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April 16, 2012

Via Electronic Mail and Express Mail

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

**RE: May 16, 2012 MEDCAC Meeting on Evidentiary Characteristics for  
Coverage with Evidence Development (CED)**

Dear Dr. Jacques:

The Advanced Medical Technology Association (“AdvaMed”) appreciates this opportunity to provide the following comments to the Centers for Medicare & Medicaid Services (“CMS”) in connection with the upcoming meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) on May 16, 2012.<sup>1</sup>

AdvaMed’s member companies produce the life-saving and life-enhancing medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. Our member companies are affected by CMS’ process for deciding whether an item or service meets the evidentiary standard to be found “reasonable and necessary” under the Medicare statute,<sup>2</sup> and thus covered as a Medicare benefit.

We understand CMS is in the process of revising the current Medicare guidance document on coverage with evidence development (CED), and that one of the primary purposes of the MEDCAC meeting on evidentiary characteristics is to inform the process for making those

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<sup>1</sup> Centers for Medicare & Medicaid Services: *Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee—May 16, 2012*, 77 Fed Reg 15372 (March 15, 2012).

<sup>2</sup> Social Security Act § 1862(a)(1)(A).

revisions. As you know, we responded to CMS' public solicitation on CED earlier this year, and we look forward to an ongoing discussion with the Agency regarding this important document.

Our industry has long supported the use of sound evidence to inform medical practice. When CMS decides that it will require CED in order to allow certain Medicare beneficiaries access to a medical technology, it adds additional requirements for manufacturers and providers and delays access for other Medicare beneficiaries. It appears that CMS is seeking, through this MEDCAC meeting, to identify criteria for identifying when the available evidence for products is sufficient, and when it suggests that coverage conditioned upon additional evidence development is warranted.

The questions being addressed at this MEDCAC forum, and discussed in more detail below, refer to an "evidentiary threshold" for CED. It is not clear whether CMS is seeking to identify an evidence level or grade below which an item or service would not be considered to be "reasonable and necessary," and at which CMS would presumably invoke CED, or whether this threshold refers to the evidence level or grade that CED studies must meet. Nevertheless, charging the MEDCAC to address the matter of an evidence threshold suggests that CMS believes identifying such an outcome is possible.

We do not believe that it is feasible to define with any precision such an evidentiary threshold for medical procedures or services. We believe that such a threshold, if it could be identified, would vary widely depending upon the item or service being evaluated and the clinical needs of individual patients.

The following concerns are addressed in more specificity in our letter:

1. Rather than attempt to define an evidentiary threshold for CED, CMS should engage in meaningful dialogue with developers and manufacturers, prior to the initiation of an NCD or a decision regarding CED, to determine whether and if additional data collection is needed, and if so, to discuss the type of evidence and method of data collection that would be necessary to reach a coverage determination about a new or innovative treatment. CMS would benefit from drawing on the experience and expertise of the clinicians, scientists, engineers and other experts working with, or employed by, medical device companies regarding evidence generation. This would allow both CMS and the manufacturer to determine the best pathway to timely coverage for Medicare beneficiaries. Manufacturers' input throughout the process is important to the ultimate coverage determination, particularly given these experts' unique knowledge about the existing data and ongoing studies.
2. CMS should use CED infrequently and only when the Agency is expanding coverage for new or innovative technologies. The CMS guidance on CED, issued in 2006, included eight "principles" to govern the use of coverage with evidence development. AdvaMed continues to agree with those principles, particularly as they relate to these concepts.

