Public Comments for
Draft Guidance Documents Addressing:
Factors CMS Considers in Opening a National Coverage Determination;
Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee; and
Factors CMS Considers in Commissioning External Technology Assessments
March 9 – May 8, 2005

Commenter: Robert G. Britain
Organization: NEMA

This letter represents the comments of the National Electrical Manufacturers Association (NEMA) in response to the following three draft guidance documents issued on March 9, 2005:

1. Factors CMS Considers in Opening a National Coverage Determination;

2. Factors CMS Considers in Commissioning External Technology Assessments;

3. Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee

NEMA is the largest U.S. trade association representing the U.S. electroindustry. The Diagnostic Imaging and Therapy Systems Division of NEMA represents over 95% of the market for x-ray imaging equipment, CT (including mammography), radiation therapy, magnetic resonance, diagnostic ultrasound, nuclear medicine imaging and medical imaging informatics equipment.

NEMA appreciates the opportunity to share its views and concerns with you on the development of guidance documents for clarification of the national coverage determination (NCD) process. Development of clear and rational guidance documents is integral to a sound and efficient national coverage determination process.

General comments

NEMA believes that collaboration between CMS and stakeholders in development of guidance documents for the CMS national coverage determination process is a positive step and provides benefits for both CMS and industry. This can best be accomplished by affording stakeholders sufficient time to review and comment on draft guidances issued by CMS. This policy should apply both in the case of seeking public response to a notice soliciting written comments, or with respect to a notice of a public meeting in which oral presentations will be presented.

We note that these three draft guidance documents, which were the subject of the March 10, 2005 Open Door Forum, were posted only the night before the meeting. This did not allow for sufficient time for review prior to the Forum. Although CMS has also provided an

opportunity for written comment on these draft guidances, the quality of the discussions at the March 10 Forum would have been significantly improved if stakeholders were given ample time to prepare comments for the meeting. We appreciate that CMS expressed its intent at the meeting to provide sufficient time for stakeholders to review and prepare their oral presentations in advance of future meetings.

Draft Guidance 1

Factors CMS Considers in Opening a National Coverage Determination

This draft guidance is concerned with how the national coverage determination process is initiated. NEMA agrees with CMS that holding preliminary meetings between requestors and CMS is mutually beneficial, since it helps clarify important issues pertaining to specific requests for coverage before formal requests are submitted. These preliminary meetings will go a long way in helping the requestor and CMS avoid unnecessary and wasteful expenditure of resources, by identifying the kinds of evidence CMS will need to consider an NCD request.

While we agree that holding preliminary meetings will be of great value, it is only when a "complete, formal request" is received by CMS that the NCD process can begin. However, clarification is needed with regard to the CMS definition of what constitutes a "complete formal request" for an NCD.

Specifically, CMS must receive from the requestor "adequate supporting documentation submitted by the requestor along with the formal letter, including a full compilation of the supporting medical and scientific information currently available that "measures" the medical benefit of the item or service." (emphasis supplied).

This provision raises four critical issues:

1. What is "adequate supporting documentation"?

2. What is considered to be a "full compilation" of supporting medical and scientific information?

3. How should "measurement of medical benefits" be defined? Would this term be limited to narrow "clinical outcomes" or would this definition be extended to include such benefits as avoidance of surgery, or more radical medical interventions, reduction in hospital length of stay etc. ?

4. Will these "requirements" be applied differently to diagnostic imaging technologies, and what is the justification for a different application of the "requirements" ?

The meaning of these policies and definitions must be clearly understood by both CMS and requestors, because the opening of an NCD cannot begin until all the steps constituting a formal request have been completed.

(We understand that CMS has recently issued a draft guidance document on coverage with evidence development. Guidance in this area will be critical to understanding those specific instances in which data collection will be needed to support a request for an NCD. Review of this document will be needed in order to determine if additional clarification from CMS is necessary to enable stakeholders to more fully understand the requirements for submission of a request for NCD in other cases).

CMS states in the draft guidance that it may generate a request for an NCD "in the interest of the general health and safety of Medicare beneficiaries." NEMA has some concerns with this statement. It is FDA's jurisdiction to evaluate safety and effectiveness of medical devices; these issues are not within CMS' mandate. Instead, CMS is statutorily authorized to evaluate whether an item or service is "reasonable and necessary." This should be the foundation for the internal generation of NCD requests.

With respect to internally generated NCD requests, NEMA believes that CMS should set forth a list of clear, definitive reasons why a particular request has been generated. This will provide greater predictability and transparency in the NCD process. We would also recommend that CMS post those issues which are still in the discussion stage within the Agency as to whether they will be generated under the national coverage determination process. Moreover, we recommend that stakeholder input be permitted and encouraged at this earlier stage. Allowing stakeholder input at this earlier stage would provide a broader perspective on the issues under discussion, and ultimately aid in making more informed coverage determinations. We believe this policy should apply both to internally generated, as well as externally generated, NCD requests.

Once the request for an NCD is posted via a CMS tracking sheet, the draft guidance provides that interested individuals can participate in and monitor progress of the NCD process. Again, we would like to emphasize that participation in the NCD process through providing input should be permitted while the issues are still being considered by CMS, prior to posting. However, once the request for an NCD is posted, the question arises as to the time limit for public participation and submission of additional evidence. NEMA believes that the length of this period for public participation should be discussed and determined with input from stakeholders.

Another area of concern is the prioritization of the requests for national coverage determinations received by CMS. CMS states in its draft guidance that if they receive a large number of NCD requests to review at once, they must have the flexibility to prioritize these requests based on the "magnitude of the impact on the Medicare program and beneficiaries". While it is understood that CMS must have flexibility to manage the NCD process, we believe it is important that requestors and other interested parties be permitted to have input into the prioritization process for CMS' consideration.

A number of issues are raised with respect to the criteria CMS will use in its prioritization process:

1. What criteria will CMS employ in assessing the "magnitude of the impact on the Medicare program and beneficiaries"?

2. Will only immediate, life-saving items or services be given precedence, or will items or services yielding long-term benefits also be considered?

NEMA believes that relying solely on those services that produce "immediate"or "breakthrough" benefits does not fairly take into account the benefits produced by diagnostic imaging technologies. These benefits may include for example the avoidance of the costs and risks of surgery, or other invasive procedures, and shorter hospital stays. Thus, in terms of the prioritization process, CMS should recognize that the benefits of diagnostic imaging technologies can importantly impact both the Medicare program and its beneficiaries.

We believe that CMS should permit public input into the prioritization process so that CMS can benefit from a broad range of perspectives on the potential benefits of those medical technologies under consideration, prior to its prioritization of NCD requests. Stakeholders should be allowed to provide supporting documentation why a specific item or service deserves priority attention. If only those items or services which offer "immediate" benefits are considered for prioritization, those technologies which offer significant longer-term benefits may frequently find themselves relegated to the bottom of the list of national coverage determination requests. This would delay access of Medicare patients to the latest innovations in health care technology.

Draft Guidance 2

Factors CMS Considers in Commissioning External Technology Assessments

In this draft Guidance document, CMS states that it may conduct a Health Technology Assessment (HTA) of an item or service if, for example:

- There is conflicting or complex medical and scientific evidence or literature with regard to the item or service;
- There are significant differences in opinion among experts with respect to the relevant evidence or interpretation of the data, such that an independent analysis of the relevant literature would be valuable;
- The review involves specialized methodology, such as decision modeling, or meta-analysis in health technology assessment;
- There is an upcoming Medicare Coverage Advisory Committee (MCAC) meeting on the subject.

We would like to make several proposals, which we believe will enhance the process of commissioning an HTA:

First, in the interest of receiving a full review of pending clinical issues, once CMS has announced that a particular subject is under consideration for an NCD request, consideration should be given to allowing the requestor and the public to also request an HTA on those requests for national coverage determinations which are before the Agency. The stakeholder would be expected to provide supporting rationale for requesting an HTA. Grant or denial of the request would be at CMS' discretion.

Second, due to the importance of those issues under review to providers, beneficiaries and manufacturers, CMS should work with stakeholders to craft an efficient mechanism so that additional evidence may be submitted to CMS while the HTA is in progress. This would include

allowing stakeholders to frame questions for consideration. Third, diligent efforts should be made to provide CMS with the most extensive evidence which is possible to amass and then submit such evidence to the body performing the HTA. We believe that these enhancements will help provide CMS with a broader perspective of available evidence, and will help CMS make more informed coverage determinations.

Draft Guidance 3

Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee (MCAC)

MCAC provides a critical component in the national coverage decision-making process. In general, topics may be referred to MCAC by CMS in the following instances, as set forth in Section V. of the draft guidance:

"- It is the subject of considerable controversy among experts; that is, there is a split in opinion among researchers and clinicians regarding the medical benefits of the item or service, the appropriateness of staff or setting, or some other significant consideration that would affect whether the item or service is "reasonable and necessary" under the Act;

- Existing published studies contain significant potential methodological flaws (e.g., unreliable design or implementation, small size) or have not addressed policy relevant questions;

- Existing published studies show conflicting results;

- CMS desires more information and/or additional expert review of the methods utilized in the external technology assessment (TA), particularly when the TA questions were numerous, there were complex clinical issues involved, or specialized methods such as decision modeling were employed;

- CMS desires more information and/or greater public input by receiving and considering comments on the net health outcomes of a technology that could be subject to varying interpretations. Obtaining the perspective of potentially affected patients and caregivers (e.g., magnitude of potential benefit, assessment of risk or weight of side effects) through public comments and voting representatives on the panel may be particularly relevant in these instances;

- Use of a technology is the subject of controversy among the general public;

- When presentation, public discussion and clarification of the appropriate scope for the review, the preferred methodological approach, or a clinical management issue would be beneficial for undertaking future NCDs;

- Technology dissemination has the potential to have a major impact on the Medicare population, the clinical care for specific beneficiary groups, or the Medicare program overall;

- CMS determines that the NCD process would be better informed by deliberation that incorporates the viewpoint of patient advocates as well as a broad, societal perspective of factors

not directly related to the scientific review of the evidence, but nevertheless relevant to the decision."

Clearly, in the process of determining whether an item or service is reasonable and necessary, and thus eligible for Medicare coverage, MCAC plays a vital role. For example, in the evaluation of technology, MCAC may receive a referral if technology dissemination has the potential to have a major impact on the Medicare population or if the technology is a subject of controversy among the general public.

The importance of MCAC in helping CMS make national coverage determinations we believe warrants several improvements to the NCD process which will ensure that CMS is receiving a wide range of views on questions before the Committee.

In the draft guidance, it is stated that CMS will generally publish a notice in the Federal Register 30 days in advance of the MCAC meeting. NEMA believes that CMS should publish a notice not less than 30 days in advance at a minimum, and preferably, further in advance. As stated below, a 30-day notice constitutes an insufficiently short time to adequately prepare and submit input to MCAC.

The draft guidance provides that presentations, written testimony and consideration of evidence submitted by the public, which pertain to the specific issues being addressed at an MCAC meeting, must be submitted in writing to CMS at least 20 days before the date of the MCAC meeting. Further, CMS states that it will publish a notice of an MCAC meeting in the Federal Register 30 days in advance of the meeting. If stakeholders must submit their materials to CMS 20 days in advance of a meeting, the stakeholders actually have only 10 days in which to prepare and submit material to CMS if a notice of a meeting is posted 30 days in advance.

NEMA strongly believes that allowing only 10 days for preparation and submission of evidence, testimony or other material is wholly inadequate as a time limit for providing input to CMS. This time limit sharply conflicts with CMS' stated objective of permitting the public to provide comment on the important issues under consideration. Such a limit will dramatically restrict the ability to provide meaningful public input to the Committee. The issues which come before MCAC are very critical and complex, and thus stakeholders must be permitted sufficient time for thorough preparation before submission of input to MCAC.

In addition to these notice provisions, there are a number of other improvements which could be made in terms of who should be permitted to request that an issue be submitted to MCAC, and the selection of "experts" which will be permitted to serve on any specific MCAC panel.

First, NEMA believes that stakeholders should be allowed to propose to CMS that specific issues relating to a pending request before the agency be submitted to MCAC. The stakeholder proposing such an action should provide supporting documentation and rationale to CMS why a particular issue should be referred to MCAC. CMS could then apply its judgment in deciding whether or not to grant the request for referral to MCAC.

Second, while CMS is authorized to select "experts" as non-voting guest MCAC panel members at particular MCAC meetings, the opportunity to propose "experts" should be extended

to stakeholders. Those proposing these specific “experts” would be responsible for describing how the presence of such “experts” would benefit the discussion of the particular questions at issue. CMS could then decide whether or not to agree to appoint such “experts” to the particular MCAC panel.

Conclusion

NEMA wants to thank CMS for allowing us to share our views on these three draft guidance documents bearing upon the national coverage determination process. We look forward to working with you in the future as the guidance review process continues.

Commenter: Barbara J. Calvert
Organization: Guidant

Guidant Corporation welcomes the opportunity to provide comments on the three draft guidance documents referenced above. We support CMS efforts to develop guidance on important aspects of the national coverage process and believe that such guidance will help to increase the predictability of the process for manufacturers and other stakeholders.

Headquartered in Indianapolis, Indiana, with manufacturing and/or research facilities in the states of Minnesota, California, and Washington, as well as in Puerto Rico and Ireland, Guidant Corporation is a leader in the research, development, and manufacturing of medical technologies used primarily in treatment of cardiovascular and vascular illnesses. Guidant's products save and enhance lives.

Our detailed comments on the three draft guidance documents follow.

Guidance on Factors CMS Considers in Opening a National Coverage Determination

Internally generated NCDs CMS indicates conditions under which it may pursue a national coverage decision. In general, we believe that national coverage decisions should be pursued by CMS only in cases where coverage determinations cannot be adequately addressed at the local contractor level. For example, it may be appropriate for CMS to pursue an NCD to address longstanding conflicts in local policies or other situations that present a risk to the health of Medicare beneficiaries. However, we do not believe that CMS should pursue an NCD based solely on the fact that a therapy presents a substantial clinical advance or is likely to have a significant programmatic impact on Medicare, absent the identification of a potential risk to the health of beneficiaries that cannot be adequately addressed at the local level. In addition, we recommend that CMS modify the third bullet in the section on conditions for internally generated requests to refer to uncertainty concerning "medical reasonableness and necessity" as opposed to "safety and effectiveness", given that the latter is the responsibility of the FDA.

Stakeholder Input CMS indicates that it may consult with stakeholders before deciding to pursue an NCD and may announce on the CMS website topics that are being considered for an internally generated request. We recommend that CMS always consult with relevant stakeholders before proceeding with an internally generated request and announce all topics under consideration for an internally generated request prior to posting of the tracking sheet. The announcement should state the specific reason for pursuing the request and indicate an approximate timeframe for opening a formal request. The early posting of topics under consideration would provide stakeholders the opportunity to provide input to CMS regarding the need for an NCD and assure that CMS has access to all relevant information

Feedback on adequacy of evidence and CMS concerns We recommend that CMS include in this or a future guidance more detail on channels for requestors to obtain ongoing substantive feedback from CMS on the adequacy of the evidence, any CMS concerns that could affect coverage and potential data collection or facility requirements. Open ongoing dialogue between

CMS and stakeholders both prior to and during the NCD process would greatly enhance the predictability of the process.

Confidentiality We recommend that CMS include in this or a future guidance an explanation of CMS policy and procedures related to the treatment of confidential information submitted by manufacturers or other stakeholders for coverage purposes. Current policy and procedures are unclear.

Guidance on Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee and in Commissioning External Technology Assessments

Questions to be addressed by MCAC or a technology assessment We recommend that the two guidances be expanded to address the role of stakeholders in determining the scientific questions to be addressed by MCAC or a technology assessment. CMS should consult closely with the requestor and other stakeholders and seek consensus on the questions to be addressed. CMS also should consult with stakeholders in the case of an internally generated request. It is important to reach consensus on the scientific questions to be addressed, as this will have a major impact on review of the evidence and the resulting coverage determination. We suggest that CMS use preliminary meetings prior to opening the NCD as well as stakeholder meetings during the early stage of the NCD process to begin consultations on the scientific questions to be addressed for a particular therapy. Such discussions should occur regardless of whether CMS plans to convene an MCAC or commission a technology assessment.

Rights of the Requestor We recommend that the guidance specifically address the rights of the requestor with regard to MCAC and technology assessments. Some requestors may approach CMS wishing to proceed with an internal CMS decision, while others might prefer an MCAC review. Some might think an external technology assessment is needed, while others might not. Requestors should have the right to request and to provide input as to whether a technology or service is referred to MCAC or for an external technology assessment. In addition, for NCDs that are referred to MCAC, requestors should be involved not only in the framing of the questions to be reviewed by MCAC but also should have the right to review and make recommendations on the MCAC panel members and other invited "external experts" who will review the evidence. Lastly, requestors should be able to submit materials to CMS for distribution to MCAC members and invited experts prior to an MCAC meeting. We believe that many of these matters can be resolved in preliminary discussions between the requestor and CMS prior to or in the early stages of the formal NCD process.

We look forward to continuing to work closely with CMS on the development of guidance to improve the predictability of the national coverage process.

Commenter: Alexandra Clyde
Organization: Medtronic

Medtronic, Inc. is pleased to respond to the Centers for Medicare & Medicaid Services' (CMS') request for public comment on the *Factors CMS Considers for Commissioning External Technology Assessments* for national coverage decisions (NCDs) draft guidance document.[1] Under separate cover we have also submitted comments on the *Factors CMS Considers in Opening a National Coverage Determination* and on the *Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee* draft guidance documents.

Medtronic is the world's leading medical technology company, providing lifelong solutions for individuals with chronic disease and enhancing the lives of Medicare beneficiaries. Our comments below are reflective of our long history in working directly with CMS on numerous coverage decisions involving many of our products, including both Medtronic-initiated NCDs and CMS-generated coverage requests. We hope that our suggestions assist CMS in improving the manner in which external technology assessments (TAs) are developed by CMS and the Agency for Healthcare Research and Quality (AHRQ).

Medtronic supports CMS' overarching goal to ensure that Medicare beneficiaries receive appropriate, high quality health care, including access to life-saving and life-enhancing medical advancements by clarifying the criteria and process for requesting a technology assessments. The *Factors CMS Considers for Health Technology Assessment Referrals for National Coverage Decisions* will be a valuable reference to both individuals and groups interested in the coverage process; however, we would like to note that TAs are only one factor among many others that should assist CMS in the review of evidence when developing an NCD. We believe that this guidance document will be an important guide as CMS establishes a publicly-accountable, efficient, and predictable process for the development of TAs moving forward.

Recommendations for *Factors CMS Considers In Commissioning External Technology Assessments*

Medtronic is pleased to provide CMS the following suggestions on the ways in which technology assessments are requested, conducted, and evaluated by CMS.

Criteria for Requesting an External TA

Medtronic appreciates CMS' efforts to better define the criteria in which it will request an external TA from AHRQ. However, we are concerned that as currently stated the factors CMS considers are so broad that they result in a persistent lack of predictability in understanding when CMS will choose to request a TA from AHRQ. Therefore, NCD requestors should have the opportunity to recommend to CMS whether or not commissioning an external TA is appropriate. During informal preliminary meetings between CMS and NCD requestors prior to the acceptance of a formal NCD, CMS should discuss with the requestor the likelihood of a potential external TA. In cases where commissioning a TA may be appropriate, CMS should continue to work

[1] Centers for Medicare & Medicaid Services. Draft Guidance for the Public, Industry and CMS staff: Factors CMS Considers in Commissioning External Technology Assessments. Issued March 9, 2005.

with the requestor throughout the review to assure that adequate public review and comment can be submitted during the TA development process.

Process

Medtronic recognizes that at times an external TA is necessary to most effectively and efficiently synthesize existing evidence for the development of an NCD. However, the usefulness of a TA is highly dependent on the process by which the research question and scope are defined. Therefore, Medtronic believes that it is vital that CMS incorporate public input in defining the scope and questions that serve as the basis for the TA's evidentiary review. We recommend that following CMS's decision to request a TA, CMS should convene an informal public forum such as a Town Hall meeting or Open Door Forum to allow stakeholders to provide input on the scope of the external TA. Stakeholders should also have an opportunity to comment on the assessment questions and TA framework prior to their finalization. Given the limits imposed by the statutory timeframes and CMS' internal capacity to review evidence, manufacturers, professional societies, providers, and beneficiaries can be helpful to CMS in defining the scope and contributing evidence in the development of an external TA.

Medtronic also recommends that CMS allow the requestor of the NCD to submit evidence directly to AHRQ for inclusion in the TA. As part of the TA quality control process, we also believe AHRQ should solicit comments from the requestor and a select group of stakeholders, defined by CMS and the requestor, on the draft TA prior to its finalization. Finally, all TA requests, research questions, and final TAs should be placed on the CMS website as soon as they are available. Medtronic understands the importance of CMS' meeting the NCD timeframes. We believe that the suggestions above can be easily implemented without causing additional delay, and in some cases, may in fact shorten the TA development process.

