Heart Failure Post-Field Test Refinement (PFTR) Meeting Summary

MACRA Episode-Based Cost Measures: Clinician Expert Workgroups
PFTR Webinar, April 14, 2022
June 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 4, instead of the typical Clinical Subcommittee (CS) process for episode group prioritization and selection, we obtained stakeholder input on candidate clinical areas and episode groups through a public comment period from December 16, 2020, to February 5, 2021.[2] This approach provided flexibility for a wider range of stakeholders 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), CS, and Clinician Expert Workgroups ("workgroups"). The following Wave 4 episode groups were finalized based on the prioritization criteria, public comments received, and discussions with CMS: (i) Emergency Medicine, (ii) Heart Failure, (iii) Low Back Pain, and (iv) Depression.

We held a nomination period for workgroup members between April 26, 2021, and May 21, 2021. The workgroups are composed of clinicians with expertise directly relevant to the selected episode groups. Workgroups (of about 15-20 members) were finalized in June 2021, and they provided detailed input on the development of the selected episode groups during their first workgroup webinars from June 21 to June 24, 2021. 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

[1] For information on measure development in Waves 4, refer to the 2022 Episode-Based Cost Measures Field Testing Wave 4 Measure Development Process 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 MACRA Episode-Based Cost Measures: Wave 4 Measure Development Public Comment Summary Report document (https://www.cms.gov/files/document/wave-4-public-comment-summary.pdf).

testing. After the national field test from January 10, 2022, to March 25, 2022, Acumen convened the workgroups for a third meeting to continue measure specification and refinement discussions in April 2022. For Wave 4, all workgroup meetings were held virtually.

Heart Failure PFTR Webinar, April 14, 2022

This meeting summary document outlines the purpose, discussion, and recommendations from the Heart Failure PFTR Webinar. Section 1 provides an overview of the webinar goals and process. Section 2 summarizes the discussion and recommendations from the workgroup.

1. Overview

The goals of the Heart Failure PFTR Webinar on April 14, 2022, were the following:

(i) Discuss field testing feedback
(ii) Review empirical analyses
(iii) Confirm refinements to finalize the measure prior to submitting for potential consideration in MIPS

The meeting was held online via webinar and attended by 9 of the 20 workgroup members. The webinar was facilitated by an Acumen moderator, Rose Do. The chair of the workgroup is Paul Heidenreich, though he wasn't able to attend this webinar. Rosie Bartel and Mary Schramke attended the webinar as Person and Family Partners (PFPs) to discuss and address questions regarding the PFE 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]

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 webinar, workgroup members were provided with information and materials to inform their meeting discussions. After the webinar, workgroup members were sent a recording of the webinar and were polled on their preferences to ensure the measures are developed based on well-documented stakeholder input. Based on National Quality Forum practices, the threshold for support was greater than 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 sub-section summarizes the PFP findings discussed in the webinar (Section 2.1). The remaining sub-sections describe workgroup member discussions and recommendations on defining the episode group (Section 2.2), assigning services to the episode group (Section 2.3), and accounting for patient risk (Section

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

2.4), respectively. Section 2.5 includes information on additional considerations the workgroup discussed. Section 2.6 describes the next steps.

2.1 Person and Family Partner (PFP) Findings and Discussion

The attending PFPs presented findings from the field testing survey in which 3 PFE commenters provided input prior to the meeting. The comments provided feedback about the frequency of services provided in encounters with their heart failure (HF) care team, as well as indicators of quality.

PFE stakeholders reported encounters roughly every 3 months, mostly with cardiologists and electrophysiologists for pacemaker management. Encounter frequency was driven more by availability of an appointment and access to care (e.g., distance to travel) than severity of HF symptoms.

The other PFP shared the importance of telemedicine to patients and caregivers. While PFE commenters reported that the overall burden of care coordination fell to them, telemedicine greatly improved their ability to coordinate between primary care and specialists, keep their care team up-to-date on their HF status, and submit patient-reported outcomes via online platforms like EPIC. They expressed support for using such patient-reported outcomes in value-based purchasing programs to center the patient experience in the assessment of value.