3. Recent national coverage activity suggests that the Agency is increasingly conditioning coverage on evidence generation through the use of CED when it concludes that the available evidence is insufficient to support a finding that an item or service is reasonable and necessary. We recognize that the Medicare statute bars CMS from paying for items which are not “reasonable and necessary (...for the diagnosis or treatment of illness or injury...).”<sup>3</sup> Although CMS has not defined what is or what is not “reasonable and necessary,” it appears that CMS is raising the “evidence bar” compared to previous national coverage determinations with respect to the data it requires to determine that an item or service is reasonable and necessary for coverage purposes. This higher evidence bar, combined with more internally initiated national coverage analyses, has led to national coverage determinations that call for CED in more and more circumstances.
4. In recent NCD proposals, CMS has mandated the type and design of clinical studies that it will accept under CED. We believe that CED should be the exception, not the norm, in national coverage decision-making. In cases where CMS and stakeholders agree that CED is the best option for coverage, CMS should seriously consider study designs proposed by stakeholders, and should not arbitrarily rule out particular study methods that could generate sufficient evidence to address specific clinical questions about the item or service being evaluated.
5. We do not believe it is feasible to identify or define a specific evidentiary threshold for invoking CED, or for the CED study itself. Every medical intervention will have different factors that must be considered with respect to evidence, and we do not believe that it is possible to determine a “one-size-fits-all” evidentiary threshold. In fact, Section 1862(l) of the Social Security Act, added by the Medicare Modernization Act of 2003, envisions Medicare coverage guidance documents that are “similar to the development of guidance documents under section 701(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)),” a reference to the FDA guidance documents which vary by type of product. The CMS chief medical officer when the MMA was being implemented publicly stated that product-specific guidance documents needed to be developed by the Agency to guide the consideration of new technologies in the national coverage process. The question of whether the evidence is sufficient to support a conclusion that an item or service is reasonable and necessary for coverage purposes, or whether a coverage determination requires additional evidence generation must be evaluated on an individual basis. We do not believe that there is a formula or an algorithm that can standardize this process.
6. Finally, when CED is initiated, we continue to have concerns regarding the data collection requirements that CMS puts into place, as well as the way a CED study is carried out. When Medicare coverage is contingent on the collection of additional clinical or scientific evidence beyond FDA’s determination of safety and efficacy, CMS should: (a) collaborate with stakeholders to clearly identify the questions that data collection efforts should address, (b) be sensitive to the costs and the challenges

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<sup>3</sup> Id.

associated with data collection and refrain from requiring more than the data is necessary to answer the questions that are posed, and (c) work closely with stakeholders to clearly identify scientifically supported study endpoints and the duration of data collection in advance.

## **1. Drawing on Available Expertise and Experience**

We do not believe it is feasible to identify an evidentiary threshold for treatments or services under consideration for Medicare coverage that would trigger a requirement for additional evidence development. The evidentiary criteria would by necessity vary across the wide spectrum of items or services being evaluated as well as the clinical needs of individual patients. Therefore, rather than attempt to identify an evidentiary threshold for CED, CMS should instead draw on the experience and expertise of available clinicians, scientists, engineers and other experts working with, or employed by, the medical device companies that are developing new and innovative technologies and treatments regarding evidence generation. This type of meaningful dialogue, prior to the initiation of a national coverage determination, would permit CMS and the manufacturer to work together in a collaborative manner to determine the best pathway to timely coverage for Medicare beneficiaries.

As noted above, the clinical and scientific experts within these companies have substantial and unique knowledge about the existing data and ongoing studies related to the products and treatments they develop. Thus, manufacturers' input at various stages of the coverage process can provide valuable information to CMS to inform the process, and to ultimately result in better coverage determinations, and allow beneficiaries to access new technologies and treatments.

## **2. Principles Governing the Application of CED**

When CMS issued its CED guidance in 2006 after considerable public input, the guidance document included eight principles to govern the application of CED. Those principles were:

1. NCDs requiring CED will occur within the NCD processes, which is transparent and open to public comment.
2. CED will not be used when other forms of coverage are justified by the available evidence.
3. CMS will in general expand access to technologies and treatments for Medicare beneficiaries.
4. CMS expects to use CED infrequently.
5. CED will lead to the production of evidence complementary to existing medical evidence.
6. CED will not duplicate or replace the FDA's authority in assuring the safety, efficacy, and security of drugs, biological products and devices.
7. CED will not assume the NIH's role in fostering, managing, or prioritizing clinical trials.
8. Any application of CED will be consistent with federal laws, regulations and patent protections.

In 2006, AdvaMed commented on the final guidance document—and agreed with these principles. We still agree with these eight principles. These principles are patient-focused, and they recognize that the evidence required to make a coverage determination must be sufficient, but it need not be perfect.

### **3. Raising the Evidence Bar**

With several recent proposed national coverage determinations, we have noted a trend where CMS is requiring increasingly higher levels of evidence for coverage, thus raising the coverage hurdle that therapies must clear in order to obtain Medicare coverage for new products. The medical device industry in particular presents special evidence challenges associated with conducting randomized controlled trials and the need to train operators to use new technologies. When the alternative to coverage with evidence development may be a national non-coverage determination, innovators are placed in a difficult situation, as the potential for non-coverage can significantly deter innovation.

A decision by Medicare to cover an item or service involves judgment that its benefits outweigh its risks. Determining this is often no easy matter, and it involves scientific judgments regarding the sufficiency of the available evidence and its generalizability to the Medicare population in routine clinical practice, along with legal and ethical considerations. We do not believe it is realistic to expect that the available evidence for a medical intervention will be conclusive in every respect, nor do we believe that it is necessary or practical to require additional data collection as an element of every coverage decision.

