non-sepsis infectious MS-DRG, if accompanied by a sepsis diagnosis code

2.1.2 Discussion of Trigger Codes

Based on discussion of measure scope, the workgroup recommended a modified version of the broad definition, as described above. Workgroup members were unsure about how to incorporate post-operative cases of sepsis because of the difficulty in differentiating post-operative reactions from true sepsis. Workgroup members discussed how certain infectious MS-DRG groupings (e.g., endocarditis and central nervous system infections) may potentially also not be included as triggers for the measure based on their low episode counts. While the workgroup did provide input on this question in the Trigger Refinement Poll, this topic was further explored in the following session in which they would discuss various options (e.g., excluding, risk adjusting, and sub-grouping) for the various source of infection areas.

Key Takeaways from Discussion and/or Polls for Trigger Codes:

- As noted in Section 2.1.1 above following the measure scope discussion, the workgroup recommended the following codes to trigger an episode:
  - A sepsis MS-DRG (i.e., 870-872); or
  - A non-sepsis infectious MS-DRG, if accompanied by a sepsis diagnosis code

2.2 Addressing Patient Sub-Populations for Meaningful Clinical Comparison

Members also held detailed discussions about how to account for various sub-populations within the Sepsis episode group. Sub-populations are patient cohorts as defined by particular characteristics. To ensure meaningful clinical comparisons, specific sub-populations/patient cohorts can be handled in the following ways: (i) stratifying the episode group into mutually exclusive and exhaustive sub-groups to define more homogeneous patient cohorts, (ii) including as a variable in the risk adjustment model, (iii) excluding the sub-population from the measure, and (iv) monitoring and testing the sub-population for future consideration.

After Acumen provided a description of each method and presented analytic data on preliminary sub-populations (recommended either by the CS or Acumen clinicians for initial consideration), workgroup members discussed their preferences for how to address each patient cohort, and completed a post-discussion Sub-Population Poll during the meeting.

2.2.1 Sub-Groups

As part of this discussion, the Acumen team explained that sub-grouping keeps the patient cohort in the measure while ensuring that we compare episodes separately only among those in the same sub-group; with exclusions, the episodes with the given characteristic are removed from the cost measure.

The workgroup considered sub-grouping by illness severity (i.e., septic shock versus no septic shock). The workgroup briefly considered septic shock within six hours as a more granular sub-group option, but it was mentioned that claims did not allow for assessment of specific timing outside of days. The workgroup also discussed the merits and challenges of sub-grouping or excluding for infection sources that have low episode counts such as endocarditis and central nervous system infections.

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

- Members agreed to sub-group by the following:
  - Illness severity (i.e., septic shock versus no septic shock)
  - Some infection sources (i.e., osteomyelitis and septic arthritis, gastrointestinal, respiratory, kidney and urinary tract infection, and cellulitis)

- This results in the mutually exclusive and exhaustive sub-groups listed below, which may be dependent on technical feasibility and statistical considerations:
  - Sepsis Due to Osteomyelitis and Septic Arthritis Infection with Septic Shock
  - Sepsis Due to Osteomyelitis and Septic Arthritis Infection without Septic Shock
  - Sepsis Due to Gastrointestinal Infection with Septic Shock
  - Sepsis Due to Gastrointestinal Infection without Septic Shock
  - Sepsis Due to Respiratory Infection with Septic Shock
  - Sepsis Due to Respiratory Infection without Septic Shock
  - Sepsis Due to Kidney and Urinary Tract Infection with Septic Shock
  - Sepsis Due to Kidney and Urinary Tract Infection without Septic Shock
  - Sepsis Due to Cellulitis Infection with Septic Shock
  - Sepsis Due to Cellulitis Infection without Septic Shock
  - Other Sepsis with Septic Shock
  - Other Sepsis without Septic Shock

2.2.2 Risk Adjustors

Workgroup members initially suggested risk adjusting for certain infection sources as opposed to sub-grouping. However, since bacteremia would necessitate a longer course of antibiotics and treatment, the workgroup recommended to risk adjust only for bacteremia and opted to handle other infection sources differently.

