Melanoma Resection Workgroup Service Assignment and Refinement (SAR) Meeting Summary

MACRA Episode-Based Cost Measures: Measure-Specific Workgroups Service Assignment and Refinement (SAR) Webinar, January 8, 2020

January 2020

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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 (MACRA) of 2015. Acumen's measure development approach involves convening clinician expert panels to provide input in cycles of development ("waves").[1] The 4 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. Following the workgroup in-person meetings, Acumen convened the workgroups again for a Service Assignment and Refinement (SAR) webinar to revisit the specifications recommended during the in-person meeting and refine the measures prior to national field testing.

[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.

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This meeting summary document outlines the purpose, discussion, and recommendations from the Melanoma Resection workgroup Service Assignment and Refinement (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 Melanoma Resection workgroup webinar on January 8, 2020, were to provide detailed recommendations on the following:

(i) Adjustments to designations for patient 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 field testing and future consideration)

(ii) Further input on 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 online via webinar, and attended by 6 of 13 workgroup members. The webinar was facilitated by an Acumen moderator, Suzann Pershing. The Melanoma Resection workgroup chair was Oliver Wisco, who also facilitated meeting discussions, and the Dermatologic Disease Management CS co-chairs were Howard Rogers and Aamir Siddiqui. 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 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 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 on 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 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.

[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. Summary of Sessions and Discussion

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

2.1 Addressing Patient Sub-Populations for Meaningful Clinical Comparison

Members held detailed discussions revisiting their initial recommendations from the August 2019 workgroup in-person meeting regarding how to account for various sub-populations within the Melanoma Resection 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 initial sub-populations (based on recommendations from the workgroup during the August 2019 workgroup in-person meeting), workgroup members discussed their preferences for how to refine given patient cohort sub-populations and confirmed their recommendations in the post-discussion SAR Webinar Poll.

2.1.1 Sub-Groups

The workgroup discussed whether the current Head/Neck and Trunk/Extremity/Unspecified sub-groups as voted on after the August 2019 in-person meeting were still sufficient. The workgroup generally agreed that these sub-groups were still sufficient, with one workgroup member adding that Head/Neck melanomas are clinically distinct from Trunk/Extremity melanomas in terms of treatment difficulty and clinical progression. The workgroup also entertained discussion on potentially sub-grouping by excision size as a proxy for severity alongside the current sub-groups, creating 4 total (crosses between locations and size). However, workgroup members agreed doing so could create unnecessary granularity and potential data validity issues (since flap trigger codes do not use the same size ranges as excision trigger codes), and that excision size could be addressed in other ways such as risk adjustment.

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

- Members agreed to retain the original sub-groups as voted on after the August 2019 in-person meeting, resulting in the following mutually exclusive and exhaustive sub-groups listed below:
  - Head/Neck
  - Trunk/Extremity/Unspecified

2.1.2 Risk Adjustors

The workgroup discussed the current set of risk adjustment variables, which were developed based on input from the August 2019 in-person meeting. The discussion focused on if the current risk adjustment variables should be kept, how the existing variables might be further refined, and what other factors should be accounted for in risk adjustment. The workgroup discussed whether lip, ear, eyelid, and nose melanomas should continue to be treated as distinct risk adjustment variables. Some workgroup members indicated that these could likely be combined into one risk adjustor. Additionally, eyelid melanoma, for example, was noted to be

substantially more common than other types of face melanoma and to have a lower mean risk-adjusted episode cost. The Acumen team noted that separately risk adjusting for these variables would enable the workgroup and the Acumen team to better discern how these variables are performing in risk adjustment, as grouping them together at this time would not allow further investigation of clinician performance among these 4 variables.