Later in the discussion, one PFP also raised de-prescribing as an indicator of quality, which workgroup members agreed with. For aging patients with a long-term course of illness, reducing medications in certain cases may reflect the tradeoff between reduced HF symptoms and increased risk of fall, due to side effects such as dizziness, or other functional challenges. These indicators of quality are important to consider alongside a Heart Failure cost measure for a meaningful assessment of value.

2.2 Defining the Episode Group

Workgroup members discussed potential updates to the trigger codes (Section 2.2.1), patient-level exclusions (Section 2.2.2), and stratifying by ejection fraction (Section 2.2.3).

2.2.1 Potential Updates to Trigger Codes

The workgroup reviewed field testing feedback on limiting the list of cardiomyopathy diagnosis codes used on trigger claims. One member noted that the existing trigger list appropriately accounted for the coding specificity of cardiomyopathies. There was verbal consensus to keep the current trigger diagnoses without modifications.

2.2.2 Patient-Level Exclusions

The workgroup also discussed patient sub-populations that stakeholders suggested the Heart Failure measure exclude:

- Arrhythmogenic right ventricular cardiomyopathy (ARVC)
- Sarcoidosis
- End-stage renal disease (ESRD) and diastolic HF with hemodialysis

Commenters suggested excluding patients with HF with preserved ejection fraction (HFpEF) and ESRD. The reasoning was based on the fact that volume overload would sometimes be due to ESRD. Workgroup members also noted that these patients are primarily treated by nephrologists or endocrinologists, not practitioners managing HF (e.g., cardiologists).

Workgroup members noted that excluding certain diagnoses such as ARVC and sarcoid would be problematic because those may be embedded in the cardiomyopathy diagnosis codes (e.g., I42.8 Cardiomyopathy); therefore, excluding these codes may inadvertently lead to exclusion of other patients.

2.2.3 Stratifying by Ejection Fraction

In prior webinars, workgroup members have discussed the reasons to differentiate between HF with reduced ejection fraction (HFrEF) and HF with preserved ejection fraction (HFpEF), noting the challenges in identifying this in claims data. Given public comments related to this distinction, the workgroup revisited the issue during the webinar. Acumen updated the workgroup that there are efforts underway for validating claims-based algorithms against registry or electronic health record data, but there's currently no widely accepted algorithm for this. During the webinar, Acumen presented empirical data on challenges with identifying these patients. They noted that of the patients captured in the Heart Failure measure, approximately 28% have no diastolic/systolic diagnosis information in the 120-day lookback window prior to the episode, making it challenging to categorize patients into these sub-populations. Additionally, empirical results showed no difference in risk-adjusted episode cost for the subpopulations that could be created with existing claims-based information.

There was discussion about historical treatment of HF patients, and the origins of the systolic/diastolic distinction (e.g., quality metric purposes, different prognostics), as well as overlap and differences of treatment options in these 2 groups. For example, members challenged the notion that the patient cohort needs to be divided along ejection fraction at all, pointing out that other patient-level risk factors, such as kidney function, might just as well predict the beneficiary's response to treatment. Members noted that historically, ejection fraction was singled out as a key differentiator in clinical quality measures because of its relationship to appropriate use for certain medications; past CMS appropriateness measures for beta blockers and angiotensin-converting enzyme (ACE) inhibitor use were conditional on the patient's ejection fraction. However, evolving pharmacotherapy is moving towards similar treatments for both patient cohorts.

On the other hand, 2 members did note differences in evidence-based treatments between these cohorts that may be worth accounting for in the measure. Particularly, there may be significant differences in typical drug dosage between HFrEF and HFpEF patients. However, members agreed that coding is generally imprecise for these patient cohorts, and it would be difficult to update the cost measure's algorithm as clinical practice and coding informatics evolve. Another workgroup member discussed the differences in cardiac device treatments for each cohort.