Workgroup members also suggested risk adjusting for the source of admission (i.e., long-term care hospital, skilled nursing facility, etc.). The workgroup members considered care for oncology patients to be very different from the general population and considered either risk adjusting or excluding these patients but ultimately recommended risk adjustment. Previous hospice or palliative care was mentioned as a possible risk adjustor due to those patients being much sicker at the baseline.

Workgroup members also identified a few sub-populations that are already part of the base risk adjustment model but that the workgroup believed were important to discuss. Since End-Stage Renal Disease (ESRD) is already included in the base risk adjustment model, workgroup members suggested to continue risk adjusting for ESRD, since they are unique from typical patients, while also ensuring that the chronic dialysis costs are not included in service assignment. Cirrhosis patients are also included in the base risk adjustment model, but were still voted on as a possible risk adjustor because the workgroup felt they are unique from typical patients. In addition to the alcohol and drug use variables already captured in the base risk adjustment model, the workgroup also suggested risk adjusting by IV drug use.

Workgroup members also considered risk adjusting for certain infection sources such as respiratory and cellulitis hospitalizations prior to recommending that they ought to be included as sub-groups (as mentioned in the previous section).

<u>Key Takeaways from Discussion and/or Polls for Risk Adjustors</u>:

- Members recommended adding the following as risk adjustment variables:
  - Bacteremia
  - Source of Admission (i.e., long-term care hospital, skilled nursing facility, etc.)
  - Oncology
  - Previous Hospice or Palliative Care
  - ESRD
  - Cirrhosis
  - IV Drug Use

2.2.3 Exclusions

The workgroup considered excluding patients who have very different care needs from the overall patient cohort. Though the workgroup initially considered neutropenic patients for risk adjustment alongside oncology, the workgroup ultimately suggested excluding neutropenic patients because they likely represent a higher risk and cost associated with the necessary level of care. Workgroup members also considered risk adjusting or excluding patients receiving extracorporeal membrane oxygenation (ECMO) during the hospitalization as well as patients with transplants (due to the complexity of these cases); the workgroup ultimately recommended to exclude these cases.

There were other comments that the workgroup had regarding potential measure exclusions. For example, the workgroup considered excluding patients with device-related infections, as they would have more costly care; however, there was no consensus on this sub-population. Workgroup members also mentioned that it would make sense to align with exclusions for other existing sepsis measures or programs, especially on the hospital side (such as aligning with what BPCI has worked on with sepsis).

Key Takeaways from Discussion and/or Polls for Exclusions:

- Members recommended excluding the following sub-populations:
  - Neutropenic patients
  - Patients with transplants
  - Patients receiving ECMO during the hospitalization

2.2.4 Monitor for Testing

Workgroup members initially considered risk adjusting for use of IV antibiotics 24 hours prior to admission. Workgroup members also discussed intubation, with some members expressing caution with placing patients into groups based on length of intubation because it could produce perverse effects on upfront care (i.e., there could be downstream complexities because of the lack of care upfront). Other members expressed concerns that intubation greater than 96 hours may require extensive care (e.g., long-term care hospital or ventilator dependent). Another point raised was that the variability in intubation criteria may be related to practice patterns, which may be hard to identify.

Results from the *Sub-Population Poll,* distributed during the session, and the *Follow-Up Poll* distributed after the session, did not suggest a clear workgroup recommendation for patients with central nervous system (CNS) or endocarditis infections, surgical treatment of infection, or a transfer prior to hospital admission. Therefore, the Acumen clinician team will make recommendations based on the results and meeting discussions for these sub-populations for future refinement.