Conclusions

Medtronic commends CMS in its effort to foster a more transparent and predictable national coverage process. We appreciate the opportunity to provide specific recommendations to CMS on the *Factors CMS Considers for Commissioning External Technology Assessments* for NCDs draft guidance document and we look forward to working with CMS on the issues related to the production of guidance documents for CMS's NCD process.

Recommendations for *Factors CMS Considers In Opening a National Coverage Decision (NCD)*

Medtronic, Inc. is pleased to respond to the Centers for Medicare & Medicaid Services' (CMS') request for public comment on the *Factors CMS Considers in Opening a National Coverage Decision (NCD)* draft guidance document.[2] Medtronic is the world's leading medical technology company, providing lifelong solutions for individuals with chronic disease and enhancing the lives of Medicare beneficiaries. Our comments below are reflective of our long history in working directly with CMS on numerous coverage decisions involving many of our products,

[2] Centers for Medicare & Medicaid Services. Draft Guidance for the Public, Industry and CMS staff: Factors CMS Considers in opening a National Coverage Determination. Issued March 9, 2005.

including both Medtronic-initiated coverage requests and CMS-generated NCDs. We hope that our suggestions assist CMS in improving the national coverage process.

Medtronic supports CMS' overarching goal to ensure that Medicare beneficiaries receive appropriate, high quality health care, including access to life-saving and life-enhancing medical advancements by clarifying its process prior to the formal initiation of an NCD. We appreciate CMS' deliberate efforts to individually address each of these important steps in this stage. Stakeholders interested in the national coverage process such as manufacturers, professional societies, providers, and beneficiaries, have a wide range of experience and familiarity with the coverage process and will be helpful to CMS in shaping the final guidance document. The *Factors CMS Considers in Opening a National Coverage Decision Guidance Document* will be a valuable reference to both individuals and groups interested in the coverage process and believe this guidance document to be an important first step in assuring that CMS establish a publicly-accountable, efficient, and predictable process for the development of NCDs moving forward.

We have organized our comments according to sections of the draft coverage guidance on *Factors CMS Considers in Opening a National Coverage Decision* of most interest to us.

Requests Initiated Internally

Medtronic believes that the most important aspect of the NCD process is the criteria in which CMS will choose to internally generate an NCD. Without carefully defined criteria, the NCD process will be, by definition, unpredictable. Medtronic recognizes CMS' authority to "internally generate" NCDs and that CMS has stated in the past that it does so when it is in the "interest of the general health and safety of Medicare beneficiaries."[3] However, CMS has also long acknowledged the importance of the local coverage determination process and in retaining the locus of clinical decision-making in the physician-patient relationship.

If a service or technology requires a coverage determination, most determinations currently occur at the local level. The local coverage process allows for flexible evidence-based decision-making and enables contractors to use mechanisms that many private payers use to allow appropriate access to new technologies without granting unrestricted coverage. These mechanisms include:

- The ability to implement and revise decisions quickly, if necessary, in response to new clinical evidence.

- The ability to make case-by-case determinations for individual patients until use merits a formal coverage policy.

- The ability to obtain input from Carrier Advisory Committees and local physicians in the development and application of local coverage reviews.

[3] Medicare Program; Revised Process for Making National Coverage Determinations, September 26, 2003 (68 *Federal Register* 55634-55641).

- The ability to allow gradual diffusion from clinical centers to the broader medical community, which reflects the natural development cycle, including the diffusion pattern, of new medical technology.

In contrast to the local coverage process, the national coverage process has no such mechanisms and has been, in some cases, too rigid to deal effectively with coverage determinations for new technologies and procedures. For example, as indications expand for a new technology covered by an NCD based on new clinical evidence, the national coverage process requires lengthy new national reviews to keep current with every change. Typically, the exclusionary nature of NCDs means that national non-coverage is in place for the new indication during the review. For those technologies that are supported by evidence from large, well-designed randomized clinical trials resulting in little controversy regarding their use, the lengthy national coverage process may cause unnecessary delays in beneficiary access to these technologies. CMS lacks the appropriate tools at the national level to provide coverage for new technologies or indications after clinical studies have ended but prior to implementing a national policy.

CMS' goal should be to allow doctors and patients to select the right course of treatment for Medicare beneficiaries within an evidence-based framework. The local coverage process fosters this type of patient-by-patient focus and appropriate use by allowing evidence-based decision-making to be guided by local practicing physicians. Contractors also have the experience and ability to determine access to new health technologies as they become available that is responsive to the needs of Medicare beneficiaries in their areas.

Medtronic strongly believes that CMS should make clear its intention to presumptively rely on the local coverage process in its discussion of when it is appropriate to internally generate an NCD. CMS should only exercise its authority to internally generate NCDs in the following situations:

- When an existing national non-coverage policy limits access to proven technologies;
- When there are demonstrated quality of care concerns related to a covered service;
- When multiple contractor policies conflict in a manner that jeopardizes patient access to needed treatments due to persistent problems in claims submissions; or
- When program integrity issues exist surrounding significant over-utilization of an item or service that are unlikely to be addressed at the local level.

By chiefly relying on the local coverage process and limiting internally generated requests to only the above situations, CMS would help provide predictability to the NCD process and avoid premature national assessments of a service or technology that may inappropriately restrict physician choice and patient access to needed therapies. CMS should give the local process a chance to work and pull issues up to the national level only when demonstrated concerns exist that meet the criteria defined above.

<u>Prior to Initiation</u>

Horizon Scanning

We would like to encourage CMS to outline in its guidance document greater detail regarding the process followed prior to when the agency initiates an NCD, including any CMS horizon

scanning activities. A stated main objective of the newly created Council for Technology and Innovation (CTI) is to increase CMS' capacity to conduct "horizon scanning" activities to identify technologies and services that may benefit from more timely coverage or payment decisions. Medtronic supports the need for CMS to monitor and track changes and advancements in clinical practice; however, we believe that CMS' should clearly define the nature and scope of its horizon scanning efforts in its guidance documents, including identifying the personnel and methods it plans to use to complete this activity. CMS also should consider making horizon scanning topics publicly available so that interested stakeholders may submit information and comments relevant to the issue areas.

CMS should also develop a process, outlined in the guidance document, to review existing national non-coverage policies to identify those in which restrictive language does not reflect the current standard of care or advancements in the field and, therefore, are no longer applicable. In situations where CMS' horizon scanning efforts identify new information on a technology, which then leads to reconsideration of an existing non-coverage policy, CMS should allow contractors to provide local coverage of the technology until the reconsideration is complete.

Finally, we recommend that all meetings CMS conducts with other government agencies such as the FDA or the National Institutes of Health for the purpose of horizon scanning be open to the public.

Preliminary Meetings

Medtronic recognizes the value of CMS conducting preliminary meetings and informal contacts/inquiries with interested stakeholders about new products and services for Medicare beneficiaries. Stakeholders have the opportunity to request a meeting with CMS staff, specifically those in the Coverage and Analysis Group (CAG) and the Center for Medicare Management (CMM), regarding coverage and payment issues. For technologies with the potential to be involved in an NCD, preliminary discussions can help CMS and stakeholders identify and discuss future coverage and reimbursement issues.

However, CMS also should indicate clearly in the coverage guidance document that preliminary discussions will not always lead to the initiation of a NCD and most coverage determinations occur at the local level by individual contractors. In particular, CMS should clarify during preliminary discussions whether the local coverage process is a more appropriate course than the national process for a particular procedure or technology. We recognize that CMS lacks the resources to review every medical innovation at the national level in a timely manner and, therefore, the local coverage process may be better suited than the national process for reviewing the majority of services and technologies and allowing patient access to needed services.

In regards to the nature of preliminary discussions, Medtronic supports many of the issues outlined in the draft coverage guidance of what should be discussed during preliminary meeting. Specifically, we support the following three issues CMS recommended stakeholders should be willing to discuss with CMS during a preliminary meeting:

- Review the supporting documentation related to the request;
- Review clinical trial data; and

- Provide information on the applicability of the item or service in question to the Medicare population.

However, CMS should make clear that this list is only suggested and not required. Medtronic also supports each of the issues outlined in the draft coverage guidance that CMS will plan to discuss during preliminary meetings and believe this list should also include:

- Whether an existing NCD is relevant to the technology or procedure under discussion;
- Whether the technology or procedure under discussion may be the subject of a future NCD;
- Short- and long-term action items that stakeholders should adopt in order to expedite and secure a favorable coverage decision;
- CMS' expectations regarding evidence needed for a favorable NCD (for example, appropriate endpoints, "ideal" treatment comparisons, and the desired study population);
- Need for and timing of future meetings with the agency; and
- Ways in which to coordinate coverage and payment issues, as appropriate, for the procedure or technology under discussion.

Further, the agency should work with the requesting party in advance of such preliminary discussions to assure that the appropriate topics, information, and personnel are represented.

CMS should assure that all proprietary information shared during preliminary meetings will remain confidential. CMS should provide additional guidance to stakeholders detailing how information can be delivered to the agency without compromising proprietary or trade secret information. If materials can be accessed by the public through the Freedom of Information Act process, CMS should indicate this in the coverage guidance document.[4]

<u>What Constitutes a Complete, Formal Request for an NCD</u>

Establishment of a Benefit Category

Medtronic understands that Medicare coverage is only extended to items and services that CMS finds to be "reasonable and necessary," and for which there is an established benefit category(s). While the benefit category determination process is considered part of the NCD process, we are unclear about exactly what the benefit category determination process entails. CMS typically does not provide information in its coverage decisions about the rationale behind benefit category determinations, nor has the agency made available an opportunity for NCD requestors or other interested parties to either appeal or formally discuss the designation of a benefit category. In the draft guidance, CMS proposed that it will now issue an NCD explaining when coverage could not be granted based on the lack of an applicable benefit category. We recognize that CMS has not routinely issued NCDs for negative benefit determinations and support CMS' willingness to better communicate the process and benefit category determinations.

It is often a challenge for requestors to understand the coordination between CAG, from which they request an NCD, and CMM, which determines the benefit category. In order to promote consistency among benefit category assignments, it would be helpful if CAG outlines in the

[4] Centers for Medicare & Medicaid Services Web Site. Available at: http://www.cms.hhs.gov/foia/.

coverage guidance document the process by which it requests and receives a benefit category recommendation from CMM, including the staff involved. In addition, CMS also should publish guidance explaining existing benefit categories so potential NCD requestors can more accurately define the appropriate benefit category in their coverage request. CMS guidance on the process for establishing a benefit category should include the specific information required to receive a benefit category designation. We believe CMS, through CTI, should develop a formalized timeline for establishing a benefit category as it would encourage consistency and predictability among coverage decisions.

Finally, CMS should formalize the stakeholders' role in establishing or confirming a new technology or procedure to a covered benefit category. For example, a process should be developed to notify requestors on the progress of establishing a benefit category. The process also should include an opportunity for stakeholders to comment and appeal a benefit category decision, including the option for stakeholders to present relevant information to CMS.

Process for Requesting a National Coverage Review

The period in which an NCD is first initiated is vital for defining the scope of the analysis and the questions that will serve as the basis for evidentiary review. Medtronic believes that CMS should use this period to assure that all stakeholders have an opportunity to raise issues that may be relevant to both the scope of the NCD and the information that will be reviewed during the coverage process.

Explicitly Defining the Scope of the NCD

For the public to better understand the nature of an NCD, we request that CMS develop and communicate explicitly the research questions that will guide its assessment of evidence for the procedure or technology under discussion. These questions should serve as the basis for both CMS' internal evidence assessment, as well as any external assessments requested. We believe that CMS should publish these research questions in draft form on the tracking sheet for each NCD during the initial 30-day comment period. CMS then should revise the research questions, as appropriate, based on the comments received.

Additional Public Input to the Scope of the NCD

We recognize also the efforts that CMS has made to ensure public participation such as the opportunity to provide feedback on the scope of an NCD in the 30-day public comment period following its initial posting. In addition to these efforts, we encourage CMS to further solicit public comment through more informal public forums such as Town Hall meetings or Open Door Forums within 30 days of the initiation of an NCD. Plans for these public meetings can be published via a press release, a posting on CMS' website, or an announcement on the Medicare Coverage listserv. These meetings would give stakeholders additional opportunities to provide comments on the scope of the NCD, the questions that should be addressed during an internal review or external technology assessment, and the type of data that should be required to develop the NCD. CMS also should explicitly solicit a list of clinical experts that it should contact during the coverage review process.

Continued Collaboration Throughout the Development of an NCD

Medtronic also believes that NCD requestors should have the option to meet with CMS throughout the review process in order to understand CMS' progress and be available to provide appropriate feedback and additional evidence as appropriate. Specifically, requestors should have the option of meeting with CMS staff during the following times:

- Prior to requesting an NCD as outlined above in the "Prior to Initiation" section;
- During the initial 30-day public comment period after an NCD is requested or initiated;
- During the 30-day public comment period following release of the draft NCD.

For each of these meetings, CMS should work with requestors to clarify the scope of the meeting, topics for discussion, useful information needed, and who from CAG or CMM likely will be present.

Finally, we urge CMS to consider sharing draft final NCDs and instructions to contractors with the requestor(s) immediately prior to publication. This would allow both parties to resolve any factual errors or omissions that may arise in the NCD language and save both parties the time and effort of opening a new tracking sheet and prevent any unnecessary delay in patient access.

Conclusions

Medtronic commends CMS in its effort to foster a more transparent and predictable national coverage process. We appreciate the opportunity to provide specific recommendations to CMS on the *Factors CMS Considers in Opening a National Coverage Decision* draft guidance document and we look forward to working with CMS on this exciting initiative.

Recommendations for *Factors CMS Considers In Referring Topics to the Medicare Coverage Advisory Committee (MCAC)*

Medtronic, Inc. is pleased to respond to the Centers for Medicare & Medicaid Services' (CMS) request for public comment on the *Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee (MCAC)* draft guidance document.[5]

Medtronic is the world's leading medical technology company, providing lifelong solutions for individuals with chronic disease and enhancing the lives of Medicare beneficiaries. Our comments below are reflective of our long history in working directly with CMS on numerous coverage decisions involving many of our products, including both Medtronic-initiated national coverage decisions (NCDs) and CMS-generated coverage requests. We hope that our suggestions assist CMS in improving the NCD process.

Medtronic supports CMS' overarching goal to ensure that Medicare beneficiaries receive appropriate, high quality health care, including access to life-saving and life-enhancing medical advancements by clarifying the factors in which CMS considers in referring topics to the MCAC.

[5] Centers for Medicare & Medicaid Services. Draft Guidance for the Public, Industry and CMS staff: Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee. Issued March 9, 2005.

This guidance document will be a valuable reference to stakeholders interested in the coverage process and the role and function of the MCAC.

Medtronic is pleased to provide CMS the following suggestions on the ways in which MCAC meetings are requested and conducted by CMS. CMS' draft guidance outlines a number of circumstances in which CMS will choose to convene an MCAC meeting. Medtronic supports CMS' efforts to clarify its criteria for referring topics to MCAC and recommends that CMS should publicly state its intention in convening an MCAC meeting in order to best allow the public to engage in the public meeting. Recently, CMS held two MCAC meetings on issues for which there were no open NCDs and did not explicitly state the rationale for these meeting nor provide any indications about how the Agency would proceed working on these issues depending on the outcomes of the panel's deliberations.[6]

Without greater clarity regarding CMS' intentions in convening these MCAC meetings, interested parties were handicapped in contributing relevant scientific and clinical information that could have been useful to the agency. We also believe it would be appropriate for CMS to maintain a tracking sheet for MCACs convened outside of the scope of an individual NCD. The tracking sheet should include information on CMS' intentions in convening an MCAC, and the materials and participants involved with each meeting. We believe that this will allow stakeholders to be properly informed of the scope of the MCAC meeting and help them to develop and contribute useful materials during the discussion. By doing so, the public will have an opportunity to better understand the information and materials that will serve as the basis for the panel's discussion.

The draft guidance acknowledges that an MCAC may be convened outside of a formal NCD review to address "broad, significant issues" related to coverage policy development. The guidance further states that that an MCAC meeting may be convened to recommend the types of study designs that will be needed to determine whether a particular item is reasonable and necessary. We recommend that CMS should publicly state in the Federal Register announcement of an MCAC meeting whether recommendations that will stem from the meeting will assist CMS in the development of an existing NCD, in initiating an internally-generated NCD, or to inform the agency in the development of coverage with evidence development policies.

Finally, the draft guidance document states that CMS will refer topics to the MCAC when CMS requires deliberations of "the viewpoint of patient advocates as well as a broad societal perspective of factors not directly related to the scientific review of the evidence but nevertheless relevant to the decision." Medtronic is not aware of any recent decisions that reflect these criteria and urge CMS to provide greater clarity around this criteria and how it might be applied in the future.

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[6] Centers for Medicare & Medicaid Service. MCAC on Usual Care of Chronic Wounds. Available at: http://www.cms.hhs.gov/mcd/viewmcac.asp?where=index&mid=28 . Accessed April 13, 2005.

Centers for Medicare & Medicaid Service. MCAC on Physician-Supervised Behavioral Interventions for Patients with Symptomatic Coronary Artery Disease. Available at: http://www.cms.hhs.gov/mcd/viewmcac.asp?where=index&mid=27. Accessed April 13, 2005.

We strongly support the inclusion of patient advocates on the MCAC, and believe that CMS should consider an expanded role for affected beneficiaries in this process. Furthermore, we have been disappointed at CMS' inability to provide information in a timely manner to the public that will be discussed at subsequent meetings, and recommend that the Agency develop a more detailed and transparent process around how it develops and disseminates MCAC materials. As part of this effort, we believe that CMS should engage interested stakeholders at all stages of MCAC meeting development, specifically soliciting feedback from the public about the scope of any review and the specific questions the panel should be asked.

Conclusions

Medtronic commends CMS in its effort to foster a more transparent and predictable national coverage process. We appreciate the opportunity to provide specific recommendations to CMS on the *Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee (MCAC)* draft guidance document and look forward to working with CMS on the issues related to the production of guidance documents for CMS's NCD process.

Commenter: Kay Cox
Organization: AAHomecare

Re: Comments on the Centers for Medicare and Medicaid Services' Guidance Documents on the National Coverage Determination Process

The American Association for Homecare (AAHomecare) submits these comments in response to the Centers for Medicare and Medicaid Services' (CMS') guidance documents on the national coverage determination (NCD) process, issued March 9, 2005. The American Association for Homecare (AAHomecare) is the only national association that represents every line of service within the homecare community. Our members include providers and suppliers of home health services, durable medical equipment services and supplies, infusion and respiratory care services and rehabilitative and assistive technologies, as well as manufacturers and state associations. With more than 700 member companies at 3,000 locations nationwide, AAHomecare and its members are committed to advancing the value and practice of quality health care services at home.

In March, CMS published three guidance documents addressing important aspects of the NCD process. The documents addressed: 1) factors CMS considers in opening an NCD process; 2) factors CMS considers in referring topics to the Medicare Coverage Advisory Committee (MCAC); and 3) factors CMS considers in commissioning external technology assessments. These documents represent an important step towards making the NCD process more transparent and accessible to all interested stakeholders. While AAHomecare supports these efforts and recognizes that CMS is making progress towards these goals, we believe that there remains a need for greater clarity and precision on aspects of CMS' approach to coverage and the way it engages the public in the NCD process. We address these issues in greater detail below.

I. COMMENTS

A. Initiating an NCD

General Procedural Issues

The first guidance document describes the process that CMS may use for initiating both externally and internally generated NCDs. In general AAHomecare notes that, as described in this document, CMS retains significant discretion in administering the NCD process. In fact, the guidance document states that the approaches contained in the guidance are not binding on CMS or the public. With respect to both internally and externally generated NCDs, AAHomecare suggests that CMS articulate procedural rights for NCD requestors and other stakeholders such as beneficiaries.

Notice

CMS must consider the impact of the process that it uses to identify and notify interested stakeholders that it is initiating an NCD and the timing of that notice. For both internally and externally generated NCDs, CMS should provide stakeholders notice that it is *considering* initiating an NCD and the rationale on which it is proceeding *before* publishing the tracking sheet. The guidance document suggests that CMS may be inclined to follow this process for some, but not all internally generated NCDs. It is unclear to us how CMS would arrive at a decision to provide this type of notice for some NCDs but not others. AAHomecare

recommends that CMS establish a process to give the public notice that is considering an NCD before commencing the national process.

CMS' goal in providing notice of NCDs under consideration should be to assure that the broadest possible group of stakeholders has an opportunity to participate meaningfully in the NCD process. CMS should also review what mechanisms are appropriate to notify beneficiaries that it is initiating an NCD for an item or service. AAHomecare agrees that the CMS website is an efficient mechanism for providing this type of notice, but also encourages CMS to consider engaging in more aggressive outreach to the beneficiary and provider communities. AAHomecare suggests that CMS directly contact beneficiary and provider representatives to promote their participation in the process even before the tracking sheet is published. As part of this effort, CMS should describe to the public its efforts to target specific stakeholders as well as the rationale it used to select them.

Public Comment Period

Likewise, AAHomecare suggests that CMS more carefully examine the impact of the timeframe it allows for public comment. Inasmuch as coverage determinations may require supporting evidence, it can be difficult for some stakeholders to provide supporting evidence in the thirty (30) day comment period CMS currently allows. While AAHomecare appreciates that CMS is also subject to time constraints for completing the NCD, allowing a sixty (60) day comment period will improve the overall quality of the comments and supporting data CMS receives.