Workgroup members noted these challenges and agreed to hold off on HFrEF/HFpEF distinctions at present. There was verbal consensus to revisit this issue once more reliable methods of differentiating patients could be implemented.

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

- Members agreed that it would be challenging to exclude certain diagnoses (e.g., ARVC), noting sarcoidosis would be problematic because those may be embedded in the cardiomyopathy diagnosis codes. The workgroup voted to keep the current trigger diagnoses without modifications.
- The workgroup voted to continue not differentiating between HFrEF and HFpEF patients, and reached verbal consensus during the webinar to revisit this issue once more reliable methods of differentiating patients could be implemented.

2.3 Assigning Services to the Episode Group

Acumen revisited 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. These assigned services should be inclusive enough to identify a measurable performance difference between clinicians but also not introduce excessive noise. The following paragraphs summarize discussions of the categories of assigned services.

Workgroup members raised a different way of thinking about service assignment and service exclusions, which had also been discussed in previous webinars. All episode-based cost measure development to date has built cost measures to calculate the clinically relevant cost of care. Prior workgroups have selected services that exemplify usual, expected care, unexpected events, complications, and other services within the influence of the attributed clinician. Some stakeholder comments from field testing suggested removing services that are expensive but highly effective, and may decrease mortality (i.e., "carving out" costs from the list of assigned services). Some examples of these types of interventions include implantable cardioverter-defibrillators and HF drugs. While members generally agreed that the ideal approach would be to include the costs of these interventions and pair the cost measure with quality measures on the patient outcomes, they also recognized that this doesn't reflect the availability of related quality measures in MIPS.

Relatedly, workgroup members also discussed public comments on excluding new technology services (e.g., cardiac contractility modulation, pulmonary artery pressure monitoring, etc.) and outpatient cardiac inotropes. Workgroup members noted that some new technologies haven't yet been firmly established. With regard to many services, Acumen also noted the challenge of excluding only some services that fall under Clinical Classifications Software (CCS) categories that are otherwise included in the measure.

Workgroup members discussed some therapies that were potential candidates for exclusion. They proposed a definition for these excluded services as "services that: (i) have high class of recommendation by guidelines, (ii) are well-established and associated with decreased mortality, and (iii) will not potentially result in stinting of care." The workgroup also discussed the current challenge of reliably determining features such as ejection fraction, QRS duration, and symptoms from claims data. The following therapy services were discussed: implantable cardioverter-defibrillator, cardiac resynchronization therapy, angiotensin receptor-neprilysin inhibitor (ARNI), and sodium-glucose cotransporter 2 inhibitor (SGLT2 inhibitor).

Additionally, during the 2022 field testing, stakeholders suggested removing costs related to respiratory failure admission as well as heart valve, extracorporeal membrane oxygenation (ECMO), tracheostomy, operating room heart procedures, and other cardiothoracic procedures from the measure. Workgroup members revisited prior workgroup votes in which these were previously voted to be included. Verbal consensus indicated that these services should remain as-is in the measure. Finally, some workgroup members agreed with stakeholder comments and advised that sacubitril/valsartan should be treated similarly to other HF drugs in the measure. During the webinar, there was verbal consensus to think of sacubitril/valsartan in the same light as SGLT2 inhibitors when thinking of available heart failure treatments.

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

- Members voted to keep the service assignment rules as-is, where the following services should continue to be assigned as previously voted by the workgroup:
    - Implantable cardioverter-defibrillator

    - Cardiac resynchronization therapy
    - Cardiac devices
    - Heart valve procedures such as Mitra-clip
    - ECMO, tracheostomy admissions
    - Inpatient admissions for operating room heart procedures, other cardiothoracic procedures, and respiratory failure
    - SLGT2 inhibitors
- Members voted to use the same service assignment rules for SGLT2 inhibitors as for sacubitril/valsartan (e.g., if SGLT2 is excluded as a "carve-out", these drugs would also be excluded. Conversely, if SGLT2 is included, these drugs would also be included).
- The workgroup voted to exclude medications for pulmonary hypertension from the Heart Failure cost measure.