Key Takeaways from Discussion and/or Polls for Monitor Variables:

- Members voted to monitor the following sub-populations:
  - Patients on IV antibiotics 24 hours prior to admission

2.3 Assigning Services to the Episode Group

Acumen described the purpose of service assignment so that members could identify and discuss which services associated with the clinician's role in managing the condition should be included in the cost measure. These assigned services should be inclusive enough to identify a measureable performance difference between clinicians but also not introduce excessive noise. Acumen also re-introduced the concept of the episode window to facilitate this session's

discussion. Section 2.3.1 presents the discussion of episode window length, and Section 2.3.2 summarizes the assigned services discussion.

2.3.1 Discussion of Episode Window Length

Members discussed what episode window length they preferred and weighed the options between a long and short window. Workgroup members agreed that the point or date of presentation should be when the episode window begins (i.e., at the emergency department). Acumen noted that this is also consistent with the feedback from the Person and Family Committee.

Many workgroup members were in favor of no pre-trigger period and a short post-trigger period (e.g., 30 or 45 days) for the episode window, at least for services related to serious infections. While there was discussion about a seven-day post-trigger window, this was ultimately deemed to be too short as members mentioned that the influence of the attributed clinician should extend further.

From a technical perspective, Acumen noted the episode window begins at admission rather than discharge. A workgroup member mentioned that for sepsis hospitalizations, they tend to think of days after discharge (rather than admission), and thus, would suggest using a window that is long enough to incorporate what they think of as an average hospital stay plus additional days. These considerations led to discussion about 30 days versus 45 days for the post-trigger window, with the workgroup ultimately recommending 30 days.

Key Takeaways from Discussion and/or Polls for Episode Window:

- Pre-trigger period: 0 days (no pre-trigger period)
- Post-trigger period: 30 days

2.3.2 Discussion of Assigned Services

Approximately four weeks prior to the workgroup meeting, workgroup members had participated in an optional *Categories of Assigned Services Survey* to provide preliminary input on the types of services to assign for the Sepsis episode group. This was intended to serve as the starting point for discussion during this portion of the session.

During the meeting, workgroup members provided details on which specific services related to sepsis to assign, especially considering readmissions and post-acute care. For readmissions, assigning outpatient visits within one week prior to the readmission was considered because patients could present symptoms there after the initial hospitalization. For post-acute care (PAC), members considered that it would be reasonable to include PAC services if they occur in relation to the hospitalization.

Though separate from the discussion on assigned services, workgroup members also inquired about how the attributed clinician is being defined, and the Acumen team explained that the attributed providers for acute inpatient medical condition episodes (like sepsis) are the clinician groups (identified by TIN, or tax identification number) that bill at least 30% of the evaluation and management (E&M) codes on Part B Physician/Supplier claims during the trigger inpatient stay; additionally, episodes would also be attributed to clinicians (identified by TIN-NPI, or the unique combination of TIN and national provider identifier, or NPI) within the attributed TIN if they bill at least one E&M code for that inpatient stay. One suggestion raised by the workgroup was to consider attributing the admitting ER physician and the discharging physician as they have a large amount of influence on treatment course and post-hospitalization course.

Workgroup members provided their input on these categories of assigned services as well as other categories of assigned services that they did not have time to fully discuss during the meeting in a follow-up survey after the meeting. Acumen clinical and technical teams will take into consideration these results in producing a draft set of measure specifications for future refinement.

2.4 Next Steps

In the final session, Acumen provided an overview of the next steps in the measure development process. Acumen will gather and review the input provided during the workgroup meeting's discussions and polls to create draft measure specifications. These can then be used for future testing and potential measure refinement.

After the meeting, Acumen distributed the *Follow-Up Poll* to gather input from members on episode window and services assignment, which were discussed during one of the last sessions of the meeting, and on follow-up confirming questions related to earlier survey questions about the patient cohorts. The survey also consisted of open comment boxes, including a question about the patient, family, and caregiver perspective.

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

3.1 Introduction and Overview of Shared Materials

Section 3.2 provides an overview of materials shared with the workgroup members prior to the meeting. Section 3.3 provides a recap of the main concepts of the measure development process and measure framework presented by Acumen. Section 3.4 presents various stakeholder input and research from a brief literature review conducted by Acumen that workgroup members could consider.