AAHomecare notes favorably that, for the pending NCD for mobility assistive equipment, CMS provided additional forums for public comment. These included "town hall" style meetings that gave beneficiaries the opportunity to provide comments either in person or by phone. These opportunities to provide comments are important for the beneficiary and clinician communities who may not otherwise submit formal written comments to CMS. This kind of public participation also serves to crystallize for CMS the "day-to-day" impact of the NCD under consideration. CMS should consider incorporating this type of public meeting in the NCD process.

CMS Response to Comments

The final decision memorandum CMS publishes is an extensive document that typically includes the procedural history of the NCD, identifies the stakeholders that submitted comments and summarizes the data that CMS reviewed. While this is already a comprehensive document, AAHomecare suggests that CMS include within its analysis a more detailed discussion of the weight it accorded the data submitted during the NCD process.

The Role of the Local Coverage Process

The local coverage process relies on the participation of stakeholders and generally provides the public with precise procedural rights that are not available at the national level. This process includes a public comment period, the opportunity to meet with the carrier medical directors in a public forum, and a requirement that the carrier respond to the public comments in issuing the coverage determination. Importantly, under the local coverage process, new therapies and equipment can be more readily accessed by beneficiaries who can benefit from the technology. The DMERC medical directors also play an important role in approving coverage for beneficiaries based on the recommendation of their physicians.

The guidance document states that unwarranted variation in coverage at the local level may prompt CMS to consider an internally generated NCD. The mere fact that there may be some variation on coverage decisions at the local level should not, without more, be the basis for initiating the national process. CMS should carefully articulate its rationale for considering an NCD for therapies or equipment that are already available to beneficiaries as a result of local coverage decisions. For example, how will CMS assess whether the variation is "unwarranted"? As we suggested above, CMS should notify the public whenever it is contemplating initiating an NCD for equipment or therapy that beneficiaries currently use *before* publishing the tracking sheet. This early notice may provide CMS with important data and insight on issues surrounding the local variation, avoiding the need to undertake a national process.

Finally, AAHomecare agrees that a national NCD would be appropriate where CMS can identify program integrity issues occurring as a result of a policy that local carriers will not revise. Similarly, where there is a quantifiable disparity that adversely affects beneficiaries in a specific way, a national NCD may also be justified.

Consideration of Safety Issues

CMS also identifies questions surrounding the safety of an item or therapy as a basis for initiating an internally generated NCD. AAHomecare agrees that the safety of new and existing technology is an important public concern. However, AAHomecare does not believe that safety issues are within CMS' purview. With respect to coverage, CMS must determine whether an item or service is "reasonable and necessary" as that standard is defined under the Social Security Act. The FDA is responsible for evaluating safety issues, and CMS should not revisit those issues in the context of an NCD.

B. CMS Referrals to the MCAC and External Technology Assessments

The guidance documents also address factors CMS considers in making referrals to the MCAC and in commissioning external technology assessments. As we noted above, CMS retains significant discretion under the circumstances described in the guidance documents. Consistent with the recommendations we made above, AAHomecare believes that the NCD process will benefit from a more precise definition of how CMS arrives at the decision to engage an external technology assessment or make a referral to the MCAC. More importantly, AAHomecare recommends that CMS allow more direct participation by the public in determining when it is necessary to engage an external technology assessment or a review by the MCAC.

Specifically, CMS should consider stakeholder input in determining whether an MCAC referral or an external technology assessment is appropriate. Clearly, the individual or entity requesting the NCD should have the ability to ask for a technology assessment if it believes one is necessary. AAHomecare recommends that other stakeholders also be given the opportunity to request an external technology assessment. CMS should establish a protocol that defines when and how stakeholders can make the request, the factors CMS will consider in evaluating the request, and the timeframe in which CMS must respond. Along these lines, stakeholders should be able to identify the individuals or entities they believe have appropriate experience and skill to perform the technology assessment. Finally, the public should have access to the full technology assessment via the CMS website.

CMS should engage stakeholders who understand the technology and the needs of beneficiaries who will use it in developing the issues that will be reviewed by the MCAC or the technology assessment. Framing the issues in this fashion establishes the scope of the inquiry and will serve to inform the process from its inception. The guidance document should establish how CMS intends to engage stakeholders in identifying the issues that need to be addressed. In this context, CMS needs to also consider how it will respond to and resolve differences among stakeholders in their approach to the NCD.

Likewise, there should be a mechanism to ensure greater public participation in the MCAC meeting. For example, clinicians with experience in using the item or therapy that is the subject of the NCD, or with experience treating the patient population that
would benefit from it, should be allowed to address the MCAC on relevant matters. At a minimum, this process should give stakeholders the opportunity to submit evidence and comments directly to the MCAC prior to a meeting. We note that CMS employed town hall style meetings in developing the NCD for mobility assistive devices and believe that that format can be successfully incorporated into the NCD process, if it is not part of the MCAC meeting.

MCAC Selection Process

Finally AAHomecare notes that the MCAC Charter specifies the qualifications and credentials of candidates for membership on the committee. What remains unclear is how CMS exercises its discretion in making a selection for MCAC membership from among the qualified candidates. AAHomecare requests that CMS articulate the criteria that it will use in making appointments to the MCAC.

II. CONCLUSION

As we have expressed in these comments, AAHomecare supports CMS' efforts to make the NCD process more transparent. We recognize that these guidance documents are important steps towards that goal. While CMS has made significant progress in clarifying the processes underlying an NCD, there is still a need for more precision and a better definition of stakeholder rights throughout the NCD process. AAHomecare especially emphasizes the need for public notice that CMS is considering an NCD *before* it commences the national process. Likewise, AAHomecare believes that CMS needs to clearly state that it intends to preserve the local coverage process as an important avenue for ensuring beneficiary access to equipment and services. Finally, CMS should define a process that engages the public in determining when to seek an MCAC review or an external technology assessment.

AAHomecare appreciates the opportunity to submit these comments and remains available to discuss them with you in greater detail at your convenience. Moreover, we look forward to working with CMS on these important issues in the months ahead.

Commenter: Lucia DiVenere/Gordon Wheeler
Organization: Alliance of Specialty Medicine

Founded in 2001, the Alliance of Specialty Medicine (the Alliance) represents over 200,000 physicians in 13 medical specialty organizations and serves as a strong voice for specialty medicine.

The Alliance appreciates the opportunity to comment on CMS' recent guidance documents outlining the process for Medicare's national coverage process. We also thank CMS for its continued efforts to improve the national coverage process and make decisions within substantially shortened statutory timeframes. In this letter, we address issues of concern to us in all three guidance documents.

Factors CMS Considers in Opening a National Coverage Determination (NCD)

CMS briefly describes its process for internally generating a national coverage decision. We recommend that CMS provide more specific criteria on reasons why an NCD request may be generated internally. As mentioned in the guidance document, we encourage CMS to contact the relevant professional medical specialty societies prior to a formal announcement on the CMS website that it has generated an internal review. This contact may be helpful to CMS in providing available medical expertise and in formulating policy questions for public consideration.

We also recommend that CMS specify its list of reasons why an internally generated review is best dealt with as an NCD versus a local coverage decision. It is essential to maintain the local coverage process which provides access to much needed therapies for Medicare beneficiaries in a more timely fashion. At some point, however, conflicting policy among local carriers or significant variations in utilization around the country of a technology may be cited as reasons why an issue is better addressed at a national versus local level.

Furthermore, we also recommend that CMS post all items on its website that are being considered for national action where there have been discussions between CMS and the potential NCD requestor. The guidance document currently states that CMS may from time-to-time, announce potential topics on its website. It is crucial to post all issues for consideration and contact the professional medical societies as early in the process as possible, especially in light of the strict timeframes and the ability of key stakeholders to work through their own internal processes.

We realize that it is in industry's best interest to request coverage for new technologies or expansion of coverage on existing technologies for expanded indications as early as deemed possible. Professional medical societies, however, have different timeframes and evidence standards prior to issuing clinical guidelines or expert clinical consensus documents. Many of these documents are considered the "gold standard" and are valuable resources to CMS. Some societies may not publish a guideline or statement until peer reviewed literature is available whereas another society may announce its support for coverage based on late-breaking clinical trial results. Therefore, we encourage CMS to contact professional societies as early as possible in its deliberations on a potential NCD in order to receive the best possible review of clinical evidence that they can provide.

We also encourage CMS to work out any potential research questions or issues with the requestor prior to starting the official comment period. This will prevent timeframe delays throughout the process, which in past decisions has delayed the overall timeframe to announce a positive coverage decision.

Last, the draft guidance raises safety issues as a reason that an internally generated NCD request may be initiated. We note that the appropriate mechanism for determining safety is within the purview of the

Food and Drug Administration and that CMS' role is to determine whether a service or technology is reasonable and necessary.

Draft Guidances on Factors CMS Considers in Commissioning External Technology Assessment and Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee (MCAC)

As professional medical societies, we are available for consultation on framing the questions for technology assessments or review by the MCAC. It is important that CMS work at the outset with the professional medical societies, as well as the NCD requestor or other important stakeholders.

We ask that you specify the reasons an issue is referred for a technology assessment versus to the MCAC in the final guidance documents.

We appreciate the improvements that have been made in the MCAC process over the past several years and have several suggestions for continued improvement. First, MCAC meetings need to allow more time for stakeholder and public comments and allow for greater public participation that is currently lacking. Second, the questions for deliberation at the MCAC meetings need to be finalized and disseminated prior to the meeting date with adequate time for review by the panelists and the public. There have been recent occasions where the questions for consideration by the panelists have been worded during the actual meeting. This prevents the process from working to the best of its ability and prevents the MCAC panelists from sufficiently preparing for the meeting.

Last, we recommend that CMS include in the guidance documents that the initiation of a NCD or referral of an issue for a technology assessment or to the MCAC does not mean that local coverage is pre-empted. Carriers need to be instructed in the Medicare Coverage Manual that current coverage prevails until the announcement of any national policy decision.

The Alliance of Specialty Medicine thanks CMS for the opportunity to comment on the draft guidance documents. Again, we offer our expertise to CMS as the professional medical societies in any way possible that may assist CMS to make sound coverage decisions using evidenced-based medicine.

Sincerely,

American Academy of Dermatology Association
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Emergency Physicians
American College of Obstetricians and Gynecologists
American Gastroenterological Association
American Society for Therapeutic Radiology and Oncology
American Society of Cataract & Refractive Surgeons
American Urological Association
Congress of Neurological Surgeons
National Association of Spine Specialists
The Society of Thoracic Surgeons

Commenter: Pamela S. Douglas/Michael Crowley
Organization: American College of Cardiology/ Society for Cardiovascular Angiography and Interventions

The American College of Cardiology (ACC) and the Society for Cardiovascular Angiography and Interventions (SCAI) appreciate the opportunity to comment on proposed revisions to the CMS National Coverage Determination (NCD) process. The ACC is a 31,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care through education, research promotion, development and application of standards and guidelines, and to influence health care policy. The SCAI is a professional association representing 3,200 interventional cardiologists nationwide. SCAI promotes excellence in cardiac catheterization and angiography through physician education and representation, clinical guidelines and quality assurance to enhance patient care.

We commend CMS for its continued efforts to improve the national coverage determination process. A more transparent and understandable process is vital to ensure a level playing field for requestors, and in general, a more predictable process.

The ACC and SCAI submit the following comments and suggestions to help ensure that the national coverage request and determination process serves to promote Medicare beneficiaries' access to breakthrough technologies. Millions of patients covered by private insurers would also be likely to benefit, as private insurers often review CMS' actions when formulating their own procedures and policies.

Factors CMS Considers in Opening a National Coverage Determination

1) We encourage CMS to set forth a list of specific criteria that must be met in order to initiate an internally generated national coverage determination request.

2) It would be helpful for CMS to more fully outline its intentions regarding off label use. We are concerned that the potential exists for CMS to compromise the local coverage process, and ultimately, deny patients access to much needed therapies.

3) We believe it is very important for CMS and FDA to collaborate and agree on safety criteria, so that criteria accepted by FDA are accepted by CMS. This would make the process less ambiguous for physicians, industry and patients.

4) To provide optimal care to Medicare beneficiaries, it is essential that CMS solicit input from medical professional societies early in the course of the coverage determination process. Rather than post topics for consideration on a "time to time" basis, we encourage CMS to post all topics on a regular, quarterly basis, and if feasible, more frequently than every quarter. Professional societies often have advanced and up-to-date information about the latest medical technologies and may be developing clinical guidelines even before published data are available.

Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee (MCAC); Factors CMS Considers in Commissioning External Technology Assessments

1) As professional medical societies, we would be pleased to consult with CMS in formulating assessment questions for MCAC or in providing clinical input for the design of External Technology Assessments. An adequate basis for consideration of the technology is essential for a full and fair evaluation.

2) We encourage CMS to post on its website all requests for new Technology Assessments and all Assessments currently underway. We also would like the opportunity to review and comment on draft External Technology Assessment reports.

3) CMS should clarify how decisions are made to refer a topic for consideration to MCAC or for an External Technology Assessment. Why is one path chosen over the other?

4) It would be helpful to implement several procedural reforms. Specific evidentiary questions should be finalized and published prior to the MCAC meeting date; MCAC panelists should receive all available evidence prior to the meeting date in order for a topic to receive full and timely consideration; CMS should extend the public comment period during the MCAC meetings.

5) ACC and SCAI believe it is important for CMS to include a statement in these guidance documents that local coverage is not pre-empted merely by the initiation of an internal or external National Coverage Determination request or referral of a topic for consideration by MCAC or through an External Technology Assessment.

Commenter: David V. Foster
Organization: Biogen idec

(Comment on next page)

biogen idec

May 9, 2005

VIA HAND DELIVERY

Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mail Stop: C1-12-28
7500 Security Boulevard
Baltimore, Maryland 21244

RE: Guidance Document: Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee

Dear Sir or Madam:

Biogen Idec appreciates the opportunity to comment on the above-referenced draft Guidance Document created under Section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Biogen Idec's products and development programs address a variety of key medical needs in the areas of oncology, neurology, dermatology and rheumatology. We are a global leader in biotechnology headquartered in Cambridge, Massachusetts with Centers of Excellence in San Diego and Cambridge. Biological therapies have increasingly offered Medicare beneficiaries new hope for cure or remission from life-threatening illnesses such as cancer, and for improved health outcomes and greater quality of life from chronic debilitating illnesses such as Multiple Sclerosis.

Biogen Idec offers the following recommendations with respect to the draft Guidance Document concerning referral of coverage matters to the Medicare Coverage Advisory Committee (MCAC):

- Due to the potential for the MCAC to incorporate the comments and opinions of beneficiaries, providers, and other stakeholders, we urge CMS to provide a process through which a manufacturer or other proponent of a particular item or service can request referral to the MCAC

- CMS states that materials generated for MCAC review and consideration will be disseminated at least 30 days in advance of a scheduled MCAC meeting and in most cases the material is made available to the public. Because the MCAC is a validly chartered FACA committee acting through open public meetings, it is imperative that all materials be readily available to any entity requesting that information. We request that CMS, at a minimum, notate the tracking sheet upon dissemination of review materials and provide the public with the ability to receive this information.

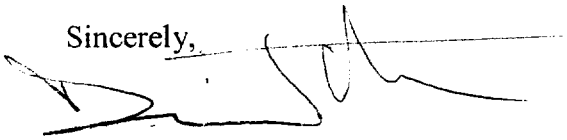
Biogen Idec 801 Pennsylvania Avenue, N.W. Suite 710 Washington, D.C. 20004 Phone 202 393 1440 Fax 202 347 1066 www.biogenidec.com

Expedited requests could be filled at the expense of the requesting entity, however, we urge CMS to process these requests outside the normal timeframes for processing Freedom of Information Act (FOIA) requests.

- Biogen Idec suggests that CMS coverage decisions will benefit from public input in response to review materials submitted to MCAC members. The requirement that commenters submit information no later than 20 days prior to the meeting may not facilitate meaningful public comment if MCAC members receive documents 30 days prior to the meeting and the information is not readily available to the commenting public until days or weeks later. We urge CMS to ensure that public stakeholders have a reasonable opportunity to request and receive MCAC review information, and no less than 14 days between the opportunity for receipt of information and the deadline for comments.

Biogen Idec applauds CMS in its efforts to further illuminate its National Coverage Decision process. If you have any questions regarding our comments, please feel free to contact me at (202) 383-1444.

Sincerely,



David V. Foster
Vice President, Government Relations

biogen idec

May 9, 2005

VIA HAND DELIVERY

Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mail Stop: C1-12-28
7500 Security Boulevard
Baltimore, Maryland 21244

RE: Guidance Document: Factors CMS Considers in Opening a National Coverage Decision

Dear Sir or Madam:

Biogen Idec appreciates the opportunity to comment on the above-referenced draft Guidance Document created under Section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Biogen Idec is a global leader in biotechnology headquartered in Cambridge, Massachusetts with Centers of Excellence in San Diego and Cambridge. Our products and development programs address a variety of key medical needs in the areas of oncology, neurology, dermatology and rheumatology. Biological therapies have increasingly offered Medicare beneficiaries new hope for cure or remission from life-threatening illnesses such as cancer, and for improved health outcomes and greater quality of life from chronic debilitating illnesses such as Multiple Sclerosis.

We have presented our comments under headings that coincide with those contained in the draft Guidance Document.

I. Prior to Initiation

A. Informal contacts and inquiries

Biogen Idec expects that CMS receives far more general, informal inquiries regarding coverage of particular items and services than it receives formal requests for a coverage decision. We also expect that stakeholders may be hesitant to approach CMS in these informal discussions due to the potential that an inquiry may trigger coverage scrutiny that is not otherwise indicated. Biogen Idec requests that CMS clarify:

- the circumstances under which an informal inquiry may trigger an internally generated request for a National Coverage Decision, i.e., does the existence of an informal inquiry in and of itself trigger a national coverage decision?;

- the applicability of the informal contacts and inquiries process to CMS contractors; and

- the nature of the "assistance" CMS expects to offer inquiring parties in meeting the "reasonable and necessary" threshold for Medicare coverage of particular items and services.

B. Preliminary Meetings

Biogen Idec supports CMS in its reliance on preliminary discussions between the agency and requestors to streamline the NCD process. Given that these discussions appear designed to occur prior to receipt of a formal request for a NCD, Biogen Idec suggests that CMS also utilize this process to determine whether the technology is appropriate for a NCD. For example, many new drugs and biologicals receive FDA approval while the manufacturer engages in clinical trials evaluating additional potential indications. The relatively lengthy NCD (and NCD reconsideration) process mitigate against initiating coverage review of such products unless the therapy is known to be harmful to specific subpopulations, or is clearly subject to fraud and abuse that cannot be addressed at the local contractor level.

Biogen Idec encourages CMS to definitively include the manufacturer of any drug or biological in any preliminary meeting relating to a possible NCD for that manufacturer's product. In some cases, the requester of a formal NCD may be a party other than the manufacturer. In order to promote a fair and reasonable discussion during the preliminary meeting, Biogen Idec urges that CMS include in the Draft Guidance a provision requiring that the manufacturer be invited to participate in the preliminary meeting process.

Similarly, Biogen Idec requests that manufacturers be notified affirmatively when CMS initiates an NCD related to that manufacturer's product(s). As currently written, it is possible that the manufacturer would learn of the NCD only via the website, and does not require specific notification to the manufacturer. In order to facilitate a collaborative process, specific, affirmative notification is required.

Biogen Idec urges CMS to engage in the preliminary meeting process when the agency expects to issue an internally-generated request for a NCD. Although the draft Guidance Document appears to suggest that preliminary meetings serve to streamline the NCD process for external requestors, the same benefits (avoidance of duplicative work and timely availability of relevant evidence) would accrue to the agency in assessing the need to generate its own request for an NCD. Moreover, the cooperative public/private partnership envisioned by the NCD process may be undermined when a manufacturer receives its first notice of coverage scrutiny in the form of an entry on the CMS coverage tracking sheet.

II. Who Can Request an NCD

Requests Initiated Internally

Biogen Idec appreciates that CMS has articulated the factors that might trigger an internal request for a National Coverage Decision. Our review of the Coverage Database reveals that a significant portion of NCDs have been initiated based upon an internal request. Biogen Idec reiterates its previous contention that the NCD process is not well-suited to the evolving nature of physician prescribing patters for drugs and biologicals.

Specifically, CMS indicates that it may embark on an NCD when off-label use of a drug raises "significant concerns" about the "safe and effective use of a therapy." Biogen Idec urges CMS to proceed cautiously in fashioning NCDs directed to limit use of drugs and biologicals, as off-label prescribing has long been recognized as an essential component of medical practice. Similarly, variation in local policies is not in and of itself undesirable, even absent a medical basis for such variation. For newer products in particular, the local coverage decision process has long served as a means for the Medicare program to test various approaches devised by the medical professionals who manage claims processing and review at the local level. These local contractors are in the best position to gather data and other information from providers serving Medicare beneficiaries, and to fashion policies that protect the fiscal integrity of the Medicare program while permitting physicians to utilize therapeutic advances according to their professional judgment and the needs of their specific patients. The local coverage process also retains the flexibility to quickly respond to provider introduction of new evidence that a particular treatment is beneficial for a previously non-covered indication.

