November 22, 2011

Louis Jacques, MD
Director, 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: Solicitation on Potential National Coverage Determination (NCD) Topics

Dear Dr. Jacques:

On behalf of the Advanced Medical Technology Association (AdvaMed), we appreciate the opportunity to respond to the Centers for Medicare & Medicaid Services’ (CMS’’) recent web site solicitation for input on potential Medicare National Coverage Determination (NCD) topics. In the September 28, 2011, solicitation, CMS states that it seeks to update its current list of potential NCD topics after considering input from stakeholders regarding “potentially ineffective or harmful items or services.” CMS is requesting input concerning items or services that may be “inappropriately used (i.e., underused, overused, or misused)” or that provide “minimal benefit” in certain health care settings. AdvaMed has a keen interest in Medicare’s NCD process, and has provided comprehensive comments in the past on CMS documents and notices related to coverage and evidence issues.

As you know, 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.

We have long supported efforts to make the Medicare coverage decision-making process more transparent and open, and we have worked for more opportunities for public participation in the NCD process. While we appreciate the fact that CMS is asking the public to provide assistance in identifying topics for CMS to consider in the future with respect to national coverage, we note that the opportunity already exists for any member of the public to request a Medicare NCD. CMS makes this clear in its guidance document issued on April 11, 2006, which states that CMS may assist the requester if needed.²

In our experience, the generation and posting by CMS of listings of potential coverage topics suggested by the public is not sufficient, in itself, to provide the sort of transparency that is needed in the Medicare national coverage process. We recognize that CMS can receive advice from the public on potential coverage topics in various ways, including the submission of written requests and the suggestion of potential coverage topics. We also recognize that Medicare’s contractors provide guidance on these topics, and that CMS has identified topics for which it is considering internally generating national coverage determinations. We believe that if CMS proceeds to post a listing of national coverage topics, it should list topics from all of these sources, along with an annotation stating its views on the topics identified.

In moving forward with this matter, we also urge CMS to proceed with caution with respect to items and services identified by stakeholders as potentially providing “minimal benefit” in hospitals or other health care settings. In addition, we request CMS to provide an additional comment period on any revised list of potential NCD topics that emerges from this web site solicitation, in order to ensure an open and transparent process.

Our comments on these two recommendations are discussed in more detail below.

I. Minimal Benefit

CMS has invited public comment regarding items and services that may be inappropriately used or that provide “minimal benefit in hospitals, clinics, emergency departments, doctors’ offices, or in other health care settings.” We have concerns about this language and ask CMS carefully consider any national coverage determination activity that may grow out of public responses under this category. We would fully expect that CMS would only base any national coverage review on the statutory requirements for Medicare coverage and payment, i.e., that Medicare will condition payment on whether on that item or service:

- Falls within a Medicare benefit category;
- Is not specifically excluded from coverage; and
- Is “reasonable and necessary” for the “diagnosis and treatment of illness or injury or to

improve the functioning of a malformed body member.”

Therefore, while a stakeholder or commenter might provide input to CMS regarding items or services the commenter feels are of limited or minimal benefit, CMS should only review that item or service in light of the statutory requirements for coverage, and avoid any attempt to establish a higher threshold for coverage based on some undefined degree of benefit.

In existing CMS guidance documents on the NCD process, the agency has detailed factors it may consider in opening an NCD. The Agency has stated that it may generate an NCD on an existing technology in circumstances where:

- Providers, patients or other members of the public have raised significant questions, that are supported by CMS’s initial review of available data, about the health benefits of currently covered items or services, specifically regarding the Medicare population;
- Interpretation of new evidence or re-interpretation of previously available evidence indicates that changes may be warranted in current policies;
- Local coverage policies are inconsistent or conflict with each other to the detriment of Medicare beneficiaries. For instance, the noted variation is not related to local differences in the capabilities of health care providers to use the technology effectively which can be resolved over time, but rather is causing significant disparities in the care available to Medicare beneficiaries that are unlikely to be addressed effectively through provider training and education or through the local coverage process;
- Program integrity concerns have arisen under existing local or national policies; that is, there is significant evidence of wide variation in billing practices not related to variation in clinical need, or of potential for fraud under existing policies.

Again, while CMS may take interest in comments it receives regarding potential NCD topics and may use this input to inform future NCD activity, the agency should base determinations about opening an NCD on the circumstances above, and not on some arbitrary determination about the level of benefit.

II. Additional Comment Period

CMS states in its solicitation notice that it intends to publish a revised list on the CMS website at some future date. We ask that CMS post on its website the public comments received as a result of this solicitation, as is typically the case for a request for comments on coverage topics. We also urge CMS to provide another comment period when the revised list is posted, so that stakeholders may have the opportunity to provide substantive input on the actual proposed topics that result from this solicitation.

Our review of the recent solicitation notice raises a number of questions, detailed below.

- The notice does not identify the process CMS will use to generate and update the list of potential NCD topics. We suggest that CMS address this matter in its next website posting.

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3 Social Security Act §1862(a)(1)(A); see also, Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 Federal Register 55634 (September 26, 2003).
4 “Factors CMS Considers in Opening a National Coverage Determination” (April 11, 2006); see FN2 above.
• The notice does not address whether the revised list will include topics that are being considered for internally-generated NCDs, or topics suggested by contractors. We suggest that CMS include these items, in addition to topics that come in through the public comment process.
• We suggest that CMS make public the identity of the requestor for each new topic that appears on the revised list as a result of the comments received.
• We suggest that CMS provide rationales for each of the topics included on the final list, as well as a prioritization of the listing.
• We suggest that CMS identify how the topics on the potential NCD topics list relate to other CMS efforts to establish Medicare evidence priorities (such as issues presented at MEDCAC meetings).

We believe that a CMS response to the matters we have raised above, along with an opportunity for comment on a draft list prior to a final decision would be consistent with the Agency’s overall efforts to improve the openness and transparency of the Medicare national coverage decision-making process.

AdvaMed and its member companies have greatly appreciated CMS’ open door policy with respect to the national coverage determination process and we look forward to working with CMS in the future. We are available to meet in person or via conference call at your convenience to discuss these and other issues.

Should you or your staff have any questions, please contact me or Chandra Branham, J.D. (cbranham@advamed.org or 202-434-7219).

Thank you for your attention to this letter.

Sincerely,

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

Cc: Patrick Conway, MD, CMS Chief Medical Officer