3.2 Overview of Meeting Materials

One week prior to the meeting, workgroup members were provided with the following information to inform their discussions and votes during the meeting:

- *Analytic Key Findings Document*, which summarized a selection of high-level key findings from empirical analyses ("investigations")
- Investigation workbooks presenting detailed findings from empirical analyses:
  - *Sub-Population Summary Investigation Workbook,* which provided data on the frequency and cost associated with an initial set of potential sub-populations suggested by Clinical Subcommittee members during and after their May-June meetings and by Acumen internal clinicians to serve as a starting point for workgroup member discussions
  - *Candidate Services Over Time Investigation Workbook,* which contained information on frequency, cost, and timing for up to 200 of the most commonly performed services before and after a trigger event to inform discussions on service assignment
  - *Clinician Attribution Investigation Workbook*, which provided the frequency and cost of episodes attributed to (i) individual clinicians (identified by TIN-NPI) by HCFA specialty and (ii) clinician groups (identified by TIN) by the TIN size
  - *Inpatient Cost Variability Investigation Workbook*, which provided statistics demonstrating the variability in cost of all services assigned to Sepsis episodes, stratified by measure scope and severity level; results were intended to help inform workgroup discussions on refining episode group scope
- *Literature Review/Quality Alignment Document*, which was an environmental scan that provided an overview of (i) opportunity for improvement for the cost measure identified through the literature, and (ii) quality measures with potential for alignment
- *Person and Family Committee (PFC) Findings Document*, which summarized input from the PFC regarding patient and caregiver perspectives

The materials shared were based on analyses run on triggering methodologies with preliminary trigger codes and specifications, which will be revised during measure development.

3.3 Overview of Cost Measure Development and Framework

In the beginning of the meeting, Acumen presented a short introductory session to cover the following topics:

- Role of episode-based cost measures within the context of the cost performance category of MIPS
- Recap of measure development to-date with 19 acute inpatient medical condition and procedural episode-based cost measures developed
  - Eight of these are currently used in the 2019 MIPS performance period alongside two broader cost measures that have been in use since the 2017 performance period: Medicare Spending Per Beneficiary and Total Per Capita Cost

- Details of Acumen's measure development approach, which includes stakeholder input throughout, including a guiding Technical Expert Panel (TEP), CS and workgroups providing detailed clinical input, and a Person and Family Committee (PFC) providing patient and caregiver perspectives[5]
- Overview of Wave 3 CS structure and input on cost measure components, which include defining an episode group, attributing episodes to clinicians, assigning costs, risk adjusting, and aligning cost with quality

Acumen also introduced the episode-based cost measure framework, covering the following topics:

- The types of episode-based cost measures (acute inpatient medical condition, procedural, and chronic condition)
- The five essential components of episode-based cost measures (defining the episode group, attributing the episode group to clinicians, assigning costs to the episode group, risk adjusting episode groups, and aligning cost with quality) along with an example illustration of how episodes work
- The steps for construction of an episode-based cost measure and goals that cost measures are meant to accomplish
- Information on the various types of data, literature, and stakeholder input that is considered in the development of episode-based cost measures

3.4 Overview of Stakeholder Input and Literature Review

Prior to discussion on measure specifications, Acumen presented additional information for workgroup members to consider, including existing literature that identifies opportunities to improve cost performance and care outcomes and a list of quality measures for potential alignment consideration.

Additionally, the Westat team provided a summary of the PFC input on cost measure development. The PFC was a focus group of Medicare patients and caregivers that shared their feedback and perspectives regarding care management for procedures and clinician cost performance.

[5] Additional detail on the measure development process and stakeholder roles is available on the MACRA Feedback Page within the Episode-Based Cost Measure Field Testing Measure Development Process document (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/2018-measure-development-process.pdf)