We continue to believe CED should be reserved for situations where the generation of additional information to address a specific clinical question regarding a promising new technology would better inform patients, providers, and policy makers on the benefits of the intervention. However, if the evidence is lacking, or if significant improvement in outcomes is still needed, or if capturing data on suitable interim markers would resolve some uncertainty, then CED may provide an important pathway to coverage. CED should not be imposed when the available evidence is sufficient to determine an item or service is “reasonable and necessary” for Medicare coverage.

### **4. Specifying Clinical Study Methodologies**

In several recent national coverage determination proposals that invoked CED, CMS has not only limited coverage in a very strict manner, but also has prescribed the manner in which clinical studies should be designed, for example, by requiring prospective, randomized, controlled clinical trials, or requiring a “superiority” study design as opposed to a “non-inferiority” design, thus precluding coverage for items and services in the context of valid studies already underway.

We are concerned that CMS is inappropriately discounting other valid methodological approaches that can generate sufficient evidence to address CMS’ questions with respect to the item or service being evaluated. We do not believe that CMS should arbitrarily disallow the use

of any particular research approach or methodology, but rather should consider specific methodologies and approaches proposed by stakeholders that can generate valid data bearing on the issue at hand.

## **5. Evidentiary Threshold**

MEDCAC will consider several questions that seek to identify or define an “evidentiary threshold” for coverage with evidence development (CED). We do not believe that it is feasible to define such a threshold to identify whether the evidence to support Medicare coverage for a particular item or service is met, or whether CED should be invoked. We also do not think that it is appropriate to set an evidentiary threshold for CED studies themselves. An evidentiary threshold would vary widely depending upon the item or service being evaluated and the clinical needs of individual patients.

## **6. CED Implementation**

CED should be the exception, not the rule, and a collaborative exercise in which CMS participates with stakeholders to identify specific, well-defined clinical issues to be resolved through data collection. Such discussions should include appropriate study endpoints, the duration of data collection and should recognize funding constraints. In light of this, we reiterate our prior comments regarding CED data collection efforts. CMS should:

- *Engage a Full Range of Stakeholders in Setting Parameters for the CED Data Collection Effort.* A stakeholder group, including manufacturers, in collaboration with CMS, should determine the clinical question to be addressed by the CED data collection exercise, appropriate study endpoints, the number of patients required, and the duration of data collection after a practical consideration of the costs associated with this effort. In addition, CMS and this stakeholder group should agree to a clear data analysis plan.
- *Require the Collection of Only the “Minimum Necessary” Data.* Data collection is costly for providers and other stakeholders. CMS should ensure that CED-related data collection involves only the “minimum necessary” data to answer the specific clinical questions that the study will address. Data collection should occur only to resolve explicit and well-defined, clinical research questions bearing on an ultimate coverage determination. To the extent possible, data collection should not place an additional burden on the parties involved. We believe that data collection through claims mining is one option that should be explored. In addition, the entity that is chosen to receive the data should be independent and neutral.
- *Address the Matter of Ending CED-Required Data Collection Efforts.* Under the existing CED guidance document, CMS states that when the “length of time for data collection is not specified [in an NCD], CMS will evaluate the data on an ongoing basis to determine when the requirements of the NCD have been met and data collection is no longer

necessary.”<sup>4</sup> We disagree with this approach. CED-required data collection should have a well-defined endpoint established before the data collection begins. CMS should provide more specificity regarding the duration of the data collection or the specific issues or questions CMS seeks to address through data collection, and create “stopping rules” for data collection. We are concerned that without such specificity, a registry or other data collection method could continue for years without regard to the reporting burden and costs, and without a clear end point.

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In summary, the above comments regarding CED principles, evidentiary criteria and the CED process are intended to be constructive, so that beneficiaries and the physicians who treat them can gain access to promising medical technologies.

We appreciate the opportunity to share our views on this important issue, and would be pleased to answer any questions regarding these comments. Please contact Chandra Branham, JD, Vice President, Payment and Health Care Delivery Policy, at (202) 434-7219 or [cbranham@AdvaMed.org](mailto:cbranham@AdvaMed.org) if we can be of further assistance.

Sincerely,



Ann-Marie Lynch  
Executive Vice President, Payment and  
Health Care Delivery Policy

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<sup>4</sup> Centers for Medicare & Medicaid Services, *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).