Clearly, there may be instances in which physician prescribing patterns indicate over-utilization of specific therapies on a national scale. We, therefore, urge CMS to reserve the National Coverage process with respect to drugs for those instances in which:

- significant concerns exist (rather than "have been raised") about the safety or effectiveness of a treatment for an indication(s) for which Medicare has received a substantial number of claims; and
- there is wide variation in billing practices not related to variation in clinical need, or of potential for fraud; that is
- not adequately resolved under local policies

Biogen Idec urges CMS to recognize that drugs and biologicals are situated differently than medical devices from a statutory coverage standpoint. Because of this difference, the following factors identified as potential triggers for NCD initiation are not completely applicable to drugs and biologicals::

- The health technology represents a substantial clinical advance and is likely to result in a significant health benefit if it diffuses more rapidly to all patients for whom it is indicated

- In the absence of a national non-coverage policy for a specific therapy, this factor is not applicable to drugs and biologicals for which claims may be submitted utilizing a miscellaneous HCPCS code

- More rapid diffusion of the technology is likely to have a significant programmatic impact on Medicare and on other Medicare-related public policies

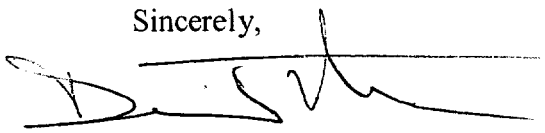
  - If this factor is cost-related, Biogen Idec suggests that CMS more clearly articulate the financial and/or utilization thresholds and other factors likely to mitigate in favor of a NCD

As previously articulated, Biogen Idec strongly urges CMS to engage the manufacturer and other potential stakeholders in preliminary discussions prior to initiating an internally-generated request for an NCD. Early discussions between these parties may illuminate an approach that is more cost-effective for CMS than the NCD process, and that does not have the potential of limiting beneficiary access to therapies proven beneficial subsequent to implementation of a restrictive NCD.

Conclusion

Biogen Idec supports CMS in its efforts to further the transparency, predictability, and public participation in its National Coverage Decision process. As always, Biogen Idec appreciates your consideration of its comments. Please feel free to contact me at (202) 383-1444 if you have any questions or request additional information.

Sincerely,



David V. Foster
Vice President, Government Relations

Commenter: David L. Gollaher, Ph.D.
Organization: California Healthcare Institute (CHI)

(Comment on next page)

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May 7, 2005

BY E-MAIL. COPY TO FOLLOW VIA FEDEX

Steve Phurrough, MD, MPA
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
Mail Stop: C1-12-28
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Baltimore, MD 21244

RE: Comments on Draft Guidance Entitled "Factors CMS Considers in Opening a National Coverage Determination"

Dear Dr. Phurrough and the staff of the Coverage and Analysis Group:

The California Healthcare Institute (CHI) welcomes this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) draft guidance document entitled "Factors CMS Considers in Opening a National Coverage Determination."[1] CHI represents the biomedical sector of the California economy and unites more than 250 of California's leading life sciences firms, universities, and private research institutes in support of biomedical science, biotechnology, and pharmaceutical and medical device innovation. California is the global leader in biomedical R&D, with more than one-third of all U.S. biotechnology and medical device firms, turning scientific discoveries into medical products at an unprecedented rate. California firms alone produce more than 20 percent of all medical instruments in the United States and lead the nation in bringing to market frontline treatments and therapies for diseases such as AIDS, breast cancer, stroke, and diabetes.

As the representative of an industry committed to research and innovation, CHI has been very active on issues regarding coverage of drugs, biologicals, and devices. Without appropriate coverage policies, Medicare beneficiaries can be deprived access to much needed therapies – not only to therapies that exist today, but to those on the horizon that offer patients and their families the hope of a much

[1] The draft document, referred to herein as the "Guidance on Opening an NCD," is available at http://www.cms.hhs.gov/coverage/download/guidanceopeninganncd.pdf.

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brighter future. We were pleased that Congress instructed CMS to develop guidance documents to allow the public to have a greater understanding of the Medicare national coverage determination (NCD) process. We appreciate the agency's timely development of a number of these guidances.

CHI views these guidance documents as a means to promote the important goals of ensuring that the Medicare coverage process is open, predictable, and transparent. We believe that the Guidance on Opening an NCD does not serve these goals as well as it could, however. For example, the agency could provide more predictability and transparency regarding internally generated NCD requests by publicizing a list of topics that it is considering before formally opening an NCD. Similarly, CHI recommends that the agency ensure that it consults with pertinent groups prior to the initiation of an NCD review, regardless of whether the request is externally or internally generated. Further, we believe that the list of circumstances that may prompt an internally generated request generally offers insufficient detail and thus creates as many questions as it answers. We discuss these and other issues below. We sincerely hope CMS will address our concerns as the coverage guidances are finalized.

I. Ensuring an Open, Transparent, and Efficient Coverage Process

The release of coverage guidance documents provides CMS an opportunity to make the NCD process more predictable and transparent than it has been in the past. Recently, for example, the agency has conducted NCD reviews without any notice and without revealing why the review was commenced. Particularly now that there are statutory timeframes for conducting such reviews, it is even more imperative that the agency conduct coverage reviews in an open, transparent, and efficient manner. CHI is concerned that a process with statutory timeframes that does not provide clear information on process and substance will result in narrow coverage determinations that will impede beneficiary access to new technologies. Accordingly, CHI urges CMS to ensure that all of its guidance documents provide clear direction so that the public can understand and predict the agency's actions.

In addition, we believe that it is critical for the agency to communicate meaningfully with the public throughout the coverage process. We see no commitment by CMS in the Guidance on Opening an NCD to engage in two-way discussions with stakeholders who have an interest in a particular item or service. As explained further in Section II below, these discussions can make the coverage process more efficient. Our members have participated in coverage meetings for specific items or services during which the agency offered no real, substantive insight into its views. The NCD process would be improved greatly if CMS worked more collaboratively and interactively with the public. Such give and take can help

both CMS and the public focus on the important issues involved in determining whether Medicare beneficiaries access to a particular item or service is "reasonable and necessary."

Finally, we believe that CMS must make a clear statement that the opening of an NCD review does not change any existing local coverage policies and that such policies remain in force until any NCD becomes finalized and effective. We understand that some contractors stop applying their local policies once an NCD review has been opened. This is not appropriate because a NCD is not established until a final NCD is issued, taking into account the comments submitted to the draft NCD. CMS could expressly dispel this misunderstanding in the final guidance document and ensure that the NCD review process does not interfere with current coverage policies. An explicit statement also should be made in the local coverage determination chapter of the Medicare Program Integrity Manual that contractors should not suspend or revise local coverage determinations in response to the initiation of a NCD review until there is an effective and final NCD.

II. Need for Transparency and Predictability in the Opening of Internally Generated NCDs

Historically, the commencement of internally generated NCD reviews has been one of the least predictable aspects of the Medicare coverage process. Typically, a tracking sheet appears on the CMS website identifying an item or service for which the agency is undertaking an NCD review. That tracking sheet is the only source of information on the review, and it seldom explains why the agency decided to initiate it. CHI believes it is incumbent on the agency to shed light on this process so that the public can understand why CMS internally generates a request and what information the agency considers.

In our view, CMS should make the NCD process more transparent and predictable by creating a list of **all** topics that it is considering for internally generated requests. The public also should have an opportunity to submit additional information for the agency's consideration. The listing would be made available to the public (e.g., through the CMS website) and would contain a statement identifying the item or service being considered for an NCD, why it is being considered, and the evidence upon which the agency is basing its consideration of internally generating an NCD. CHI believes that this listing and the accompanying information will facilitate a number of the agency's goals, especially making efficient use of industry and government resources.[2] We recommend that the agency include statistics related to this listing (e.g., the number of items and services included, duration on the list, number for which an

[2] *See* Guidance on Opening an NCD at 3.

NCD review is initiated) in the agency's annual report to Congress on NCDs so that Congress and the public can see the effect of the listing.

By identifying items or services under consideration for an NCD review and the agency's preliminary view of the evidence before the formal opening of an NCD, CMS will be able to receive valuable information from the public prior to the initiation of a coverage review and the start of the statutory clock. This information could help the agency determine whether an NCD review in fact is warranted or whether to refine its scope. For instance, the manufacturer of an item appearing on the listing could provide CMS with information that would enhance the agency's understanding of the item or the available evidence or could explain that the indication CMS is considering is one for which the manufacturer already is investigating. Such information could clarify for the agency that its resources would not be well spent on initiating an NCD for that item or service. Alternatively, the information could lead to a greater understanding of the item or service so that if an NCD review is initiated, the limited time for that review would not be spent needlessly correcting a misconception that could have been resolved prior to the start of the clock. Further, when CMS explains why it is considering various items or services for NCD review, the public will better understand why the agency internally generates NCD requests.

In addition to identifying potential topics, CMS must consult with relevant groups, including the manufacturer(s) of the technology, before initiating an NCD review. In the Guidance on Opening an NCD, CMS indicates that it "may" consult with various entities at this stage. CHI believes that the agency should commit itself to engaging in such consultations, at least with the manufacturer of the technology under consideration. Consultation with the pertinent manufacturer is likely to occur as a result of the listing of items or services under consideration for NCD review as we recommend above). In the rare event that it does not, CMS should consult with the manufacturer before commencing the NCD review to ensure that it has a sufficient understanding of the item or service before the review is opened. Although CHI is not suggesting that CMS take such initiative to obtain input from other groups, the agency should carefully consider any information offered by beneficiary and provider groups prior to initiating the review. Again, the value that these entities can bring to the process is dependent upon their knowledge that CMS is considering a particular item or service, reinforcing the need for the listing described above.

Finally, we urge CMS to consider sharing its instructions to contractors implementing a final NCD with the relevant groups, such as the requestor or the manufacturer, immediately prior to their release. This would allow CMS to resolve any factual errors or omissions before the document is made public and

implemented. We believe this process could save such groups and CMS the time and effort of having to correct and reissue the instructions, potentially avoiding an unnecessary delay in patient access.

III. Refining the Circumstances that May Prompt an Internally Generated Request

As noted earlier, CHI views the issuance of coverage guidance documents as an opportunity for CMS to create a more open, transparent, and predictable coverage process. The discussion in the draft Guidance on Opening an NCD on the circumstances that may prompt an internally generated request unfortunately does not take advantage of this opportunity. Instead, many of the bulleted circumstances contain vague and undefined language that offers the public no clear explanation why the agency decides to internally generate a request.

For new technologies, CMS indicates that an internally generated NCD may be considered because more rapid diffusion of the technology is likely to have "a significant programmatic impact" on Medicare.[3] Other than providing an example of a reduction in health inequalities, CMS offers no guidance on what constitutes a significant programmatic impact. As a result, this circumstance could be applied as broadly or as narrowly as the agency desires, with no clear standard upon which the public can rely. To the extent that CMS considers the cost to the program in ascertaining programmatic impact, we believe that the agency lacks the authority to do so in light of the fact that the agency has tried, on a few occasions, to introduce cost into the coverage criteria through rulemaking, but never has finalized such a criterion.[4] CMS cannot do through a guidance document what it has been unable to do through rulemaking.

CMS also specifies that an internally generated NCD may be considered when the technology represents a "substantial clinical advance" and is likely to result in "a significant health benefit" if it diffuses more rapidly.[5] Although CHI applauds the agency's willingness to use the NCD process to aid diffusion of a new technology, it would be helpful to understand when a technology represents a substantial clinical advance and what the agency considers to be a significant health benefit. Similarly, the agency does not explain what constitutes "significant" uncertainty about safety and effectiveness, potentially causing an internally generated NCD to begin.[6]

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3 *See* Guidance on Opening an NCD at 5.
4 *See* 65 Fed. Reg. 31124 (May 16, 2000); 54 Fed. Reg. 4302 (Jan. 30, 1989).
5 *See* Guidance on Opening an NCD at 5.
6 *See* Guidance on Opening an NCD at 5.

With regard to safety and effectiveness, CMS indicates that where there are significant questions of safety and effectiveness of an item or service, it may cause an internally generated NCD to be initiated for a new or an existing technology.[7] CHI believes that questions regarding safety and effectiveness of a technology are the authority and mandate of the Food and Drug Administration, not CMS. As a result, we recommend that CMS focus on "reasonable and necessary" and not reproduce the work of other agencies.

Likewise, generating an NCD when "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"[8] is not an appropriate circumstance for internally generating a request. This is an issue for other parts of CMS (e.g., payment policy or program integrity staff) to address rather than the coverage staff. CMS should not use its scarce resources to establish coverage policies to address billing issues.

Overall, CHI agrees that the following are appropriate reasons for CMS to internally generate an NCD:

1. Significant controversy exists on whether the item or service is "reasonable and necessary" for the care of patients and local coverage processes are unlikely to resolve or address these concerns;

2. Documented program integrity concerns have arisen under existing local or national policies, and there is potential for fraud under existing policies, and local coverage processes are unlikely to resolve or address these program integrity concerns; or

3. Interpretation of credible, new peer-reviewed evidence indicates that changes may be warranted in current policies for the kinds of reasons described above, and local coverage processes are unlikely to resolve or address these concerns.

Although we also see merit in using the NCD process to resolve inconsistent local policies, we believe that there should be a significant need for a resolution before an NCD is opened. CMS should not internally generate a NCD merely because a drug, biological, or device is newly approved or has not had adequate time to go through the local coverage process, however. The current local coverage process generally works well to ensure beneficiary access to appropriate therapies. Specifically, it permits local contractors to adjust policies as clinical evidence develops and can speed beneficiary access to new treatments. Further, it recognizes

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7 *See* Guidance on Opening an NCD at 5.

8 *See* Guidance on Opening an NCD at 5.

the variability in patient response to different treatments, allowing physicians to request individualized coverage decisions and tailor their care to individual patients accordingly.

CHI recommends that the NCD process be used to resolve inconsistencies in local practice only when they raise patient access or quality of care concerns. At the same time, in the portion of the guidance that addresses when it internally generates a request, the agency should reaffirm that coverage is determined locally unless there is an effective and final NCD regarding the item or service. In addition, CHI urges CMS to reexamine carefully the stated circumstances that may prompt an internally generated review to provide greater clarity and to ensure that only proper considerations are included in any listing of circumstances.

IV. Ensuring Compliance with Coverage Guidance Documents

CHI welcomes the opportunity to assist in the development of the various coverage guidance documents. We hope that these comments will help to produce a final document that provides more openness, transparency, and predictability to the coverage process. No matter how good any of the final guidance documents are, they will not serve their purpose if the agency does not adhere to the principles articulated therein. Accordingly, we urge CMS to establish a rigorous process to ensure that once a guidance document is adopted, it is followed. For example, the final document may include specific steps for the agency to follow prior to opening an NCD. There needs to be a mechanism to ensure that that occurs before an NCD is formally opened. We recognize that these internal steps are part of the agency's deliberative process that typically is not made public. CHI's recommendation is that others at CMS, such as the Council for Technology and Innovation, be charged with the responsibility to ensure that the agency follows its coverage guidance documents.

V. Conclusion

CHI appreciates the agency's attempt to provide guidance on the factors considered in opening an NCD and the opportunity to comment on the draft document. We believe that the draft guidance must be revised substantially, however, if the final guidance will make the NCD process more open, transparent, and predictable. We suggest a number of ways to accomplish this result, including creating and publicizing a listing of items and services the agency is considering for internally generated requests, improving CMS' communication with the public, and refining the agency's stated circumstances for internally generating a review.

CHI looks forward to working with you to shed more light on the coverage process in finalizing the Guidance on Opening an NCD and in the development of future guidance documents. Please contact Todd Gillenwater at 858-551-6677 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

David L. Gollaher, PhD
President & CEO

Commenter: Jim Greenwood
Organization: Biotechnology Industry Organization (BIO)

(Comment on next page)

May 6, 2005

BY HAND DELIVERY

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Baltimore, MD 21244

Re: Draft Guidance for the Public, Industry, and CMS Staff: (1) Factors CMS Considers in Opening a National Coverage Determination; (2) Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee; and (3) Factors CMS Considers in Commissioning an External Technology Assessment

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) draft guidance documents regarding factors CMS considers in opening a national coverage determination (NCD), referring topics to the Medicare Coverage Advisory Committee (MCAC), and commissioning external technology assessments. BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products.

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These draft guidance documents will play an important role in future coverage of technologies, potentially having a dramatic impact on patient access. Should the coverage process become overly burdensome and rigid, access to new technologies could be hindered. In addition, excessive evidentiary requirements in the form of clinical trials and registries also could divert investments in research and development for new therapies. The coverage process should be objective, involve iterative discussions with relevant stakeholders, and have the goals of ensuring high quality patient care and beneficiary access to innovative therapies. BIO urges CMS to take these factors into account as it proposes revised drafts of these and other coverage guidances in the future.

Representing an industry that is devoted to discovering new treatments and ensuring patient access to them, BIO strongly believes that the processes through which Medicare's coverage decisions regarding these therapies are made must be predictable, transparent, and open to the public. We agree with CMS that the NCD process has to embody these qualities more fully. As currently written, the draft guidance documents do not provide sufficient transparency or predictability. We offer the following comments to help CMS create guidance documents that will improve understanding of the agency's procedures and offer more opportunities for stakeholder interaction with the agency.

I. Factors CMS Considers in Opening a NCD

The draft guidance document on the factors CMS considers in opening a NCD builds off CMS' prior notices regarding the process for making coverage determinations.[1] Although the draft guidance provides more information than has been available previously on the process for internally generated requests, it leaves many important questions unanswered and fails to provide assurances that CMS will apply the same procedures for notice and input to both internally and externally initiated requests. We believe that the agency must include more transparency and opportunity for public consultation at each step of the process. Moreover, CMS must stress that beneficiaries and their access to appropriate care should be the primary focus of the NCD process.

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[1] See, e.g., Medicare Program; Revised Process for Making National Coverage Determinations, 68 Fed. Reg. 55634 (Sept. 26, 2003).

A. Provide more public notice and opportunity for consultation prior to initiation of an internally generated request for a NCD and post all potential future NCDs on a tracking sheet.

In the draft guidance document, CMS describes its possible responses to external requestors' informal, preliminary inquiries, but does not describe an analogous process for involving stakeholders in CMS' consideration of whether to generate a NCD internally. CMS encourages requestors to make informal contacts and inquiries before requesting a NCD and offers to help requestors fulfill the agency's information requirements. Although we appreciate the agency's willingness to help external requestors, we believe the agency should seek and accept similar assistance from stakeholders. Preliminary notice of topics under consideration and informal meetings with stakeholders would be as useful for CMS as they are for the requestors.

We agree with CMS that these efforts can "conserve both industry and government resources in avoiding duplicative work."[2] These early communications can help CMS to learn more about the item or service for which it is considering a NCD, potentially eliminating the need for a NCD or providing an early resolution of issues that otherwise would have to be considered during the statutorily limited timeframe for making NCDs. These contacts also would give stakeholders early notice of CMS' proposed actions, allowing them to provide more meaningful comment and offer greater assistance to the agency at the outset to decide whether a NCD should be undertaken. If it is, they can offer greater assistance to the agency during the statutorily limited timeframe for making NCDs. Accordingly, we urge CMS to reach out to patients, providers, and manufacturers during its initial consideration of whether to request a NCD.

The recent national coverage analysis for radioimmunotherapy for Non-Hodgkin's Lymphoma (CAG-00163N) is an example of an item or service that would have benefited from greater consideration before the NCD formally was opened. We are pleased that CMS' recently released proposed decision memorandum would not change current coverage policy for use of either

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[2] Draft Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, Mar. 9, 2005, at 3.

Zevalin® or Bexxar®;[3] however, both the agency's and stakeholders' resources could have been conserved had the agency engaged in the processes we are recommending prior to officially internally generating the NCD request.

We recommend three changes to the draft guidance to address our concerns. First, the guidance must include means for CMS to inform the public of the topics it is considering for an internally generated request at the earliest possible stage. The draft guidance says that CMS "may, from time-to-time, announce on [its] website the topics that are being considered for potential internally generated requests before the posting of a tracking sheet."[4] We urge CMS to make this announcement in all cases and to provide sufficient detail about the item or service being considered, why it is being considered, the evidence CMS has reviewed, and the individuals or organizations with whom the agency has consulted all before formally opening a NCD. This information is necessary to help stakeholders understand CMS' concerns about the particular item or service as well as the agency's approach to NCDs in general. CMS also should allow the public an opportunity to provide feedback on these topics and reasons for consideration. A point of contact and his or her phone number an e-mail address should be provided to facilitate this collaborative process.

Second, the guidance must include a commitment from CMS to involve stakeholders in its decisions to generate a NCD. The draft guidance says, "CMS may consult with the relevant beneficiary groups, professional bodies and/or manufacturers of the technologies in question" before deciding whether to generate a NCD,[5] but provides no assurance that such consultation will occur or their comments factored in the decision making. We urge CMS to state explicitly that it shall confer with relevant stakeholders, including manufacturers, before formally initiating a NCD to ensure that the process is transparent from the beginning and that the review is necessary and can be pursued as efficiently as possible. Directly affected stakeholders then should be given adequate time to respond, and CMS should carefully consider the additional information they provide before determining whether it is warranted to formally open a NCD.