The workgroup also discussed how to handle episodes where the patient has undergone or undergoes chemotherapy, immunotherapy, or other systemic therapy. Workgroup members noted that these therapies suppress the patient's immune system and thus impair the patient's wound healing capabilities and that this impaired wound healing may lead to additional complications compared to patients that did not undergo any systemic therapy. Additionally, without an immunotherapy variable, the current mean risk-adjusted episode cost for episodes with immunotherapy preceding the episode was $7,999, compared to just $1,922 for all episodes, suggesting that the current risk adjustment model does not adequately adjust for these cases. Because of this, workgroup members agreed that episodes where the patient has undergone systemic chemotherapy and/or immunotherapy should be handled differently than the overall patient population and ultimately recommended adding these cases to the risk adjustment model. Additionally, the workgroup briefly discussed how Rural Health Center (RHC) status might be an important consideration in risk adjustment due to potentially different patient clinical characteristics present in RHCs. The Acumen team noted that RHC status can be identified in claims data but has not been used as a risk adjustment variable in past measures. Acumen added that it will conduct future testing on all cost measures for rural status as part of the investigation suite looking at social determinants of health with CMS after the initial development of the measure concludes. Acumen noted that workgroup members will have an opportunity in the poll distributed after the meeting to provide input on clinical factors that could be used as proxies for rural health status for potential risk adjustment.

Finally, Acumen provided a list of current monitor populations that might warrant further consideration for designation as risk adjustors, with the note that the workgroup will be able to provide additional input on those variables and the other risk adjustment topics in the poll to be distributed after the meeting.

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

- Members recommended adding the following as risk adjustment variables:
  - Systemic chemotherapy/immunotherapy
- Members recommended continuing to risk adjust separately for the following variables:
  - Lip Melanoma
  - Eyelid Melanoma
  - Ear Melanoma
  - Nose Melanoma

2.1.3 Exclusions

The workgroup considered excluding patients who have very different care needs from the overall patient cohort. The workgroup discussed exclusion criteria for episodes containing Mohs surgery and episodes where the patient has metastatic melanoma. The workgroup generally agreed that both of those items represent different disease states than what is within the intended scope of the Melanoma Resection episode group. Workgroup members noted that Mohs surgery procedures in the episode window should be handled according to the diagnosis code present on the claim. The workgroup seemed to indicate that Mohs surgery could qualify as a measure exclusion depending on the accompanying diagnosis code for the procedure. During the August 2019 in-person meeting, the workgroup indicated that Mohs surgery is not

typically used for the treatment of cutaneous melanoma solvable by resection, due to less well-established clinical guidelines compared to traditional resections. As such, the workgroup generally agreed on the following:

- Mohs surgery *without* a melanoma diagnosis code would likely not qualify as a measure exclusion, as Mohs surgery would not have been used in the treatment of the index melanoma
- Mohs surgery *with* a melanoma diagnosis code would likely qualify as a measure exclusion, as Mohs surgery is not part of the standard treatment protocol for cutaneous melanoma solvable by resection

The workgroup also discussed how episodes containing metastatic melanoma should be handled. The workgroup agreed that metastatic melanoma likely represents a more advanced disease process than melanomas curable by resection. The workgroup suggested that the episodes themselves could still be included for 2 reasons. First, excluding all episodes with metastatic disease (identified by the presence of various systemic therapies, including chemotherapy and immunotherapy) would further reduce the overall episode population. Second, patients may end up receiving systemic therapy after the index resection, so the intended disease treatment arc would still be captured. The Acumen team added that workgroup members would be able to provide additional input on both of these sub-populations in the SAR Webinar Poll to be distributed after the conclusion of the webinar.

Key Takeaways from Discussion and/or Polls for Exclusions:

- Members recommended excluding the following sub-populations:
  - Mohs surgery with a Melanoma Diagnosis

2.1.4 Monitor for Field Testing

The final discussion related to sub-populations of the patient cohort involved discussing what other sub-populations may be worth tracking ahead of the spring field testing period in April and May 2020. The workgroup discussed how the presence of imaging procedures (e.g., positron emission tomography [PET] scan, lymph node ultrasound, computed tomography [CT] chest/abdomen/pelvis with and without contrast), and brain magnetic resonance imaging [MRI]) during the episode window may indicate a more advanced disease state, as these procedures primarily serve to check for the presence of advanced disease (i.e., melanomas that are not curable by resection alone).

