

April 16, 2012

Via Electronic Submission

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:

On behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device market, I am submitting the following comments to the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) for its May 16, 2012 meeting on Coverage with Evidence Development (CED). MDMA represents hundreds of medical device companies, and our mission is to ensure that patients have access to the latest advancements in medical technology, most of which are developed by small, research-driven medical device companies.

We appreciate this opportunity to respond to the questions presented to the panel for the May 16, 2012 meeting on CED. Medical devices are a critically important part of the health care system and MDMA's members devote considerable resources and effort to improving and expanding the clinical evidence to help Medicare beneficiaries and providers make the most appropriate diagnostic and therapeutic decisions. MDMA therefore supports the Centers for Medicare & Medicaid Services' (CMS's) efforts to improve the CED process to reduce barriers to innovation and improve health outcomes for Medicare beneficiaries. Our primary concern is that such

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efforts do not inadvertently limit patient access to advanced medical technologies. With this concern in mind, MDMA provides the following responses to the questions to the panel.

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.

Definitions:

Binary Coverage Paradigm:

“Yes or No” final coverage decision without planned reconsideration of prespecified clinical outcomes.

Non-Binary Coverage Paradigm*:

Qualified coverage decision that may evolve as evidence base changes over time, with planned reconsideration based on the achievement of prespecified clinical outcomes.

***CED is an example of a non-binary coverage paradigm.**

MDMA’s Response:

Yes, MDMA believes there are significant, practical differences between binary and non-binary coverage paradigms. Non-binary coverage paradigms expose technologies to greater uncertainty about future coverage decisions than binary coverage paradigms. Unlike binary coverage paradigms, in which the coverage decisions are final, non-binary coverage paradigms apply only until the planned reconsideration occurs and therefore raise questions about how and when the evidence base will be reconsidered and how that reconsideration will affect coverage. Non-binary coverage paradigms require careful analysis by CMS, in conjunction with extensive discussions with stakeholders, not only to evaluate the evidence available prior to the decision but also to identify the clinical outcomes to be measured, establish an appropriate method of collecting data, collect and analyze the data, and determine if the outcomes have been achieved. If this approach is implemented appropriately, it can reduce barriers to innovative devices and

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improve the evidence base for treatment and diagnostic decisions. If such an approach is not implemented appropriately, transparently, and predictably, however, it can result in limited access to treatment options and can discourage future innovation.

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.

MDMA’s Response:

Yes, an evidentiary threshold should be identified to invoke CED for a particular item or service, but this task likely will be difficult to accomplish due to the variations in the items and services eligible for Medicare coverage. The threshold will depend on the nature of the item or service and the factors identified in questions 3 and 4, as well as the opportunities to develop evidence with and without CED. The evidentiary threshold for each application of CED must be identified through extensive input from stakeholders, such as physicians, researchers, and manufacturers who are deeply familiar with the technology, the existing evidence, and the opportunities and challenges associated with collecting additional data. The manufacturers’ input, in particular, is essential to CMS’s ability to understand the evidence supporting a technology, any gaps in that evidence, and any additional research efforts underway to address those gaps. Only with appropriate input from the manufacturer and other stakeholders can CMS identify an appropriate evidentiary threshold for invoking CED for any item or service.

In addition to defining a threshold for each specific application of CED, CMS should continue to work with stakeholders to define these thresholds in general terms in a guidance document that will help improve the predictability and transparency of CMS’s coverage decisions. CMS also should seek comments on any changes to the thresholds defined in the guidance as it gains more experience with CED.

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The thresholds for invoking CED should be established at levels that ensure that CED continues to be used infrequently and not when other forms of coverage are justified by the available evidence, consistent with the principles established in CMS's 2006 guidance document on CED. MDMA is confident that the appropriate use of CED can improve health outcomes for Medicare beneficiaries, but we also recognize that CED involves considerable investment of time and resources by CMS and stakeholders, therefore it should be applied only when necessary.

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); or**
- f. a combination or tradeoff involving two or more of the above**

MDMA's Response:

All of these factors, alone or in combination, can influence the evidentiary threshold to invoke CED for an item or service. For example, diagnostic technologies should be subject to different evidentiary thresholds than therapeutic technologies because they are used to achieve different ends. The severity of disease and the availability of acceptable alternatives also can have a significant effect on the ability to conduct research on an item or service. It can be difficult to study interventions for patients with more severe illness or who have few options for treatment. The safety profile also can be a significant factor in establishing an evidentiary threshold for CED because technologies come to market with different amounts of information available about their safety. Moreover, as patients and physicians consider their diagnostic and therapeutic options, they often must weigh each of these factors to decide on the best course of action for the patient. Patients and physicians who are seeking treatments for rare or serious diseases may be willing to tolerate a riskier safety profile in order to use the few treatment options available.

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CMS should account for all of these factors and the interactions among them when establishing evidentiary thresholds for invoking CED.

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[#]?**

[#]An example of a related condition might include a different stage of the same cancer. An example of an unrelated condition might include the use of a cancer drug for a rheumatologic disease.

MDMA's Response:

MDMA believes that all of these factors can influence the evidentiary threshold for invoking CED. The effects of these factors on an evidentiary threshold to invoke CED will depend on the technology, as well as 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.

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MDMA's Response:

Yes, an evidentiary threshold for future reconsideration of the coverage policy should be defined at the time of each CED decision. All CED decisions should employ clearly defined, meaningful endpoints that can be achieved through appropriate research methods with minimal burdens for all stakeholders. This is essential to establishing clear, predictable coverage policies that support access to appropriate care and encourage innovation.

The evidentiary threshold to trigger review must be defined through consultation with stakeholders. Because the evidentiary threshold will depend on the type of technology at issue, as well as on the factors identified in questions 3 and 4, stakeholder input, including from the manufacturer, is essential to understanding all of the factors that affect the evidentiary threshold for an item or service, and to overcoming any impediments to defining and achieving the threshold.

Conclusion

In conclusion, MDMA appreciates this opportunity to present our views to the MEDCAC on CED. We support CMS's efforts to revise its CED process to reduce barriers to innovation and improve health outcomes for Medicare beneficiaries. We look forward to working with CMS in the future on this important issue.

Sincerely,



Thomas C. Novelli
Vice President of Government Relations
Medical Device Manufacturers Association