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[3] Proposed Decision Memo for Radioimmunotherapy for Non-Hodgkin's Lymphoma (CAG-00163N), May 4, 2005.

[4] Draft Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, Mar. 9, 2005, at 5.

[5] Id.

We believe these changes will help ensure that NCDs are not opened prematurely. In the event that they still could be, we believe that the guidance should state explicitly that even after an internally generated national coverage analysis officially has been opened, the agency may close it at any time by determining that there is insufficient evidence to change current policy. We appreciate that CMS has proposed a draft decision memo for radioimmunotherapy for Non-Hodgkin's Lymphoma (CAG-00163N) that reaches this conclusion. An explicit statement clarifying that a NCD may be closed at any time and current coverage policy maintained also should be included as a potential resolution in CMS' coverage guidances.

B. CMS must provide clearer guidance about the reasons it will initiate a NCD internally.

CMS' list of the circumstances in which it may internally generate a NCD fails to ensure that the agency's actions will be predictable or appropriate. Many of the circumstances are described in vague terms that fail to offer any assurance of predictability. For example, CMS may generate a NCD internally when "more rapid diffusion of the technology is likely to have a significant programmatic impact on Medicare and other Medicare-related public policies (e.g., reduction in health inequalities)."[6] Without further explanation of what a "significant programmatic impact" means, the public will have no sense of when CMS might use this criterion to initiate a NCD. We are particularly concerned that CMS will measure "significant programmatic impact" in terms of cost and unfairly will subject innovative therapies to the NCD process simply because of their short-term expense. CMS has attempted twice in the past to propose cost as a coverage criterion in rulemakings and has failed.[7] The agency cannot accomplish through a guidance document what it has been unable to accomplish through the rulemaking process. Thus, we urge CMS to clarify this point and to define in greater detail its reasons for initiating a NCD internally so that the public can fully understand and predict the agency's actions.
We agree that the following are appropriate reasons for CMS to internally generate a NCD:

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6 Id.

7 *See* 65 Fed. Reg. 31124 (May 16, 2000); 54 Fed. Reg. 4302 (Jan. 30, 1989).

1. Significant controversy exists about the reasonableness and necessity of covered items or services and local coverage processes are unlikely to resolve or address these concerns;

2. Documented program integrity concerns have arisen under existing local or national policies and there is a potential for fraud under existing policies, and local coverage processes are unlikely to resolve or address these program in integrity concerns; or

3. Interpretation of credible, new peer-reviewed evidence indicates that changes may be warranted in current policies for the kinds of reasons described above and local coverage processes are unlikely to resolve or address these concerns.

We are troubled, however, that some circumstances suggest that the NCD process could be used to subvert the local coverage process and infringe upon carriers' authority to cover medically accepted therapies. Specifically, CMS asserts that it may open a NCD when questions are raised about the safety and effectiveness of off-label uses of drugs and biologicals or "available evidence suggests that local variation is not warranted."[8] We are gravely concerned that CMS' use of the NCD process in these situations will needlessly deny patients' access to critical therapies. For example, in our comments to the agency's draft coverage decision memorandum for anticancer chemotherapy for colorectal cancer (CAG-00179N), we discussed in depth our concerns that the implementation of the NCD actually could reduce beneficiary access to advanced colorectal cancer therapies, particularly if CMS chose not to reiterate that the local coverage process would remain unchanged.[9]

We are concerned because the current local coverage process works so well to ensure beneficiary access to appropriate drugs and biologicals. Carriers' authority to cover medically accepted off-label uses of drugs and biologicals[10] permits Medicare coverage to evolve with the standard of care. Carriers' flexibility to adjust their coverage policies as the clinical evidence develops, including the recognition of new therapeutic regimens, helps to ensure that

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[8] Draft Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, Mar. 9, 2005, at 5.

[9] Letter to Steve Phurrough, Director, Coverage and Analysis Group, CMS, from Michel Werner, Chief of Policy, BIO, Dec. 23, 2004, available at: http://www.bio.org/healthcare/medicare/20041223NCD.pdf

[10] SSA § 1862(t)(2); Medicare Benefit Policy Manual, ch. 15, §§ 50.4.2, 50.4.5.

patients have timely access to the most appropriate therapies. The local coverage process also allows patients and physicians to request individualized coverage decisions. Because all patients are not identical, carriers' coverage policies appropriately can have some variation to ensure access to needed therapies. We urge CMS to clarify its description of these circumstances to assure stakeholders that the NCD process will be used to ensure patient access to the latest technologies when the local coverage process fails to do so and that the local coverage process and its protections for access to care will not otherwise be supplanted. The agency should consult with stakeholders to determine when variation among local policies harms patient access to care. CMS should not internally generate a NCD merely because a drug or biological is newly approved or has not had adequate time to go through the local coverage process.

The guidance document also should state clearly that local coverage policies remain in effect until the NCD is final and becomes effective. Because of past problems with local carriers suspending local coverage once a national coverage analysis is initiated, the agency also should revise the local coverage determination chapter of the Medicare Program Integrity Manual to state explicitly that contractors should not revise or suspend a local coverage determination in response to the initiation of a national coverage analysis until there is a final and effective NCD.

Other circumstances appear to involve the exercise of authority not granted to CMS. CMS says that it may open a NCD when significant questions have been raised about the safety or effectiveness of currently covered items or services. As described in the draft guidance, this circumstance could include drugs and biologicals when used for Food and Drug Administration (FDA) approved indications. CMS appears to assume authority to review the safety and effectiveness of these therapies, although these issues clearly are the FDA's responsibility. We urge CMS to use its resources wisely and not duplicate the work of other agencies.

C. Apply the same standards for reviewing internally generated requests as it applies to external requests.

As in its description of the pre-request stage, the draft guidance section on review of requests does not shed light on CMS' procedures for handling internally generated requests. When a request is generated externally, CMS

will not consider the request complete unless the requestor provides "adequate supporting documentation," "including a full compilation of the supporting medical and scientific information currently available that measures the medical benefits of the item or service."[11] CMS will review this material and will allow the requestor to present this evidence to Coverage and Analysis Group (CAG) personnel.[12] This process allows a stakeholder to discuss the proposed NCD with CMS and to identify additional information that might be needed to reach a decision. We believe these procedures will help improve stakeholders' understanding of the NCD process and will encourage efficient review of requests for NCDs.

When the request is generated internally, however, the draft guidance provides no insight into how CMS will determine whether its evidence is complete or whether it will involve stakeholders in its review of the materials. The draft guidance suggests that CMS could collect and evaluate what it determines to be complete information without ever consulting with the stakeholders who know a product best – its manufacturers and the providers who use it as well as relevant patient groups. Once again, we believe that CMS must allow relevant stakeholders to contribute to its discussions to ensure that the decision to pursue a NCD is based on complete information, gathered with maximum efficiency. CMS must consult with these stakeholders before deciding that it has sufficient evidence to pursue a NCD. Given the importance of the coverage process to beneficiary access to care, transparency and public input is critical at all stages of the NCD process, particularly the decision to initiate a NCD in the first place.

CMS also should describe how the CAG will review the information gathered to support an internal request for a NCD. When an external requestor presents its evidence to the CAG, the requestor and CMS benefit from the exchange of ideas about the evidence and its potential usefulness to CMS. Yet, when CMS initiates a NCD request internally, the draft guidance provides no assurance that the agency will discuss its evidence with its stakeholders. CMS must consult with the relevant stakeholders to be sure that its decisions are based on an accurate interpretation of all necessary information.

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11 Draft Guidance for the Public, Industry and CMS Staff: Factors CMS Considers in Opening a National Coverage Determination, Mar. 9, 2005, at 6.

12 Id. at 7.

Additionally, CMS should make available to the public a listing of the evidence it considered in evaluating a request for a NCD and the names and contact information of individuals and organizations who initiated the request or whom the agency otherwise consulted. The agency should make this information available regardless of whether a request is generated externally or internally. It could be listed in the form of a bibliography attached to the tracking sheet that would help stakeholders to comment more knowledgably about CMS' decision and would help to minimize duplication of effort.

CMS also notes that it has discretion to assign an item or service to the most appropriate benefit category.[13] We agree that CMS should make this determination, but we also urge CMS to clarify that the assignment must be based on legal standards. The guidance should state that CMS will assign an item or service to a benefit category in accordance with the Medicare statute.

Finally, we believe CMS should establish a rigorous process to ensure that the final coverage guidance documents are followed. Specifically, if the final guidance document outlines distinct steps the agency must take before initiating a NCD or information it must consider as part of its deliberations, there should be an internal mechanism to ensure these requirements are met for each and every consideration. BIO also recommends that groups outside CAG be involved in this process. The Council of Technology and Innovation is a potential partner. The openness, transparency, and predictability promised by the coverage guidances will not be realized unless the agency creates some rigorous mechanism to ensure compliance with them.

II. Factors CMS Considers in Referring Topics to the MCAC

Transparency and opportunity for public input are essential to the MCAC's review of medical technologies. BIO supports the current procedures for providing notice and public participation in MCAC meetings, and we urge CMS to include more opportunities for consultation with stakeholders.

First, the MCAC's review of an issue can have a significant effect on the coverage process, yet the draft guidance does not describe a means for relevant stakeholders to provide input on whether to request MCAC review, which panel members should participate, and what questions should be posed. The guidance should permit requestors and other stakeholders to provide recommendations on

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[13] Id. at 6.

these issues. Knowledgeable stakeholders could help CMS decide whether there is sufficient disagreement about a technology to merit the MCAC's review. Stakeholders and requestors also should be allowed to propose particular MCAC members and outside experts with relevant experience to participate in the review. Additionally, stakeholder input could help CMS to define the questions for review. The questions are extremely influential for shaping the answers provided by the MCAC. Unless the right questions are asked, the scope of the MCAC's review will not be appropriate and the outcome will not be useful. We thank CMS for posting the questions before each meeting, but we urge CMS to allow stakeholders to provide feedback on these questions before they are disseminated to the MCAC. The guidance document should state that CMS will post the questions on its website and accept recommendations for an appropriate period before submitting the questions to the MCAC.

Second, the draft guidance does not assure stakeholders that the MCAC will review all relevant information on an issue. Public testimony is allowed at MCAC meetings, but because we often are unaware of the information CMS already has provided to the Committee when we submit our statements 20 days before the meeting, we may not know until the day of the meeting that the MCAC has not received important information. CMS could better ensure that the MCAC is provided with all relevant information if it made available all of the information it plans to submit to the Committee and allowed stakeholders to submit materials for distribution to the Committee. This would help stakeholders to identify gaps in the evidence and provide additional data to the MCAC in a timely manner. It also would allow stakeholders the same opportunity as CMS to prepare for the meeting fully. Furthermore, MCAC meetings' brief periods for public testimony often allow members of the public to make very short statements only. CMS should extend the length of MCAC meetings or provide an alternate forum to allow fuller stakeholder participation in the MCAC process. Here, as well as elsewhere in the coverage process, we cannot stress enough the absolute need for full transparency in order for the public to perceive that the coverage process is an open one and that decisions are scientifically based.

III. Factors CMS Considers in Commissioning External Technology Assessments

Similar to our concerns about referrals to the MCAC, we believe that public input is needed to ensure that external technology assessments (TAs) are used efficiently. Stakeholders who know a technology well could be of great assistance to CMS in determining whether the evidence about a technology is sufficiently complex or vast to require a TA. We recommend that the guidance document include a statement that, before CMS commissions a TA, stakeholders will be allowed to provide recommendations regarding whether it is necessary and offer guidance on the questions to be included in the TA.

We are pleased that CMS has contracted with the Agency for Healthcare Research and Quality (AHRQ) to acquire TA reports. AHRQ has a set of well-defined standards for conducting systematic reviews.14 We believe that any other reviewers CMS contracts with must meet these standards to ensure that the TA uses the most up-to-date and appropriate methods. We recommend that the guidance document state that, at a minimum, all external reviewers will be required to meet AHRQ's standards for TAs.

IV. Conclusion

In conclusion, BIO supports CMS' efforts to make the NCD process more easily understandable to the public. We firmly believe that the ultimate success of the process depends substantially on transparency and the opportunity for public involvement, helping CMS to operate more efficiently and predictably. We urge CMS to more fully embrace these goals as the agency proposes revised drafts of these and other coverage guidances.

We hope our suggestions will help CMS address these important issues. Please contact Jayson Slotnik at 202-962-9200 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

/s/

Jim Greenwood,
President and CEO
Biotechnology Industry Organization

14 See http://www.ahrq.gov/clinic/epcpartner/.

Commenter: Sally Hart
Organization: Arizona Center for Disability Law

(Comment on next page)

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April 25, 2005

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Re: **NCD Draft Guidance Documents:**
I. Factors CMS Considers in Opening a National Coverage Determination;
II. Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee;
III. Factors Medicare Considers in Commissioning External Technology Assessments (TAs).

Dear Sir or Madam:

The Center For Medicare Advocacy, Inc. is a private, nonprofit organization that provides education, analytical research, advocacy and legal assistance to help elders and people with disabilities obtain needed health care. We have long been particularly interested in the Medicare National Coverage Determination process, and we appreciate the opportunity to comment on these three draft NCD Guidance Documents.

I. Factors CMS Considers in Opening a National Coverage Determination.

1. The guidance document states, in Section III. "Prior to Initiation," that CMS plans to issue specific guidance in the near future describing the agency's approach to evaluating the scientific evidence with regard to NCD development. We applaud this plan, as the entire NCD process must be guided by clear standards for Medicare coverage. Historically, CMS has attempted on several occasions to adopt specific standards for Medicare coverage rules, and then

given up the effort. See the discussion below of problems caused by the current lack of standards, both as to criteria for NCDs and evidentiary standards for applying the criteria.

2. In Subsection C. of Section IV. "Who Can Request an NCD," the guidance document makes several statements about the criteria used for NCDs. One statement is that CMS has generally required that the item or service should "improve health outcomes overall for Medicare beneficiaries." A second statement identifies situations where "[s]ignificant uncertainty exists concerning the safety and effectiveness, patient selection, or appropriate facility and staffing requirements for the new technology." We believe that these two statements set out criteria for coverage of services that are more restrictive than the statutory language prohibiting coverage only of services that have been found to be "not reasonable and necessary." There is no provision in the Medicare statute that covered services must improve health outcomes. Additionally, there is no authority for CMS to prohibit coverage of items and services prescribed by licensed physicians for their patients simply because the agency perceives a lack of certainty about their benefits and risks, or the setting in which they should be delivered.

3. In Section VI. "Review of a Formal Request," this guidance document states that CMS may conclude that an item or service is not reasonable and necessary unless the requestor provides adequate evidence to support it under the high CMS evidentiary standard. This position is unfortunate in that its effect is to delay or foreclose coverage of items and services for which there is no well-financed campaign to fund the requisite "gold standard" studies. As a result, coverage may be denied or delayed indefinitely.

II. Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee.

1. As it is currently constituted, the Medicare Coverage Advisory Committee (MCAC) has only token participation by consumers. Only six out of one hundred members are consumers, and these have no vote. The number of consumer members should be increased so that there is a majority of such members on the MCAC, and they should be given voting rights.

2. In Section V. "Criteria For Referral to the MCAC," the draft guidance document sets out some criteria that involve consideration of scientific points and some criteria that focus on public policy concerns. As it is presently constituted, the MCAC is better suited to address the scientific points, but in this respect it merely duplicates the expertise of technology assessors. It makes more sense to significantly improve the qualifications of the MCAC to address public policy concerns, and provide these members with ~~technology~~ assessments prepared by CMS staff and outside experts in the area.

III. Factors Medicare Considers in Commissioning External Technology Assessments.

1. This guidance document fails to address the need for CMS to adopt clearly stated standards or criteria for NCDs before it can legitimately use technology assessments. The closest

it comes to setting out criteria is the statement, "An External Technology Assessment (TA) can involve the evaluation of a technology's performance characteristics, safety, efficacy, effectiveness, outcomes, appropriateness and economic impacts." But this statement is relatively vague; furthermore, the criteria it lists are not entirely consistent with the Medicare statute. Particularly, the reference to "economic impacts" introduces a coverage criteria that is more restrictive than the statutory language. In addition, the statement reverses the burden of proof set out in the statute, which simply prohibits coverage of a service that is "not reasonable and necessary" rather than requiring that the proponents of coverage provide evidence that the service is "reasonable and necessary."

2. The guidance document also fails to set out a clear evidentiary standard for External Technology Assessments. The document refers to "a rigorous review of scientific evidence" but doesn't further define what kind and how much scientific evidence is required. CMS' recent insistence on a rigorous application of principles of "evidence based medicine" is unfair in a number of ways. First, it slows down the coverage both by the rather extensive lengths of time required to conduct "gold standard studies", and the further lengths of time required for CMS to satisfy itself that those studies were sufficiently numerous and scientific. Second, it places Medicare coverage at the mercy of private industry, which funds studies only of items and services for which it expects to make a profit.[1] Finally, the requirement of "gold standard" studies precludes coverage of treatments for rare conditions, which are unlikely to ever be the subject of multiple, rigorous scientific studies.

3. The draft guidance document refers to a determination of the "assessment questions to be addressed by the TA" through discussion with the Agency for Healthcare Research and Quality (AHRQ). These questions are likely to be determinative of the ultimate decision made by the Medicare Coverage Advisory Committee (MCAC) after receiving the TA report, so their design controls whether a procedure is covered in whole or in part. Thus, when the assessment questions assume coverage standards that are more demanding than the general coverage standards prescribed in the Medicare statute, the resulting NCD may be unduly restrictive.

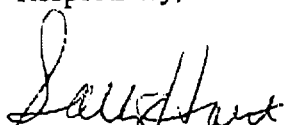
This draft guidance document asks how the public might play a role in assisting in the development of questions to be addressed in the TA. It is difficult to design such a role, for a number of reasons. First, the public and its representatives lack financial resources to play this role, although certain consumer advocacy groups may have a limited ability to prepare input on particular services. Second, the general public is not interested in Medicare coverage rules until a particular rule denies them a particular service that their physician has prescribed for them – too late for involvement in development of the rule. Third, consumer advocates who have attempted to be involved in the Medicare coverage process have found themselves marginalized by CMS and private "experts," who write off disagreements with advocates to lack of sufficient technical

[1] We are aware that CMS is now paying for participation in a few studies, but this effort is not sufficiently broad to eliminate the problem.

knowledge rather than disagreements concerning the standards for coverage.[2] Increased public input would require a greatly expanded number of consumer advocates on the MCAC, and voting rights for such members. It would also require CMS to design a role for consumer advocates within the agency, perhaps by funding an ombudsman-like committee to provide input on such matters as the questions and design of External Technical Assessments.

Thank you for giving us the opportunity to comment on the draft guidance documents.

Respectfully,



Sally Hart
Of Counsel

[2] The writer served as a consumer member of the MCAC for several years.

Commenter: Carol A. Kelly
Organization: AdvaMed

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,300 members and subsidiaries manufacture nearly 90 percent of the $75 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $175 billion purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies. Nearly 70 percent of our members have fewer than $30 million in sales annually.

Guidance Documents Addressing the National Coverage Process

AdvaMed considers the topic of the three guidance documents dealing with the Medicare national coverage determination (NCD) process (issued March 9, 2005) to be extremely important. Over the years, the Association has consistently pressed for a clear, predictable, and timely national coverage process, as well as the opportunity for active public participation. As we have stated in our previous comments on the guidance document development process, we believe that CMS's initial focus on the NCD process is appropriate and consistent with the congressional intent underlying the MMA's creation of the guidance document process.

We have been pleased by a number of CMS initiatives we have seen in recent years. National Medicare coverage decision-making has become more transparent as CMS has issued notices in the *Federal Register* that attempt to explain the coverage processes it uses. CMS has also made use of its web site to post information on matters being reviewed nationally—and to solicit comments from the public. In addition, outside experts are consulted and evidence is weighed by the Medicare Coverage Advisory Committee in a FACA-compliant process. As you know, we have commented on these Federal Register notices, as well as a number of coverage determinations, and we regularly follow MCAC's activities. Your efforts in these areas are steps in the right direction.

However, while important steps have been taken by CMS in opening the national coverage determination process to public view, key aspects and procedures of this process are less than clear to us, and make national coverage decision-making less predictable than it should be. Therefore, we support the Agency's efforts to provide a more detailed explanation of how national coverage decisions are made in the three guidance documents it is developing.

Draft Guidance Document 1--Initiating a Medicare NCD

Internally-Generated NCDs. While much of CMS's efforts to date have concentrated on how outside parties can initiate a national coverage determination and the information that is required, we note that this first draft guidance document provides more information on how CMS "internally generates" NCDs. An increasing number of national coverage issues have been internally generated and we have noticed that the Medicare Coverage Advisory Committee (MCAC) is increasingly deliberating on issues not tied to specific outside requests.