2.4 Adjusting for Patient Risk

Members also engaged in a detailed discussion about how to account for patient cohort heterogeneity among various sub-populations within the Heart Failure measure. Sub-populations refer to patient cohorts as defined by their pre-existing conditions and characteristics. The workgroup discussed additional variables that were suggested for inclusion in the risk adjustment model, the draft specialty adjustment methodology, and aligning the measure with relevant quality measures.

Stakeholder feedback from field testing suggested accounting for the following patient characteristics:

- Chronic kidney disease (CKD), stage 3
- Obstructive sleep apnea
- Non-adherence to medication

Kidney function predicts response to treatment in HF patients, presenting different challenges to care from the rest of the population. During the webinar, Acumen noted that the Heart Failure measure currently risks adjusts for the following: (i) enrollment due to ESRD, (ii) dialysis status (hierarchical condition category [HCC] 134), (iii) CKD stage 4 (HCC 137), (iv) CKD stage 5 (HCC 136), and (v) acute renal failure (HCC 135). In addition, Acumen's testing shows that the measure currently accounts for cost differences in populations through risk adjustment. The workgroup members expressed some support for adding chronic kidney disease (stage 3) as a risk adjustor.

Members also supported including obstructive sleep apnea and medication non-adherence in the risk adjustment model, but they noted that the code Z91.1 (Patient Noncompliance With Medical Treatment and Regimen) may be unreliable due to its subjective nature and the potential that it may not be coded as consistently, especially if a patient is seeing multiple practitioners. Access to care, especially urban-rural differences, was also raised as an important predictor of cost.

Acumen shared the draft specialty adjustment methodology, which is also being considered for inclusion in other chronic condition cost measures. The workgroup expressed support for this adjustment, since different specialties typically have different patients with different case-mix and cost profiles for their care pathways. Providers in rural areas may also take on more responsibility than providers of similar specialties in urban areas because their patients don't have access to certain specialty care. Finally, members supported transparency from CMS in underlying statistics on specialty representation for high- and low-risk patients, along with

information about how this adjustment is calculated, so that HF clinicians can understand the source of their performance variation.

Key Takeaways from Discussion and/or Polls for Adjusting for Patient Risk:

- Members revisited the performance of ESRD and CKD risk adjustment variables. They ultimately voted not to include risk adjustment variables for chronic kidney disease stage 3 or non-adherence to medication.
- The workgroup voted to risk-adjust for obstructive sleep apnea (International Classification of Diseases, 10th Revision [ICD-10] code G47.3).
- Members expressed support for a specialty adjustment both during the webinar and in post-webinar poll comments.

2.5 Additional Considerations

There were additional considerations that the workgroup discussed during the webinar. Members touched on aligning the Heart Failure cost measure with quality measures, noting that, for example, past efforts by CMS to reduce hospitalizations may have had the unintended consequence of increasing patient mortality. Some indicators suggested were appropriate medication use, sufficient encounters in clinic with appropriate specialists, cardiac rehabilitation, and guideline-directed medical therapy.

Some members emphasized the importance of providing actionable information to providers so that they can use it to understand and improve their performance. One member specifically noted that clinicians are interested in learning more about the specialty adjustment and would benefit from understanding the methodology in more detail. Similarly, it would be beneficial for providers to engage with the risk adjustment methodology in more detail (e.g., better understand the parameters going into the risk adjustment model). Finally, clinicians are interested in understanding the attribution methodology, and it would be valuable for clinicians to receive information on how many new patients are being attributed to them in each performance year.

2.6 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 about potential refinements. The poll also included a section for other general comments. Acumen will operationalize input for the measure specifications based on PFTR Webinar Poll results.