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April 16, 2012

Maria Ellis
Executive Secretary for MEDCAC
Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality
Coverage and Analysis Group
S3-02-01
7500 Security Boulevard
Baltimore, MD 21244

**RE: Medicare Evidence Development & Coverage Advisory Committee Meeting:
Evidentiary Characteristics for Coverage with Evidence Development (CED)**

Dear Ms. Ellis:

The Medical Imaging and Technology Alliance (MITA) appreciates this opportunity to provide a statement for the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) meeting on Evidentiary Characteristics for Coverage with Evidence Development (CED), to be held on May 16, 2012. As the leading trade association representing medical imaging, radiotherapy technology, and radiopharmaceutical manufacturers, we have an in-depth understanding of the significant benefits to the health of Medicare beneficiaries that medical imaging, radiotherapy and proton therapy provide. MITA is pleased to work with the Centers for Medicare & Medicaid Services (CMS) to ensure appropriate use of and access to these life-saving technologies.

Medical imaging encompasses X-ray imaging, computed tomography (CT), radiation therapy, related image acquisitions, diagnostic ultrasound, nuclear medicine (including positron emission tomography (PET and PET/CT)), and magnetic resonance imaging (MRI). Medical imaging is used to diagnose patients with disease, often reducing the need for costly medical services and invasive surgical procedures.¹ In addition, medical imaging is often used to select, guide and facilitate effective treatment, for example, by using image guidance for surgical or radiotherapeutic interventions.²

¹ See, e.g., "Multidetector-Row Computed Tomography in Suspected Pulmonary Embolism," Perrier, et. al., *New England Journal of Medicine*, Vol 352, No 17; pp1760-1768, April 28, 2005.

² See, e.g., Jelinek, JS et al. "Diagnosis of Primary Bone Tumors with Image-Guided Percutaneous Biopsy: Experience with 110 Tumors." *Radiology*. 223 (2002): 731 - 737.

MITA's members also develop and manufacture innovative radiotherapy equipment used in cancer treatment as well as radiopharmaceuticals.

Question 1: Are there significant, practical differences between binary and non-binary coverage paradigms?

If the answer favors “Yes” please discuss the advantages and disadvantages of non-binary paradigms.

Yes, there are significant, practical differences between binary and non-binary coverage paradigms. MITA is concerned that non-binary coverage paradigms, such as coverage with evidence development (CED), can be burdensome and inconclusive, whereas a binary paradigm is more likely to produce predictable and clear coverage decisions. Non-binary coverage paradigms involve greater uncertainty not only about the ultimate coverage decision, but also about the types of studies that will be used to collect data, the endpoints that will need to be achieved, and the timeframes for completing data collection and for reconsidering the coverage decision.

To minimize the burdens associated with non-binary coverage paradigms, CMS should ensure that studies conducted under these paradigms employ well-defined, relevant, and pragmatic endpoints. These studies should be limited to what is necessary and sufficient to inform a decision for coverage. The data collection must be achievable within a reasonable, pre-defined timeframe and must not pursue secondary or ancillary endpoints of interest that are unnecessarily burdensome. In addition to CMS and the Agency for Healthcare Research and Quality (AHRQ), stakeholders from academia, professional societies, and industry should be included in an efficient process of evaluating the evidence available prior to initiating any additional data collection exercise. These stakeholders should also be involved in agreeing on the final design and infrastructure for an evidence-development program for the item or service under consideration.

Consistent with CMS's 2006 guidance on CED, non-binary coverage paradigms should be used rarely, and not when other forms of coverage (i.e., binary coverage paradigms) are justified by the available evidence.³ In particular, MITA believes that the labeled indications of Food and Drug Administration (FDA)-approved technologies should be covered under binary coverage determinations.

Question 2: Can an evidentiary threshold be defined to invoke CED?

If the answer favors “Yes” please discuss how this threshold should be identified.

If the answer favors “No” please discuss the impediments and recommend strategies to overcome them.

MITA believes that an evidentiary threshold can and should be defined prior to invoking CED, but we believe that the threshold may differ depending on the type of

³ Guidance for the Public, Industry, and CMS Staff: National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development, July 12, 2006, http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8 (hereinafter “CED Guidance Document”).

technology and indications under review. As we explain in our response to question 3, several factors affect the evidentiary threshold for invoking CED. Because there is potential for significant variations in the threshold, it is critical that that CMS work with stakeholders to define these thresholds for each potential application of CED. By working with knowledgeable stakeholders, such as researchers, manufacturers, members of relevant specialty societies, and providers, CMS can efficiently conduct a thorough review of the available clinical evidence to define a threshold for invoking CED for a technology, determining whether that threshold has been achieved, and achieving consensus on whether to apply CED to the technology prior to issuing a proposed coverage determination. Through this cooperation, CMS may be able to streamline the NCD process for all parties.