In particular, we note that the draft guidance document provides several examples of circumstances that may prompt CMS to generate an internal NCD request. We have several concerns about these examples. First, in addition to providing examples of circumstances in which a NCD request may be generated internally, we recommend that CMS set forth a list of the precise reasons why a NCD may be generated internally. Without very specific criteria for initiating the internally generated NCD process, the NCD process will be, by definition, unpredictable. Companies that choose to pursue local coverage, as is true with almost all new technologies and services, will have no ability to determine whether early discussions should be considered with CMS's Central Office. In addition, once technologies and therapies are in use, companies will have no ability to predict the future occurrence of internally generated NCDs.

Second, the draft guidance document raises issues of "safety" in the list of circumstances under which a NCD may be internally generated for existing technologies already in use and for new items or services (or new uses of existing items and services). While we agree that such issues are appropriate for consideration by the U.S. Department of Health and Human Services – specifically, the Food and Drug Administration – such issues are not within CMS's mandate. It is FDA's mandate to evaluate safety; by contrast, CMS's mandate in the context of coverage is to evaluate whether a given item, service, or procedure is reasonable and necessary. We recognize that CMS can and should be concerned about the quality of care Medicare beneficiaries receive, but believe that CMS should focus on reasonable and necessary rather than safety in crafting the bases for the internal generation of NCD requests.

Third, CMS has long acknowledged the importance of the local coverage process and retaining the focus on decision-making in the physician-patient relationship. Therefore, while we greatly appreciate CMS's efforts to shed light on its internal workings and rationales for internally generating NCDs, we suggest that CMS frame its list of examples by requiring that at least one of the following criteria be present to trigger an internally generated national coverage determination request on an existing technology already in use:

- Longstanding conflicting multiple carrier or intermediary policies that affect patient access due to problems in filing claims;
- Demonstrated quality of care concerns;
- Services that are currently covered, but widely considered obsolete; and
- Program integrity issues surrounding significant underutilization or overutilization of the service;

Limiting internally generated requests only to the above situations will help avoid premature national assessments of a technology or service that may inappropriately restrict patient access to needed therapies.

Fourth, the draft guidance document states that for a new item or service, a potential circumstance for internally generating a NCD is that "[a]vailable evidence suggests that local variation is not warranted." As an initial matter, we are unsure what CMS means by this statement. For example, what does "available evidence" mean? Will it be restricted to published opinions? Will it include professional medical society opinions, both local and national? We also note that the term "suggests" seems to deviate from CMS's insistence on evidence that clearly demonstrates medical effectiveness. In addition, we request further guidance concerning CMS's interpretation of "local variation" and "not warranted."

More generally, we are concerned that the inclusion of this circumstance undermines the local coverage process, which we continue to believe is valuable and constructive. When appropriate, the Medicare program should issue coverage policies that reflect consistency. Policy inconsistencies, however, do not necessarily reflect inadequacies in policy decision-making. For example, case-by-case approvals and verbal approval policies may appear to conflict with written policies, but actually may result in equivalent coverage for patients. We believe equivalent coverage should be the ultimate goal and measure of consistency. In addition, any variations in access may be temporary in nature and may reflect differing local coverage policies from legitimate variations in practice patterns.

CMS should take all of the following positive, valuable aspects of the local coverage process into consideration:

- Openness and access to coverage policy decision-makers;
- Consideration of the views and practices of physician experts/Centers of Excellence at early stages of the local coverage process, which enables a responsiveness to new research and evidence that is consistent with the flow of new therapies to the standard of care;
- Decentralization in policy decision-making that enables different perspectives to be heard, having the effect of fostering innovation;
- Flexibility in the local coverage process;
- Fairness in decision-making processes, which is ensured through contractor compliance with the local coverage process requirements at Chapter 13 of the Medicare Program Integrity Manual; and
- Prompt decision-making processes, which enable beneficiary access to medical technology.

Finally, in the alternative to setting forth circumstantial examples, we recommend that CMS consider addressing the areas CMS expects to consider in generating internal requests and how such requests will be handled in this guidance document. For example, such a guidance document could address the following issues:

- Specific reasons that CMS has generated internal requests in the past that indicate a pattern under which CMS is almost certain to generate an internal request;
- Specific circumstances in which CMS will not generate an internal request and the reasons why;
- The types and kinds of new evidence that are likely and/or not likely to generate an internal request;
- The role of published studies (critical to the evaluation of external requests) in the generation of an internal request;
- How CMS intends to handle internally generated requests related to “off-label” devices;
- The appropriate time period during which CMS will consider an internally generated request and whether the time period factors in communication with interested parties;
- Reasons and level of evidence for the modification or reversal of an existing NCD through an internally generated request;
- Expected frequency with which internally generated requests will be used to resolve conflicting LCDs; and

- Disclosure of process and reasons for resolving conflicting LCDs though internally generated requests.

Stakeholder Input. In addition, we noticed that the draft guidance document states that CMS "may, from time-to-time, announce on [the] website topics that are being considered for potential internally generated requests before the posting of a tracking sheet." We continue to believe that CMS should, as a rule, post on its web site all items that are being considered for national action that have passed the preliminary discussion stage between CMS and the potential NCD requestor, but for which CMS has not made a final decision whether or not to accept an NCD request and begin the national coverage decision process. The reason(s) for proceeding nationally should be posted as well. This should be the rule regardless of who requests the NCD. Publicizing all items under consideration will ensure that all stakeholders are able to be involved and engaged in a meaningful fashion. In the event CMS is not able to disclose all internally generated requests on its website, criteria should be established that address CMS's position related to the types of internally generated requests that should and will be announced.

Moreover, from the two notices CMS has published in the *Federal Register* dealing with the national coverage process (and the draft guidance issued recently), we have a good understanding of the information the agency requires to initiate the NCD process. However, what is not clear to us is how the agency intends to proceed if various stakeholders have different views concerning the need for a national determination.

We would prefer a process where CMS would consider the views of all stakeholders before initiating the NCD process. Again, we think this can be accomplished if CMS would post on its web site all matters that are being considered for national action and have passed the preliminary discussion phase of the process. This would not interfere with the informal discussions that take place on specific matters, and it would provide CMS with more information on the matter before proceeding.

Finally, we urge CMS to consider sharing final NCDs with the requestor(s) prior to publication and a comment period. This would allow both parties to resolve any issues (including factual errors and omissions) that may arise in the NCD prior to the comment period and save CMS the time and effort of fixing these issues post comment period.

Draft Guidance Documents 2 & 3--Determining When to Commission an External Technology Assessment; Referring Issues to MCAC

The second and third draft guidance documents address the circumstances under which CMS commissions an external technology assessment and refers matters to MCAC.

As you know, AdvaMed previously provided lengthy comments to CMS on these two topics. The following are the key concerns we have about CMS's factors for referring topics to the MCAC and commissioning external technology assessments:

- *It is important that stakeholders who know the medical technology or procedure that is the subject of an NCD be directly involved in framing the questions posed for technology assessment and MCAC reviewers.* These questions are extremely important. They lead inevitably to the level of evidence needed to provide an answer. Unless the questions are

properly posed and established at the start of the process, controversy will surround their consideration later in the process, as evidenced during recent MCAC meetings. For this reason, we suggest that the guidance document incorporate how the NCD requestor, other stakeholders, and MCAC panelists (if a TA or an internal CMS evidence evaluation will be referred to MCAC for review) will help shape these questions at the start of the coverage decision-making process. In this same vein, if CMS chooses to make a national coverage determination without referral for a TA or to MCAC for review, we think that the requestor, stakeholders, and CMS should be able to agree up-front on the evidentiary questions that will be addressed during the NCD process.

- *It is important that the MCAC have access to the full body of available evidence when conducting a review*. Any technology assessment provided to the MCAC should include all available data. We have observed that in certain MCAC meetings other bodies of evidence appear to be available, but have either not been provided to the MCAC or provided late in the process so that the evidence does not receive full and timely consideration.

- *It is also important for CMS to spell out in the Guidance Document the rights the NCD requestor(s) has with regard to the NCD process.* Some requestors may approach CMS wishing to proceed with an internal CMS decision, while others might prefer an MCAC review. Some might think an external technology assessment is needed, while others might not. As such, we believe NCD requestors should have the right to request whether or not a technology or service is referred to the MCAC or for an external technology assessment. In addition, for NCDs that are referred to MCAC, requestors should not only be involved in the framing of the questions to be reviewed by MCAC, but they should also have the right to review and make recommendations on the MCAC panel members and other invited "external" experts who will review the evidence. Lastly, requestors should be able to submit materials to CMS for distribution to MCAC members and invited experts prior to an MCAC meeting. We think many of these matters can be resolved in preliminary discussions between the requestor and CMS, prior to the initiation of the formal NCD process. However, because an NCD affects a full range of stakeholders as well as the requestor or requestors, we think CMS needs to build in a process to inform the public of matters it is seriously considering for national action, before formally beginning the NCD process, and delineate requestor rights with regard to this process.

  We recognize CMS's concern that incorporating stakeholder involvement in framing the assessment questions could endanger the Agency's ability to meet its statutory timeframes for rendering a national coverage decision. However, CMS can use preliminary meetings prior to opening the NCD as well as stakeholder meetings during the early stage of the NCD process to ensure stakeholder involvement in the development of the assessment questions without compromising CMS's ability to meet its timelines.

- *If CMS is to make use of MCAC for purposes of "horizon scanning," or to engage the public on matters of "controversy," it should consider means to promote increased public dialogue and deliberation at MCAC meetings.* Current MCAC processes are tailored toward evidence evaluation in full public view—not broad public participation. In fact, opportunities for public dialogue and deliberation are limited, and in light of the

reasons for holding such MCAC meetings, we believe broader public participation is warranted. To facilitate public participation, CMS should consider expanding the duration of MCAC meetings to allow adequate time for public comment on the evidence and issues relevant to coverage. Alternatively, CMS could hold town hall meetings in addition to MCAC reviews to obtain public comment on specific issues relating to a coverage decision. Such town hall meetings would allow for broader public input on MCAC or technology assessment decisions or other issues relevant to coverage. CMS also might consider holding a public comment period after each MCAC.

- *Finally, we think that it is important for CMS to remind its contractors that their authority for making local and regional coverage decisions are not pre-empted by the initiation at the national level of the coverage decision making process.* Most coverage decisions are made at the local and regional levels. Current policy is that Medicare's local and regional contractors have authority to make coverage decisions absent an extant national policy. We think that CMS should make this policy clear to its contractors to clear up any misconceptions. Such a clarification could be included as part of these guidances or included in the Medicare Coverage Manual.

Guidance Document Development Process

Finally, we note that AdvaMed has already provided detailed comments on the topic of guidance documents and the process of developing these guidance documents. We continue to believe that in general, FDA's "Good Guidance Practices" can and should be translated easily to CMS's coverage guidance document process, and that CMS's guidance document procedures should themselves be set forth in a guidance document. While we appreciated CMS's Federal Register notice issued last year to implement the guidance document process mandated by section 731 of the MMA, we continue to believe that establishing further clarity in the process of guidance document development will ultimately result in clarification of regulatory requirements, enhancements in CMS coverage decision-making processes, and overall benefit for all stakeholders.

We recognize the limits of guidance documents and understand that a guidance document cannot contradict the contents of the *Federal Register* notice CMS issued last year on the guidance document process. We also understand that there are certain issues that are properly addressed through rule-making and not through guidance documents. However, we ask not for any guidance that would be contradictory to the notice or the subject of rule-making. Rather, we believe that a guidance document can appropriately add a level of detail to what has already been published in the notice. The very purpose of having guidance documents is to interpret with greater specificity the existing laws and regulations implemented by a given agency.

While the CMS *Federal Register* notice on guidance documents was helpful, it provided few details. As a general point of comparison, the FDA final rule on "Good Guidance Practices," filled 12 pages while the CMS notice took less than one. Certainly FDA's final rule was longer because it needed to provide more background by responding to comments and suggestions, but we note that FDA also provided much more content generally on how the guidance process would work at that agency.

To illustrate the point further, the following is a list of open questions where the answers were not found in the CMS notice:

- Does CMS plan to encourage pre-proposal discussions with the public? Such pre-proposal collaboration could include, for example,
  - ✓ Public meetings, including CMS workshops, conferences and the like;
  - ✓ Private meetings with specific industry groups on CMS' premises;
  - ✓ Industry-hosted meetings that CMS attends;
  - ✓ Continuing meetings without uniform composition;
  - ✓ Capitol-Hill convened meetings;
  - ✓ Meetings convened by neutral third party; and
  - ✓ Written pre-proposal dialogue, either by e-mail or other correspondence.

- How does CMS plan to ensure that it avoids addressing topics that more appropriately should be the subject of rulemaking?
- What is the pathway within the Agency to request reconsideration of a final guidance if the public disagrees?
- What does the Agency mean when it says "usually, guidance documents will not be considered in effect until CMS has analyzed public input"? Specifically, what does "usually" mean?
- Under what circumstances will the Agency consider that there is "immediate need" for a guidance document such that obtaining comment beforehand will not be feasible?
- How long, in the usual instance, will the public have to file comments?
- Will the public have the opportunity to propose a whole guidance document itself, as opposed to merely proposing the topic?
- What nomenclature will the Agency use so the public knows what is and is not a guidance document?
- Are there existing documents that CMS will now characterize as guidance documents?
- What kind of language will CMS use in guidance documents to communicate their nonbinding affect?
- Will CMS monitor guidance documents to ensure compliance with these procedures?
- What Office or Officer within the Agency will have the authority to issue guidance documents?

We encourage CMS to communicate with the FDA's Office of General Counsel to obtain a full understanding of good guidance practices and the appropriate role guidance can play in clarifying existing regulations and *Federal Register* notices.

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Thank you for this opportunity to share AdvaMed's views on these draft guidance documents. AdvaMed believes that the development of guidance documents will greatly benefit the agency and the public. We look forward to working with you on these and other important issues. Please let us know if you would like to discuss anything in this letter.

Commenter: Mark Leahey
Organization: Medical Device Manufacturers Association

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 these comments in response to the following three draft guidance documents relating to National Coverage Determinations:

- Factors CMS Considers in Opening a National Coverage Determination (NCD);
- Factors CMS Considers for Requesting a Medicare Coverage Advisory Committee Referral for a NCD; and
- Factors CMS Considers for Requesting an External Health Technology Assessment When Making a NCD.

The mission of MDMA 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.

As you know, medical devices are an increasingly important part of the health care system. We appreciate CMS's desire to provide a clear, predictable and timely national coverage process, and we support the Agency's efforts to provide a more detailed explanation of how national coverage decisions are made.

1. Factors CMS Considers in Opening a NCD

Recommendation: CMS Should Set Clear Threshold Criteria for Initiating a NCD in order to Preserve the Role of the Local Coverage Process.

For many years, CMS has acknowledged the importance of the local coverage process by allowing new technologies to disseminate through coverage at the local level before consideration for coverage at the national level. The local coverage process is a particularly valuable mechanism for disseminating coverage of innovative devices to Medicare beneficiaries. MDMA is concerned that the increased focus on the national coverage determination process will result in a diminishment or even the elimination of the local coverage process.

MDMA is particularly concerned that CMS has been triggering the NCD process too early, often in cases where there is insufficient evidence developed to draw conclusions. In such a circumstance, the local coverage process is a much more effective way of gradually diffusing the technology out to the broader Medicare population. If the NCD process is triggered too early, before there has been much experience in clinical settings with use of the device, no meaningful coverage policy results (or coverage is denied or limited to a narrow set of circumstances, to the detriment of beneficiaries who could benefit from the technology). To preserve the important role of the local coverage process, CMS should more clearly establish threshold criteria for initiating an NCD, such as requiring the technology to impact a certain percentage of beneficiaries or requiring the technology to have achieved local coverage for a threshold percentage of beneficiaries prior to internally initiating a NCD.

We note that CMS states in the guidance that the Agency may generate a NCD if "available evidence suggests that local variation is not warranted." As noted above, MDMA has serious concerns about the viability of the local coverage process given the Agency's recent focus on national coverage. In some cases, gradual dissemination of technology through the local coverage process may be highly desirable, and the best process for getting technology to Medicare beneficiaries. We ask CMS to clarify under what circumstances it will internally generate a NCD because of its concerns about "local variations" in coverage. Because of the impact that even the initiation of the national coverage process has on local carrier decisionmaking, it is critical that CMS not include a vague statement in the guidance expressing concerns about "local variation" without providing further clarification about how it will it implement that provision.

Because local coverage is trumped by the national coverage decision, and because carriers often will not even consider coverage of a device that is even subject to a national coverage review, it is critical that CMS not even begin to consider a device for national coverage unless the use of the technology has achieved a certain threshold or there are compelling reasons for doing so. CMS should also make clear to local carriers that local coverage should continue when a NCD is pending. Innovative device companies in particular often strive for a more limited launch for specifically applied technologies in order to have coverage naturally elevate from the local to the national level. Premature engagement of the national coverage process forecloses this option, and places obstacles to beneficiary access to new, innovative technologies.

Recommendation: CMS Should Publicize its Intent to Open a NCD and Allow for an Initial Public Comment Period on Whether NCD Review is Warranted.

We acknowledge that CMS has attempted to establish some factors the Agency will consider in determining whether or not to engage in a national coverage review. But we believe further clarification is needed, particularly in the area of NCDs that are generated internally by CMS. CMS notes in the guidance that "from time to time" it will announce topics being considered for potentially internally generated NCDs. MDMA believes CMS should publicize any proposals to engage in the national coverage process, whether that process is being triggered by an external or internal request, and provide for a period of public comment on whether or not the Agency should engage in a national coverage review of a particular technology. The period of comment does not need to be long (no more than 30 days), and could take place before the formal NCD process is considered to be triggered, so the timeframes set forth in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 would not yet be triggered.

We agree with the Agency's characterization of questions about coverage as informal agency contacts and not formal requests for coverage determinations. We agree that these informal contacts do not need to be publicized. But once an external request for a NCD comes to CMS, or once the Agency reaches the stage where it is considering internally generating a NCD, the proposed NCD request should be posted on the CMS website and be open to a brief public comment period. Once a NCD request is formally accepted or formally generated (after this informal comment period), the timeframes set forth in the statute can be triggered.

Recommendation: CMS Should Leave Concerns About Safety to the Expertise of the Food and Drug Administration (FDA).

With respect to the factors for consideration of an internally-generated NCD, we note that CMS has included "significant uncertainty exists concerning the safety" of a particular technology. MDMA believes that concerns about safety are within the jurisdiction of the FDA, and not CMS. Although we share the Agency's concern about ensuring that devices on the market are safe for Medicare beneficiaries, CMS should defer to the FDA's authority and significant clinical expertise on and staff resources dedicated to safety issues. No device is eligible for Medicare coverage unless it has been approved by the FDA, or has Category B IDE status. CMS should confine its coverage review to whether the device is "reasonable and necessary" for the Medicare population – in other words, whether it improves health outcomes for beneficiaries.

Recommendation: CMS Should Clarify that the Agency will not use Information Gathered in "Preliminary Discussions" to Launch a NCD.

We also note that CMS is encouraging potential NCD requestors to engage in preliminary discussions with the Agency. CMS does not state expressly that the Agency might internally generate a NCD request based on information learned at one of these preliminary meetings – but the Agency also does not foreclose that possibility. In order to encourage stakeholders to come to the Agency in the preliminary stages of research, or prior to launch of a new technology, CMS needs to be clear in the guidance that it will not use information gathered in these preliminary discussions to launch an internally-generated NCD on the technology that is the subject of the preliminary discussions. Unless CMS provides clear threshold criteria for opening a NCD, and commits to not using information gleaned from preliminary discussions with the Agency to internally generate a NCD, the opportunity for initial informal discussions with CMS will be meaningless.

Recommendation: CMS Should Provide More Guidance on How the Agency will Use Benefit Category Determinations as Part of the NCD Process

Finally, CMS states in the draft guidance that the Agency will consider whether the technology fits into a particular benefit category. CMS provides very little guidance about how the coverage process will engage the issue of benefit category determinations as part of the national coverage determination process. We request that CMS provide further clarification on this point or omit it from the draft guidance.

2. Factors CMS Considers for Requesting a Medicare Coverage Advisory Committee Referral for a NCD

Recommendation: CMS Should Provide More Clarification on the Threshold Criteria for Initiating a Referral to the MCAC.

MDMA appreciates CMS' efforts to provide more clarification on the process of referring NCDs to the Medicare Coverage Advisory Committee (MCAC), but we believe the Agency needs to provide more detail on the threshold criteria for MCAC review. Under the current process, stakeholders have no idea when a technology will be referred to MCAC for review, or what

distinguishes technologies that are referred to the MCAC from those that are not. As with the guidance for initiation of the NCD process, CMS should provide more transparency to the MCAC process and provide more clarity in the final guidance on the threshold criteria for MCAC review. For example, CMS could rely more on the recommendations of specialty societies, whose members are clinicians on the front lines of patient care, in determining which technologies need referrals for MCAC review and which have already been sufficiently tested in the clinical setting.

Recommendation: CMS Should Not Use MCAC to do "Horizon" or "Environmental" Scans of Particular Health Care Issues to Inform an NCD on a Particular Technology.