Additionally, the workgroup briefly discussed how services provided during a post-trigger hospitalization might be related to the melanoma excision. One workgroup member noted that the vast majority of hospitalizations are likely unrelated to the melanoma surgery, even for admissions due to some infections. Given that an infection-related hospitalization might not be directly caused by the melanoma resection, the workgroup discussed how the timing of the hospitalization may indicate relation to the excision procedure.

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

- Members voted to add the following sub-population as a variable to monitor for future testing and consideration:
  - Presence of imaging procedures
- Based on the workgroup's recommendations, the following sub-populations will remain as a monitor:
  - Metastatic Melanoma
  - Metastatic Melanoma – Chronic Lymphocytic Leukemia

- Research Protocol
- Melanoma of Lower Limb, Including Hip
- >4cm excision of Scalp, Neck, Hands, Feet, or Genitals
- Melanoma of Scalp or Neck
- >30cm Reconstruction
- >3cm Excision on Face
- >4cm Excision on Trunk or Limbs
- Melanoma In Situ (MIS) of Scalp, Neck, Hands, Feet, or Genitals

2.2 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 (set at 30 days pre-trigger and 90 days post-trigger for the Melanoma Resection measure) to facilitate this session's discussion.

The Acumen team revisited the categories of assigned services recommended *not* to be assigned per the workgroup's recommendations after the August 2019 in-person meeting, specifically services related to pathology, systemic cancer treatment, anesthesia/pain, aftercare, and anemia.

Previously Discussed Categories of Services Related to Pathology, Cancer, Anesthesia/Pain, Aftercare, and Anemia

During the webinar, workgroup members in attendance generally agreed that pathology services are not always under the influence of the attributed clinician, citing that different clinicians may not be able to influence the type of pathology report ordered/performed by the pathologist. Workgroup members added that clinicians may only have access to certain pathologists, suggesting this limits their influence as to what reports are ordered. The workgroup also reached general consensus during the discussion to not include the costs of services related to cancer treatment (e.g., related to metastatic melanoma), indicating that cancer services in the episode window suggests a non-localized disease process that is outside of the definition of the Melanoma Resection episode group.

Workgroup members briefly discussed not assigning services related to anesthesia/pain. Members in attendance expressed that the availability or use of services related to anesthesia/pain depend on patient characteristics and/or any facility-specific rules, such as always using full anesthesia, feeling that these are not necessarily under the influence of the attributed clinician. Considering aftercare services, the workgroup generally concurred that these should likely continue to not be assigned as services, suggesting that it would be difficult to discern in claims data what services are related to the melanoma versus prior patient characteristics or the surgeon. Lastly, the workgroup touched on anemia services. Workgroup members stated that anemia-related costs are likely not associated with actual resection procedure and thus likely not under the influence of the attributed clinician.

Post-Operation Care Products

Workgroup members discussed how certain post-operation ("post-op") products could be captured as assigned services due to their likely relation to the treatment of melanoma. Workgroup members added that skin substitutes, wound matrices, and pig skin grafts used in repairing skin after resection could reasonably be assigned in the 0 to 90-day post-trigger

window. Workgroup members noted a few considerations regarding the usage of post-operation care services:

- Skin substitutes may be applied as frequently as weekly until the excision wound has healed, with no formal guidelines regarding their usage
- Patients with compromised wound healing due to the presence of systemic chemotherapy may require additional services compared to those not receiving systemic chemotherapy

Workgroup members also discussed other post-op services for consideration to be assigned in the post-trigger period, including negative pressure wound therapy, hyperbaric oxygen, and tissue expander codes.

The Acumen team indicated that service assignment-related input for post-op services (including skin substitutes, negative pressure wound therapy, hyperbaric oxygen, and tissue expander codes) would be included in the poll to be distributed after the meeting.