CMS also should continue to work with stakeholders to develop clear guidance that will explain the general criteria for determining whether there is enough evidence for CED, but not enough for a binary coverage determination. In the past, discussions of CED have used terms such as “suggestive” to describe the clinical evidence that could support use of CED but otherwise would be insufficient for a positive coverage determination. The lack of a clear definition of this term has hindered stakeholders’ ability to understand when an item or service might be a candidate for CED, rather than non-coverage or coverage without evidence development. Thus, CMS’s guidance should explain the applicable terms to improve the predictability and transparency of future coverage determinations and to continue to encourage innovation.

Question 3: How would an evidentiary threshold to invoke CED be influenced by the following?

- a. whether the item or service is a diagnostic v. a therapeutic technology;**
- b. the severity of the disease;**
- c. the safety profile of the technology;**
- d. the availability of acceptable alternatives for the same disease/condition;**
- e. other factor(s);**
- f. a combination or tradeoff involving two or more of the above**

MITA believes that each of these factors can influence the evidentiary threshold to invoke CED. First, as we have explained in prior statements to CMS, we believe that diagnostics are different. Diagnostic technologies are subject to different standards for approval than therapeutic technologies and also should be subject to different evidentiary thresholds for coverage. CMS has correctly recognized this in past in the PET/CT CED national coverage determination (NCD) by considering evidence on how PET/CT affects physicians’ treatment decisions, not how it affects patients’ therapeutic outcomes. When considering the evidentiary threshold to invoke CED, CMS should continue to apply appropriate criteria to evaluate studies of diagnostics. As in the PET/CT CED NCD, CMS should measure diagnostics against their intended use, i.e., to achieve diagnostic outcomes such as diagnosing a condition, measuring disease progression, or helping to determine a treatment plan, instead of therapeutic outcomes.

Second, we believe that CMS needs to be pragmatic when establishing an evidentiary threshold for invoking CED for each technology. Each of the factors CMS identified can influence the evidentiary threshold for CED and can affect the ability of CED to produce useful data. The risks and benefits of the technology, as well as the burden of gathering additional data through CED, need to be considered in light of the severity of the disease, the safety profile of the technology, and the availability of acceptable alternatives for the same disease or condition. As a starting point for evaluating the risks and benefits of a technology, any FDA-approved product should be considered by CMS to be safe and effective for its approved indications. For uses beyond those approved by the FDA, CMS should consider how these factors affect evidence development for that use. CMS should also bear in mind that clinical studies and registries can be difficult to conduct for technologies used for patients with rare diseases or severe illnesses with multiple complications and comorbidities. While patients should be encouraged to participate in clinical research, their access to care should not be dependent on participation in a study.

CMS also should be sensitive to the fact that the “acceptable alternatives” may be different for each patient, as judged by the patient and his or her physician. CMS should support beneficiaries’ access to appropriate diagnostic and treatment options by providing coverage for a range of technologies and allowing physicians and patients to select the best option for each patient.

Question 4: How would an evidentiary threshold to invoke CED be influenced if the outstanding questions focused only on the generalizability of a strong but narrow evidence base to:

- i. additional settings;**
- ii. additional practitioners;**
- iii. broader clinical indications for related or unrelated diseases?**

As noted above, MITA believes that the labeled indications of Food and Drug Administration (FDA)-approved technologies should not be subject to CED. At times, CED might be appropriate for additional indications, after considering the factors identified in question 3.

Question 5: Can an evidentiary threshold be defined to trigger an evidentiary review to determine if CED should cease, continue or be modified?

If the answer favors “Yes” please discuss how this threshold should be identified.

If the answer favors “No” please discuss the impediments and recommend strategies to overcome them.

Please discuss whether the factors identified in Questions 3 and 4 are relevant to Question 5.

MITA believes that an evidentiary threshold that triggers review to determine if CED should cease, continue, or be modified should be defined at the time the CED decision is announced. Such a threshold should be established based on agreement from the technology’s sponsor, CMS, and any relevant and mutually agreeable professional

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societies based on the need for CED and the research protocols to be applied under CED. As discussed in our responses above, this threshold likely will vary from technology to technology, and input from stakeholders is critical to establishing an appropriate threshold, as well as to identifying the endpoints to be achieved.

Conclusion

MITA appreciates this opportunity to present our views on CED to the MEDCAC. We are hopeful that we can continue to work with CMS to ensure that the agency has access to the clinical evidence necessary to make informed decisions, enable access to new products and services with reasonable boundaries, and encourage innovation in imaging technologies. We thank CMS for its interest in improving this process and for the opportunity to submit these comments. If you have any questions or would like to discuss these matters further, please contact me at 703-841-3235. Thank you for consideration of these comments.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gail M. Rodriguez". The signature is written in a cursive, flowing style.

Gail M. Rodriguez, Ph.D.

Executive Director, Medical Imaging & Technology Alliance