MDMA is concerned that CMS has recently been using the MCAC and external technology assessment process to do horizon or environmental scans on a particular health care concern or area of treatment, such as the recent MCAC review of bariatric surgery. Although information gathered from these types of broad reviews can be useful to CMS, they are inappropriate vehicles to inform NCDs on particular technologies. An environmental or horizon scan of a health care issue or treatment area is too broad to provide the precise type of information needed to inform a determination about whether a particular technology should be covered for all Medicare beneficiaries. It is often this type of horizon scanning that could lead to premature decisionmaking by the Agency on national coverage because the technology at issue is not the actual focus of the MCAC review. If CMS determines that a particular technology subject to a pending NCD meets the threshold criteria for MCAC review, the Agency should refer the technology to MCAC for a specific review of that technology, and not use a horizon or environmental scan as a substitute.

Recommendation: MCAC Reviews Should Include All Available Evidence About the Technology Under Review, and Provide Substantial Opportunities for Input from Clinicians.

The MCAC should have the opportunity to do a complete review of all of the available evidence about the technology under consideration, including all information that CMS has relevant to the technology, such as peer reviewed literature and clinical practice guidelines, as well as information that is submitted by the manufacturer of the technology. Under the current process, the evidentiary review is often truncated, with CMS determining which evidence should be reviewed by MCAC. Further, the process includes very little opportunities for public input and deliberation or consideration of technology assessments conducted external to the Agency for Healthcare Research and Quality (AHRQ). Although MDMA appreciates the opportunity to be present at MCAC meetings, these meetings should be structured in a way that promotes the consideration of all of the available evidence.

The MCAC review process should also be structured to provide for more open public dialogue about the technology under consideration. In particular, it is critical that manufacturers and clinicians with experience in either using the technology or who can attest to the need for the technology in a clinical setting have substantial opportunities to submit testimony and evidence to the MCAC. CMS should provide more transparency on the experts consulted during an MCAC review, and these experts should always include clinicians with practical experience in treating patients with the disease or disorder ameliorated or treated by the technology. Further, CMS's response to MCAC should be more detailed, and should include the Agency's rationale for either accepting or rejecting a recommendation from MCAC.

Recommendation: CMS Should Provide More Clarity on When External Technology Assessments will be Referred for Further MCAC Review.

Finally, CMS should subject external technology assessments to further MCAC review only in rare circumstances, and the draft guidance should provide more clarity on the criteria for further MCAC review of external technology assessments. If the external technology assessment is done appropriately, there will be few circumstances under which further medical review will be necessary. The Agency is provided with only an additional three months in the NCD timeframe for an external technology assessment and MCAC review. In order to maximize the use of this additional three month time period, the Agency should determine which type of further review is appropriate and provide further clarification in the guidance documents regarding how the Agency will make this determination.

3. Factors CMS Considers for Requesting an External Health Technology Assessment When Making a NCD

Recommendation: CMS Should Provide Further Clarification on Threshold Criteria for Referring Technology for External Assessment, and Should Refrain from Doing "Horizon" Scans as a Substitute for Assessments of a Particular Technology. CMS Should also Ensure that Technology Assessments Include Consideration of All Available Evidence.

As with the decision to refer a technology to the MCAC for review, CMS also needs to provide more detail in the guidance on the threshold criteria for referring technology for an external health technology assessment. The technology should have reached a certain threshold of use, or represent a potential substantial clinical breakthrough, before the external technology assessment process is triggered. As with potential referrals for MCAC review, the medical community, and in particular, the specialty societies, should play a greater role in advising CMS on the appropriate technologies to review for external assessment.

MDMA believes that as with MCAC reviews, CMS should refrain from using external horizon or environmental scans as substitutes for external assessments performed on technology that is the subject of a formal NCD. If technology subject to a NCD requires external technology assessment, that assessment should focus on that technology so that it receives the type of exhaustive review that is appropriate to inform decisions about national coverage. Also, external technology assessments should review all of the available evidence, including all data that CMS has internally as well as data submitted from external sources, and provide opportunities for public input.

Recommendation: CMS Should Include a Process to Confirm the Accuracy of Technology Assessments and for Updating Them Over Time.

Often technologies are referred for external assessment prematurely, resulting in a negative assessment that persists even in the face of changed clinical circumstances after clinicians become more proficient at using the technology, or the technology is improved. At other times, technology assessments have been based on truncated reviews of the available evidence and thus from time to time contain inaccurate information. CMS needs to establish a public process for review of draft external technology assessment reports, so that inaccurate information in those

reports can be corrected before the report is publicly disseminated as final. CMS also needs to establish a schedule for when these assessments will be revisited and revised to incorporate the most recent available data.

Recommendation: CMS Should Not Include Economic Impact in External Technology Assessments.

Finally, MDMA believes it is inappropriate for CMS to request that an external technology assessment consider the economic impacts of a technology. Assessment of a technology's economic impact reaches beyond CMS's reasonable and necessary authority, which, according to the draft guidance, is designed to consider whether a technology improves health outcomes. The issue of whether CMS should be performing cost/benefit calculations as part of national coverage reviews is not a new one, and further consideration of that issue should be the subject of substantial public debate. MDMA believes it would be inappropriate to consider an issue of that magnitude in this context.

Conclusion

In conclusion, MDMA believes that it is important that stakeholders and CMS work together from the initiation of a NCD to the NCD final determination. Further clarity from the guidance documents will ultimately enhance the coverage decision-making process and benefit all stakeholders, particularly beneficiaries.

MDMA looks forward to working with CMS on the further development of these draft guidance documents.

Commenter: Harvey Neiman
Organization: American College of Radiology

The American College of Radiology (ACR), representing over 32,000 members in radiology, radiation oncology, interventional radiology and nuclear medicine would like to thank CMS for this opportunity to provide comments on the national coverage decision guidance documents. Overall, the draft documents for 1) opening a national coverage determination (NCD), 2) referring NCD topics to the Medicare Coverage Advisory Committee (MCAC), and 3) referring NCD topics for Health Technology Assessments are straightforward and correspond well to the existing NCD processes. However, the ACR recommends that CMS clarify Section IV (C) "Requests initiated internally", and Section V "What Constitutes a Complete, Formal Request for an NCD" for opening an NCD (see guidance document 1), as well as Section VII "Review Material" for referring an NCD topic to the MCAC (see guidance document 2). Below for your consideration are the ACR comments and recommendations for these draft guidance documents.

1. ***Opening an NCD/Request Initiated Internally [Section IV(C), bullets 3 and 4]***

As described in the draft guidance document for opening an NCD, the sections referenced below are circumstances that may prompt CMS to generate an internal NCD request on an existing technology already in use.

- Section IV (C), bullet 3 of the draft guidance document on opening an NCD states that an internal request by CMS for an NCD could be generated when "**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".

The ACR recommends that CMS provide clarification on bullet 3 above and define parameters which would clarify the meaning of "significant disparities in the care available to Medicare beneficiaries" in that context. The ACR feels strongly that the types of inconsistencies and conflicts in local coverage policies that might generate an NCD request should focus on broad issues (e.g., general health and safety of Medicare beneficiaries), as described above in bullet 3. It is important that CMS maintain a balance between NCD and LCD processes. Therefore, the ACR requests that CMS maintain their Carrier Advisory Committee (CAC) process and continue to ensure local physician input on local level consolidation and development of local coverage determinations (LCDs), as this is an invaluable system for health policy.

- Section IV (C), bullet 4 of the draft guidance document on opening an NCD states another indication for a CMS generated internal request as "**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**".

The ACR recommends that CMS clarify bullet 4 above and set forth specific criteria to help define what is considered 1) significant evidence, 2) a wide variation in billing practices, and 3) potential for fraud under existing policies. In addition, the ACR requests that CMS disclose what resources/data are used to determine the respective types of Program Integrity concerns that generate an NCD request and identify whether and/or how this impacts the LCD processes.

As previously mentioned, the ACR strongly feels that the CAC with local physician input is an invaluable system for health policy. The ACR has nationwide networks of Radiology and Radiation Oncology CAC representatives who review draft LCDs in detail and provide comments to their local Carrier Medical Directors (CMDs). Local CAC and LCD development processes are vitally important to the functioning of physician practices, the education of providers and the exchange of information between providers and Medicare contractors.

- Section IV (C), last paragraph, bottom of page 5, CMS states that "Before deciding whether to generate an NCD, CMS **may** consult with the relevant beneficiary groups, professional bodies and/or manufacturers of the technologies in question. We may also, **from time-to-time**, announce on our website topics that are being considered for potential internally generated requests before the posting of a tracking sheet".

The ACR encourages CMS to routinely consult with relevant medical specialty societies and stakeholders and routinely post announcements on the CMS website topics that are being considered for potential internally generated requests before the posting of a tracking sheet. Therefore, the ACR recommends that CMS add the word "routinely" in place of the words "may" and "from time-to-time" in the above referenced language.

2. ***Opening an NCD/What Constitutes a Complete, Formal Request for an NCD (Section V, bullet 3)***

- Section V, bullet 3 of the guidance document on opening an NCD states that "The requestor should state the benefit category or categories of the Medicare program to which the requestor believes the item or service applies. Examples of benefit categories include durable medical equipment, **physician services**, inpatient hospital services, and **diagnostic test**".

Since diagnostic imaging examinations involve the services of highly qualified physicians, in an effort to help eliminate potential ambiguity, the ACR encourages CMS to clarify the benefit categories and specify within which category these examinations are included.

3. ***Referring an NCD Topic to the MCAC/Review Material Timeline (Section VII)***

- Section VII, first paragraph states that "The MCAC receives background material in preparation for the meeting. This pre-meeting material is usually distributed to the members at least **30 days** prior to the meeting".

- Under "Process", Section VI, paragraph 2 states that "…We ask via the Federal Register notice that all requests for presentations, and any written testimony and

consideration of evidence for the MCAC, be submitted to us in writing at least **20 days** before the meeting".

The 30 day deadline for distribution of the pre-meeting material under Section VII would seem not to allow MCAC members to receive the material referenced in the 20 day deadline under Section VI. The ACR recommends that CMS either cross walk these deadlines so that both reflect "30 days" prior to the meeting, or require a second distribution to members of the material referenced in the above 20 day deadline. This process would allow for all written testimony and respective evidence to be distributed to the MCAC in advance of the meeting.

The ACR appreciates CMS' consideration of the comments above and welcome any questions.

Commenter: Natalie Nicosia, MA. PT.
Organization: American Physical Therapy Association

I am a member of the Geriatric Section of the American Physical Therapy Association and would like to comment on the draft guide to Medicare National Coverage Determination Process. I provide physical therapy homecare services in New York City where housing often causes a person to become homebound.

I would like to participate in the development of programs in the 5 boroughs of New York City providing the opportunity for those who wish to remain living in their own home during their senior years and avoid falls and injuries that require long term care through, screening and treatment from optometry and physical therapy. I believe a system of simple steps could be developed to reduce the need for long-term care and to improve the quality of life for those who wish to remain living in their own home. Identifying and correcting vision, combined with improving postural stability has the capacity to act as a system control for those who are willing to protect themselves in advance.

Under the Eye Care America initiative, Medicare beneficiaries age 65 years and older who have diabetes who haven't had a medical eye exam in the past 3 years are matched up with an ophthalmologist in their area and receive an evaluation and treatment. I propose this service be available to all beneficiaries and also to match up beneficiaries with a physical therapist in their area. It is well documented that eye diseases exacerbate age-related visual loss, increasing falls and concomitant hip fractures. Maximizing postural stability in the mature individual requires the evaluation of visual acuity, contrast sensitivity, depth perception, glare sensitivity, and dark adaptation by an ophthalmologist. A physical therapist must screen for postural hypotension (often in combination with urinary incontinence), gait and balance impairments (insuring some reliable reflexive protective extension exists and is active, and some combination of hip, knee, ankle, or stepping strategy is also active and reliable), sensory and perceptual deficits, provide a home evaluation for environmental hazards (providing environmental cues based on their visual exam), and if necessary refer foot and footwear problems to a pedorthotist.

By insuring that residents are able to safely manage stairways, escalators, and are able to safely enter and exit their apartment or home, residents will be more likely to preserve their independent status and reduce the likelihood they become homebound, reducing the need for nursing home admission or long term care. Age related sensory changes and motor function should be screened within a residents local vicinity taking account their culture and lifestyle within the area of the community they frequent. Because many older adults with a history of falls have no identifiable neurological or musculoskeletal disease, yet perform poorly on tests of senorimotor function, falls risk assessment programs and medical management to reduce the number of falls should be organized into community based programs to fit the individual needs of the communities they serve.

Nocturia, a symptom that occurs in up to 80% of the ambulatory elderly predisposes individuals to falls, especially when the number of visits to the bathroom interferes with the level of continuous restful sleep. Many elderly individuals are reluctant to approach this topic with their health care provider, or deny that a problem exists and frequently reduce their fluid intake so that

they maintain a low level of chronic dehydration further increasing their risk of falls. Continence regimes would be more successful if they were delivered and executed in a client's home while also developing a safer path from bedroom to the bathroom.

By keeping residents independent in activities of daily living and frequently accessing the community, they are less likely to develop complications secondary to a sedentary lifestyle. An estimated 450,000. New Yorkers know they have diagnosed diabetes, and because 1 in every 6 adults is obese (BMI between 25 and 30) this number can be expected to increase. As African Americans, Asian Americans, and Latino individuals are at higher risk of developing diabetes, their communities will suffer from a higher rate of secondary complications including peripheral neuropathies that increases their risk of falls. Visual impairment also increases the risk of falls by reducing the ability of those with diabetes to perform daily foot inspections that prevent lower extremity wounds that hampers mobility and often leads to amputation. Low levels of diabetes symptoms are often tolerated among groups where diabetes affects a high number of persons within the community, and therefore these individuals wait to seek medical attention until they have visible symptoms of peripheral neuropathy, peripheral vascular disease, or a non healing wound. We are morally and financially obligated to prevent these recurrent secondary complications that have been tolerated due to the non-preventative atmosphere in our health care arena.

S.1217 Keeping Seniors Safe From Falls Act should be exercised through the Geriatric Section of the American Physical Therapy Association and the American Academy of Ophthalmology. Programs must be designed and implemented to suit the needs of the immediate communities they serve, allowing regional physical therapists' to work with the city to identify and eliminate architectural barriers. The programs should allow for variability in each of the 5 boroughs, and data collection could be exchanged to provide the most effective and efficient care.

The scientific evidence is adequate to determine that multifactorial risk reduction strategies are cost effective in reducing the rate of falls, reducing functional decline, and nursing home admissions. Therefore providing screening through opthalmolgy and physical therapy to all Medicare beneficiaries so that they can safely and regularly access the community and are safe within their home is a reasonable and necessary service.

Commenter: Joshua Ofman
Organization: Amgen, Inc.

(Comment on next page)

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May 4, 2005

Re: Comments on the National Coverage Decision (NCD) Draft Guidance Documents Released March 7th 2005.

Dear Dr. McClellan and the staff of the Coverage and Analysis Group,

Amgen appreciates the opportunity to submit comments on the draft guidance documents regarding national coverage decisions (NCD), particularly the guidance documents titled *"Factors CMS Considers in Opening a National Coverage Decision (NCD),"* *"Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee,"* and *"Factors CMS Considers in Commissioning External Technology Assessments."*

Amgen is a leading global biotechnology company. Our research mission is to discover therapies that treat grievous illnesses and address unmet medical needs. We support the production and promotion of scientific knowledge that enhances patient safety, health outcomes and quality of medical care. In keeping with these goals, our research has produced products that have positively impacted millions of lives worldwide. However, these positive outcomes would not have been possible without adequate Medicare coverage, which has enabled patient access to these and other needed medicines.

As CMS establishes guidance for coverage policy in the U.S., it must recognize the value of biotechnology products and other innovations in improving the health of the Medicare

population and the nation. Recent studies have shown that each additional dollar spent on healthcare has yielded $2.40-$3.00 in health gains over the past 20 years.[1] Economists have estimated that a 10% decrease in cardiovascular and cancer mortality alone would result in approximately a $10 trillion dollar gain in national wealth.[2] As the value of innovation is recognized, CMS must consider the potential impact of coverage policy on both the innovative process, as well as patient health outcomes. Coverage delays, price controls, and restrictive reimbursement policy have become commonplace in Western and Central European and Asian countries, where free-market principles are not upheld, resulting in a chilling effect on both technology diffusion and innovation.[3] The Department of Health and Human Services has acknowledged that restrictive regulatory policy in the U.S. would have a similar impact:

> "If applied broadly in the United States, government-controlled restrictions on the coverage of new drugs could put the future of medical innovation at risk and may retard advances in treatment and in the development and introduction of new products. Moreover, government controls may reduce or delay access to specific drugs for seniors."[4]

National coverage assessments for many products are frequently subjected to processes and cost containment tools that are neither consistently applied nor sufficiently transparent.[5] This creates significant marketplace uncertainty and impediments in the ability to forecast revenues into the future, all of which impact the ability to attract investment from the capital markets.[6] Moreover, uncertainty and inconsistency in coverage and reimbursement policy can affect provider willingness to utilize products,[7] which impacts patient access to care. This uncertainty not only affects existing products, but also impairs the ability to make effective decisions in early drug development and to forecast the long-term financial potential of mid-to-late stage development projects. Transparent, consistent and predictable coverage and reimbursement policy will facilitate drug development and investment decision-making, which should result in a more productive biomedical research enterprise resulting in greater improvements in patients' lives. Biomedical innovation is an important objective of the Department of Health and Human

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[1] Medtap International, "The Value of Investment in Health Care: Better Care, Better Lives (Executive Summary)," (Bethesda, MD: Medtap, 2003).

[2] Murphy KM, Topel RH. 2003.*Measuring the Gains from Medical Research: An Economic Approach*, The University of Chicago Press, Chicago.

[3] US Department of Commerce – International Trade Administration. *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research, Innovation and Development*. Washington DC, Dec 2004.

[4] US Department of Health and Human Services – Office of the Assistant Secretary for Planning and Evaluation. *Securing the benefits of medical innovation for seniors: the role of prescription drugs and drug coverage*. Washington DC, July 2002.

[5] U.S. Government Accountability Office, *Medicare: Divided Authority for Policies on Coverage of Procedures and Devices Result in Inequities,* Pub. no. 03-175 (Washington: GAO, April 2003).

[6] Vernon JA, Santerre RE, Giaccotto C. *"Are Drug Prices Good for Your Health?"*, Manhattan Institute, Dec 2004. New York

[7] Submission to the House of Commons Health Select Committee, *Inquiry Into the National Institute for Clinical Excellence* , ABPI, January 2002.

Services (HHS).[8] The FDA critical path initiative seeks to streamline and speed the diffusion of innovative technologies.[9] CMS should ensure that its policies do not impede these initiatives but instead facilitate use of important and innovative technologies.

Thus, the NCD process must be transparent, predictable and science-based with a primary goal of ensuring patient access to needed therapies, and the rapid diffusion of medical technology. CMS has stated that the aforementioned guidance documents do not carry the force of regulation and therefore are not binding on CMS and other stakeholders. Nevertheless, these policies will have a profound impact on Medicare coverage of certain therapies. The nature of the criteria in these documents sets thresholds for policy decision making that will significantly impact patient access, quality of medical care and health outcomes for Medicare beneficiaries. We imagine that these policies will also have a dramatic influence on private plan enrollees in addition to Medicare beneficiaries, given commercial plans' views of Medicare as a leader in policy-setting.

Medicare beneficiaries are older, have a higher disease burden, are more likely to be disabled or on dialysis, and are poorer compared with patients who are insured through the private sector. These factors place Medicare beneficiaries at particularly high risk of poor health consequences if restrictive coverage policies limit access to needed treatments. Empirical data demonstrate that lack of adequate coverage or excessive cost sharing is associated with poor health outcomes and increased health services utilization.[10] [11] [12] Coverage limitations across several chronic conditions have been associated with increases in ambulatory and emergency room visits, as well as increased direct medical costs.[13]

For these reasons, coverage guidance must be carefully constructed to improve the current Medicare coverage process while not denying patients access to necessary therapy. We propose that guidance development should proceed based on certain fundamental, patient-centered principles that have led to advances in societal health and improved patient outcomes.

GUIDING PRINCIPLES FOR COVERAGE POLICY

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[8] 69 FR 21839 (Vol. 78 April 22nd 2004).

[9] US Department of Health and Human Services – Food & Drug Administration. *Innovation Stagnation – Challenge and Opportunity on the Critical Path to New Medical Product,* March 2004.

[10] Lurie N, Ward NB, Shapiro MF, Gallego C, Vaghaiwalla R, Brook RH. Termination of Medi-Cal benefits. A follow-up study one year later. *N Engl J Med*. 1986;314(19):1266-1268.

[11] Lurie N, Ward NB, Shapiro MF, Brook RH. Termination from Medi-Cal—does it affect health? *N Engl J Med.* 1984; 311(7):480-484.

[12] Rice T, Matsuoka KY. The Impact of Cost Sharing on Appropriate Utilization and Health Status: A Review of the Literature on Seniors. Kaiser Foundation. 2004. http://www.kff.org/medicare/med120104oth.cfm. Last accessed 04/28/05

[13] Soumerai SB, McLaughlin TJ, Ross-Degnan D, Casteris CS, Bollini P. Effects of a limit on Medicaid drug-reimbursement benefits on the use of psychotropic agents and acute mental health services by patients with schizophrenia. *N Engl J Med.* 1994; 331(10):650-655.