Imaging Services
The workgroup noted the complexity in how/when imaging services during the episode window should be assigned. One workgroup member offered that imaging after a biopsy may not be appropriate, noting that the biopsy would more likely be used to confirm the presence of a disease relative to imaging. Another member added that all imaging prior to an excision should be excluded, but cited that imaging after an excision could be included because it's likely related to the complete treatment arc of the melanoma, which aligns with the workgroup input provided after the August 2019 in-person meeting. The workgroup talked about excluding all services after a sentinel lymph node (SLN) biopsy, noting that this test tends to be the first step in identifying and treating metastatic/systemic disease, which is outside of the scope of the measure; however, the Acumen team explained that this selective criteria for service assignment of not assigning services after the presence of another service is not currently possible under the measure framework. Acumen stated that the post-meeting poll would include opportunities for workgroup input related to assigning services used in treating metastatic/systemic disease.

Chemotherapy/Immunotherapy/Systemic Therapy Services
The workgroup generally agreed that chemotherapy/immunotherapy/systemic therapy services are not relevant to the treatment of cutaneous melanoma and should not be included as assigned services. Workgroup members noted that these services are typically handled by oncologists and not by dermatologists or plastic/reconstructive surgeons and suggested that parsing for metastatic melanoma (treated by these kinds of services) is challenging in claims data due to the lack of an ICD-10 diagnosis code for metastatic melanoma.

Mohs Surgery
Workgroup members generally agreed that costs related to Mohs surgery should not be included as assigned services because Mohs surgery is not typically used in the treatment of melanoma. Acumen indicated that additional questions related to if/how Mohs surgery should be assigned would be included in the poll distributed after the meeting.

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

- Workgroup members recommended not assigning the following services:
  - Mohs surgery
  - Systemic chemotherapy/immunotherapy

- Workgroup members recommended assigning the following categories of services:
  - Services related to post-resection treatment in 90-day post-trigger window
- Workgroup members recommended to continue to not assign the following categories of services:
  - Anesthesia/Pain
  - Pathology
  - Cancer
  - Aftercare
  - Anemia

2.3 Next Steps

In the final session, Acumen provided an overview of the next steps in the measure development process. After the meeting, Acumen distributed the *SAR Webinar Poll* to gather input from members on the discussions held during the webinar. The survey also consisted of open comment boxes to provide additional thoughts on how to build opportunities for measure performance improvement into the measure specifications and to share any additional thoughts on the measure.

Acumen will gather and review the input provided during the SAR webinar discussions and poll to create updated measure specifications. These specifications will be posted publicly as a part of upcoming national field testing. During the field testing period, Field Test Reports for the Wave 3 measures under development will be available to clinicians and will contain information showing how clinicians would perform for the measures, based on the measure specifications at that time. There will also be an opportunity for all stakeholders to provide detailed feedback about the measures during field testing.

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 SAR webinar, and Section 3.3 provides a recap of the main concepts of the measure development process and measure framework presented by Acumen.

3.2 Overview of Meeting Materials

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

- *Agenda* and *Slide Deck*, which included a list of discussion questions to be considered prior to meeting and discussed during the webinar
- Investigation workbooks presenting detailed findings from empirical analyses:
  - A re-run of *Sub-Population Summary Investigation Workbook,* which provided updated data on the frequency and cost associated with an initial set of potential sub-populations as recommended by the workgroup during the August 2019 in-person meeting
  - A re-run of *Candidate Services Over Time Investigation Workbook,* which contained updated 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 and included the share of episodes where the service was assigned based on the service assignment rules

The materials shared were based on analyses run on triggering methodologies with trigger codes and specifications developed based on input from the August 2019 workgroup in-person meetings.

3.3 Overview of Cost Measure Development and Framework

At the beginning of the meeting, Acumen presented a very brief introductory session as a refresher on the following framework topics:

- The 5 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 in distinguishing good from poor performance
- A recap on the different sources of information for the workgroup to consider in addition to their clinical expertise, including analyses and data as well as the perspectives of patients and caregivers through Person and Family Engagement (PFE)