As a science-based and patient-centered company, we are pleased to provide constructive comments and specific recommendations based on patient-centered principles for the current and future draft guidance documents. These fundamental principles are:

1. **Patients require timely access to a broad array of safe and effective drugs and biologicals, which can treat their diverse, complex, and unmet medical needs.**

   Coverage is a prerequisite for allowing patient access to technology. Therefore, the primary role of coverage policy should be to provide Medicare beneficiaries access to items and services that are "reasonable and necessary."[14] Should the calculus of coverage policy-making become predominantly focused on resource reduction through overly stringent evidence-based reviews and coverage barriers many patients would be wrongfully denied timely access to innovative therapies.

   Importantly, new technology requires exposure and access to broad patient populations to better understand the health benefits, to identify how the products are best used under real-world conditions, and to identify new conditions and groups of patients for which a product may provide health benefits. Thus, rapid technology diffusion is a vital element to bringing the value of medicines to patients and providers.

   CMS policies should also ensure that no beneficiary is discriminated against or denied access due to his or her disease or therapies used to treat disease. Special care must be taken to ensure that coverage policies do not aggravate or extenuate existing health disparities.

2. **Healthcare decisions are best made through a shared patient-physician decision-making process.**

   Shared patient-physician decision-making is the ideal model for therapy selection because it appropriately addresses complex individual circumstances. The practice of medicine requires integration of scientific knowledge, past medical history, and individual preferences for therapy. Patients and their physicians routinely personalize medicine to fit the clinical situation they face.

   Overly prescriptive coverage policies, which are based on data from patients enrolled in randomized controlled clinical trials, may have untoward consequences. While these are the most internally valid data to demonstrate efficacy and safety, they frequently cannot be generalized to Medicare beneficiaries taking medication under real-world conditions. Since Medicare beneficiaries tend not to be the "average" patients enrolled in such carefully controlled experiments, providers must be given the access to technology and the decision-making authority to treat individual patients in a medically reasonable and appropriate fashion. Restrictive coverage policy based

[14] 42 U.S.C. § 1395y(a)(1)(A).

on controlled clinical trial data ignores the aforementioned complexities inherent in a large percentage of clinical decisions, as patients vary based on mode of presentation, severity of disease, level of co-morbid disease burden, degree of social support, availability of resources and proximity to high-quality care. Coverage policies should not be overly prescriptive and restrict patient-physician decision-making.

3. **Improvements in quality of medical care will improve healthcare efficiency and decrease wasteful expenditure.**

   Coverage policies should focus on improving the quality of care rather than primarily on cost-containment. Many therapies improve patient outcomes through incremental improvements in efficacy, safety, compliance and adherence, formulation, ease of administration, dosing schedule and fewer drug-drug interactions. These newer therapies could ease burdensome steps in clinical management and lead to decreased healthcare resources. They can also prevent costly complications arising from medical care. Improving the quality of healthcare through these innovations will lead to better healthcare efficiency and decrease wasteful expenditure. The value of medicines and their role in improving healthcare quality and efficiency should be recognized in coverage policy.

4. **The coverage process should be transparent, predictable, have a scientific rationale, and involve iterative communication with relevant stakeholders.** Coverage decisions affect vast numbers of beneficiaries. The rationale for pursuing an NCD, the methodology for conducting its review and analysis and requirements for a positive decision should be clearly and iteratively determined with relevant stakeholders. The guidance documents must establish clear goals for manufacturers so that they can understand the requirements for coverage. Broad, non-specific criteria issued without discussion of their underlying rationale, scientific basis, or role in decision-making will not provide transparency or predictability to the NCD process.

5. **Since healthcare is provided locally, the local coverage process is the most appropriate method to determine what practices are acceptable.** Variations in patient mix, geography, availability of healthcare services and cultural variation in practice significantly differ across the United States. These variances have been referred to as "effective variance".[15] Local Medicare contractors are often in the best position to judge the impact of new technologies in their locale. National coverage decisions should focus on healthcare services where a lack of clinical benefit is well established.

6. **Items and services that have no evidence of effectiveness and have serious safety risks should be examined.** Medicare covers items or services that are "reasonable

[15] Berenson, R.A., Lumpers and splitters: different approaches to understanding variations research. Health Aff (Millwood), 2004. Suppl Web Exclusive: p. VAR98-103

and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[16] Items that are not reasonable and necessary are those that have no evidence of effectiveness and have serious safety risks. Limiting internally generated requests to items or services where the lack of clinical benefit is well established appropriately allows correction of harmful or non-beneficial use of technologies. Such a focus also prevents premature national assessments that may inappropriately restrict patient access to needed therapies. All new drugs and biologicals undergo extensive review by the FDA prior to approval and in most cases, we believe that that the high safety and effectiveness standards required by the FDA should be sufficient for CMS coverage.

7. **Coverage policies should not impede the innovative free-market environment that promotes investment in the discovery of new therapies that improve patient health and outcomes.** The U.S. leads the world in development of new molecular entities. This is in large part due to the pro-innovation environment that US policies and laws have set, which enables academic centers and manufacturers to discover and invent. This free marketplace model of scientific study has in large part contributed to the dramatic health gains in therapeutic areas such as cardiology and infectious diseases. As mentioned before, CMS coverage policies have also played a key role in fostering this supportive environment and should continue supporting this pro-innovation environment.

In recent years CMS has increasingly internally generated NCDs due in large part to concerns about the cost of new technologies to the Medicare program, and has issued conditional coverage policies or restricted coverage to certain subgroups based on existing interpretations of clinical evidence or lack thereof. [17] [18] Although we understand and support the need for the Medicare program to manage its costs wisely, we are concerned that the NCD process will increasingly become a regulatory hurdle for drugs and biologicals whose risk/benefit profile clearly demonstrates that they are safe and effective for individuals to use. Increased issuance of NCDs solely to restrict resources and not for clinical reasons will impede a scientifically rigorous, transparent and predictable process.

We urge CMS to fully partner with affected stakeholders throughout the NCD process and to keep focused on the aforementioned fundamental patient-centric principles in mind. CMS can readily achieve a transparent, predictable and scientifically robust coverage process if it collaborates in an iterative manner with affected stakeholders and clearly outlines the goals of coverage policy. As currently written, the draft guidance on "opening an NCD" does not accomplish these aims. We are pleased to provide our recommendation in the following sections:

1. Opening an NCD

[16] 42 U.S.C. § 1395y(a)(1)(A).

[17] Gillick, M. R. (2004). "Medicare coverage for technological innovations--time for new criteria?" N Engl J Med 350(21): 2199-203.

[18] Gardiner Harris, *U.S. Weighs Not Paying For All Uses Of Some Drugs*, N.Y.Times, January 30th, 2004. (Quoting CMS official).

a. Improving the transparency and predictability of the process
b. Criteria for external and internal requests
c. Prioritizing requests

2. Referrals for external technology assessment
3. Referral to the Medicare Coverage Advisory Committee (MCAC)

When applicable, we subdivide these recommendations based on external vs. internal requests.

RECOMMENDATIONS

Section 1a: Opening an NCD: Improving the transparency and predictability of the process

Recommendation # 1: Implement a screening phase to the NCD process during which CMS provides a notice of intent to affected stakeholders with supporting rationale for considering an NCD.

We strongly urge CMS to create a "screening phase" that outlines processes before an NCD is "accepted" for review.

Internal requests:

Internally generated requests are often a surprise to the users and manufacturer(s) of the item or service and therefore these requests should be discussed prior to the issuance of an NCD. To improve the transparency and predictability of internally generated NCDs, CMS should post a "notice of intent" of potential NCDs on the CMS website and inform the manufacturer. The website should include a complete description of the item or service, indications of interest, and rationale for an NCD review including the reasons that the item or service may not be "reasonable and necessary". The evidence, which serves as the basis for generating the NCD consideration, should be compiled by CMS. This evidence should be of the same nature and quality, as CMS requires for external requests.

CMS should consult with relevant beneficiary groups, professional bodies and manufacturers of the technologies as to whether an NCD is needed. If access to therapy is already available through local processes, an NCD is not necessary.

We recommend that all potentially affected parties be granted sufficient time to gather information and meet and discuss the merits of a CMS-generated NCD prior to formal initiation of any review. NCDs should not be pursued for items or services that do not meet the criteria established by CMS for internally generating an NCD.[19]

[19] The draft guidance criteria outlined by CMS should not be factors that lead to internally generated NCD because they are either best handled by local coverage processes, are vaguely written, make the NCD process unpredictable and opaque, or hinder access to useful technologies. We provide alternative criteria that are more consistent with previous regulations on the NCD process (64 FR 22619; CMS/HCFA notice April 27, 1999, "Medicare Program; Procedures for Making National Coverage Decisions)".

We encourage CMS to further solicit public comment during the screening phase through more informal public forums such as Town Hall meetings or Open Door Forums, and affected parties of the technology should be also able to request an MCAC meeting to evaluate and adjudicate the need for an NCD. Based on these comments, CMS and stakeholders should jointly decide on the need to pursue an NCD.

The 6-month statutory NCD decision-making timeframe starts when an NCD is opened – the initiation phase. By having a screening phase, the duration of the initiation phase may be significantly shortened, potentially resulting in timelier issuance of draft policy. During the NCD review, CMS, the manufacturer or other party reviews the supporting documentation related to the request, reviews clinical trial data, and provides information about relevance to the Medicare population. Much of this review could be accomplished during the screening phase of internally generated NCDs.

Throughout the review and completion process CMS should meet with affected manufacturers and iteratively discuss details of the process, the decision needs and merit of referring the issue for a technology assessment or MCAC.

Finally, CMS should ensure that local contractors continue existing local policies after an NCD is opened. The NCD should not override the local coverage policies until the final NCD ruling has been made.

External requests:

CMS and the requestor should discuss the merits of the external request. Given the proprietary nature of technologies, the details of the meetings should remain private, but an outline of the external NCD request should be placed on a "potential NCD waiting list" that is posted on the CMS website and opened for public comment. If the requestor is different from the manufacturer(s) of the technology, then CMS should also meet with the manufacturer(s) to discuss any potential NCD review. This approach allows for early participation by all affected parties. CMS should clarify during these discussions whether the local coverage process is a more appropriate course than the national process for a particular procedure or technology. The local coverage process is better suited than the national process for reviewing the majority of services and technologies and allowing patient access to needed services.

We agree with CMS that informal contacts and inquiries should not be posted on the CMS website.

Recommendation # 2: Provide coverage for FDA approved indications of drugs and biologicals and off-label uses that are covered by statute (anticancer drugs).

Recent coverage decisions regarding off-label uses of anticancer drugs have generated significant confusion among providers, the public and manufacturers.[20] All new technologies

[20] Gardiner Harris, *U.S. Weighs Not Paying For All Uses Of Some Drugs*, N.Y.Times, January 30th, 2004.

will have partial or incomplete evidence at the time of product launch. Despite these uncertainties, patients are willing to take new medications and physicians are willing to prescribe them because, on balance, the risk/benefit profile of the product strongly suggests a significant role in the treatment of disease. Indeed, Congress recognized this fact and passed into law coverage of off-label uses of anticancer drugs.[21] NCDs, therefore, are not appropriate for 1) FDA-approved indications of drugs and biologicals, 2) Off-label uses of anticancer drugs covered by statute and 3) medically accepted off-label uses of all drugs and biologicals [22]. Indeed many leading scientific organizations recognize the important of off-label use for the care of patients.[23] [24]

Recommendation # 3: Separate and keep independent the benefits determination process from the NCD process.

Congress has not authorized CMS to cover items or services that do not fall into a benefit category defined by statute. In the draft guidance, CMS proposed that it would now issue an NCD explaining when coverage could not be granted based on the lack of an applicable benefit category, rather than on a "reasonable and necessary" basis. We recognize that CMS has not routinely issued NCDs for negative benefit determinations and we support CMS' willingness to better communicate the process of benefit category determinations. We recommend keeping the benefit determination process separate and independent from the NCD process. Given that the benefit category determination is a prerequisite to coverage, we believe such a determination should be done quickly and not be tied to the NCD process.

If a technology clearly does not fit into any benefit category, then it should not be covered. An NCD does not need to be issued. If statutory language for benefit determination is vague or applicability of the item or service to a benefit category is in question, a process should be undertaken that consists of a short, targeted benefit category review. In order to promote consistency among benefit category assignments, it would be helpful for CMS to outline in the coverage guidance document the process by which it determines whether an item or service falls within a benefit category. This open, transparent review should involve requestors and other interested stakeholders, should be independent of the NCD review process and should focus on how the technology in question is likely to be used by Medicare beneficiaries. An appeals process should also be delineated in the event that the Agency interpretation of benefit category is controversial.

Section 1b: Opening an NCD: Criteria for external and internal requests

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[21] 42 U.S.C. § 1395x(t)(2)(B). This definition was added to the Medicare statute by a provision in the Omnibus Budget Reconciliation Act of 1993 (P.L. 103-66) entitled "Uniform Coverage of 'Off-Label' Anticancer Drugs."

[22] Medicare Benefit Policy Manual, Chap. 15 § 50.4.5.

[23] Cranston JW, Williams MA, Nielsen NH, Bezman RJ, for the Council on Scientific Affairs. Unlabeled indications of Food and Drug Administration-approved drugs. *Drug Information Journal.* 1998;32:1049-1061.

[24] American Society of Clinical Oncology, "Off-Label Drug Indications," last accessed at http://www.asco.org/ac/1,1003,_12-002217,00.asp May 2, 2005.

Recommendation #4: Increase access to technologies by handling externally generated NCD requests in an expeditious and transparent manner.

In most instances, we believe that requests for NCD review should be initiated by stakeholders who are directly and adversely affected by the lack of coverage of the technology. As we have mentioned, if the requestor is different from the manufacturer(s) of the technology, then CMS should meet with the manufacturer(s) during a screening phase to discuss the potential scope and/or appropriateness of the NCD. CMS should consider accepting NCDs for review when generally, 1) the item or service may provide a potential benefit to Medicare beneficiaries or may prevent a potential harm and 2) it appears likely that the local coverage process will result in delays in coverage.

Recommendation # 5: Promote transparency and predictability of the NCD process by revising the draft guidance criteria for internally generating NCDs.

The criteria for internally generating an NCD should be consistent with the aforementioned fundamental principles on improving health outcomes in Medicare beneficiaries. Before deciding whether to internally generate an NCD, CMS should engage affected stakeholders during the aforementioned screening phase. CMS and stakeholders should jointly decide about the need for a national assessment. We recommend revising the criteria[25] in the draft guidance for internally generating an NCD as noted below.

CMS should internally generate NCDs only if:

1. Significant controversy exists on whether the item or service is "reasonable and necessary" for the care of patients and local coverage processes are unlikely to resolve or address these concerns;

2. Documented program integrity concerns have arisen under existing local or national policies, and there is potential for fraud under existing policies, and local coverage processes are unlikely to resolve or address these program integrity concerns; or

3. Interpretation of credible, new peer-reviewed evidence indicates that changes may be warranted in current policies for the kinds of reasons described above, and local coverage processes are unlikely to resolve or address these concerns.

The draft guidance criteria outlined by CMS should not be factors that lead to internally generated NCD because they are either best handled by local coverage processes, are vaguely written, make the NCD process unpredictable and opaque, or hinder access to useful technologies. CMS lacks the regulatory authority to use cost criteria, as they were not passed

[25] Draft Guidance for the Public, Industry and CMS Staff; Factors CMS Considers in Opening a National Coverage Decision. The Centers for Medicare Medicaid Services. Document Issued on: March 9, 2005. http://www.cms.hhs.gov/providers/cti/

during prior rulemaking attempts.[26] CMS should not attempt to achieve through a guidance document what it has been unable to achieve through the rulemaking process.

CMS should not internally generate NCDs if:

1. The majority of local contractors already provide coverage for the item or service, or

2. The item or service is a newly approved drug or biological and has not had adequate time to go through the local coverage process.

Finally, CMS should provide for an appeals process that resolves disputes when concerns arise about the substance of the guidance or whether it is being appropriately followed or misapplied.

Section 1c: Opening an NCD: Prioritizing requests

Recommendation #6: Prioritize NCDs based on societal need, which requires maximizing beneficiary access to items that are reasonable and necessary

NCDs should be prioritized based on societal need. This requires maximizing access to reasonable and necessary items and services. If patients already have or are likely to have access through local coverage processes, then an NCD is not worth pursuing. If the technology in question is likely to be reasonable and necessary then CMS should not pursue an NCD. Such a prioritization schedule will effectively screen for technologies with dubious benefit.

Section 2: Referrals for external technology assessment

Recommendation #7: Involve affected stakeholders during the screening phase for views on the need for an external technology assessment.

To make the NCD process transparent, reliable, predictable and robust, CMS should partner with relevant stakeholders in deciding the role of external technology assessments. Providers and manufacturers can be very knowledgeable about product specific attributes and underlying evidence, and CMS should involve these experts early during the screening phase of NCD to discuss the unique circumstances of the technology in question and when or if a technology assessment should be triggered. Discussions centered on determining the most appropriate questions that may serve as the basis for a technology assessment should be explored in an open forum prior to any initiation of an assessment

We also believe that requestors and other interested stakeholders should have the opportunity to comment on draft technology assessments commissioned by CMS, and the details and full contents of the technology assessment should be available to the public upon completion and prior to issuance of the final coverage decision. The external technology assessment should be open and transparent and include explicit notes on the specific research questions that were

[26] *See* 65 Fed. Reg. 31124 (May 16, 2000); 54 Fed. Reg. 4302 (Jan. 30, 1989).

asked, the methodology used to conduct the review, limitations or gaps in existing research and the certainty or uncertainty about the final recommendations/conclusions.

Section 3: Referrals to the MCAC

Recommendation #8: Allow stakeholders the option of asking for an MCAC review if meetings with CMS fail to resolve important clinical and coverage issues.

The MCAC process requires a greater degree of transparency and more involvement with affected stakeholders. We believe CMS should strengthen the role of the MCAC so that it can adjudicate discrepancies among CMS and affected stakeholders, and provide opportunities for any affected parties to request an MCAC meeting prior to initiation of an NCD. Furthermore, we believe that it is imperative that informed patients sit and serve as voting members of the MCAC.

CONCLUSION

Amgen appreciates the opportunity to comment on these important and pivotal draft guidance documents. We believe the draft guidance documents need significant revisions in order to produce a more transparent NCD process. While they do not carry the force of regulation they will in fact create the de-facto standard for coverage policy that will have a long-standing impact on beneficiary access. For CMS to create a transparent, predictable and scientifically robust coverage process it should:

1. Ground its policy in fundamental, patient-centered principles.
2. Involve all directly affected stakeholders in an iterative process throughout the phases of the NCD; and
3. Apply clear standards that do not limit access for beneficiaries and set reasonable expectations for both affected stakeholders and CMS.

Amgen looks forward to collaborating with CMS on these and other draft guidance documents on coverage policy. If you have any questions, please contact Parthiv Mahadevia, MD, MPH, at (202) 585-9637.

Thank you,

Joshua J. Ofman, MD, MHS

Commenter: Hugh O'Neill
Organization: Sanofi-aventis

(Comment on next page)

Hugh M. O'NEILL

May 6, 2005

Coverage and Analysis Group
Centers for Medicare and Medicaid Services
C1-12-28
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Baltimore, Maryland 21244

Re: Comments on Coverage Process Documents Numbers 1 - 3, Excluding Document Number 4 on Coverage with Evidence Development

Sanofi-aventis[1] appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed coverage process guidance documents implementing section 731 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). These Guidance documents require the Agency to make available to the public documents explaining its process for making coverage determinations for new technologies under the Medicare program. Our comments in this letter focus on the process guidance documents concerning factors CMS considers in opening a coverage determination and in referring topics for further review to the Medicare Coverage Advisory Committee (MCAC), or for further external technology assessment.

By way of background on our company, Sanofi-aventis is committed to the fight against disease throughout the world. We have taken up the major challenges of discovering new compounds that are essential to the progress of medical science and launching pharmaceutical products all over the world that constitute real therapeutic progress for patients. Our mission is to discover, develop, and make available to physicians and their patients innovative, effective, well-tolerated, high quality treatments that fulfill vital health care needs. Backed by a world-class research and development organization, we are developing leading positions in seven major therapeutic areas: cardiovascular disease, thrombosis, oncology, diabetes, central nervous system, internal medicine, and vaccines.

We thank CMS for its efforts to describe an inherently complex process involving numerous considerations for a broad array of stakeholders. We share CMS' commitment to the ultimate goal, which is improving health outcomes for Medicare beneficiaries. Our comments focus on the mechanics of the coverage determination process. We are still considering the additional substantive guidance CMS has published around statutory authority for, and the definition and design of

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1 These comments are submitted on behalf of Sanofi-Synthelabo Inc. and Aventis Pharmaceuticals, both part of the Sanofi-Aventis Group.

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methods to collect clinical evidence supporting new and changing patient therapies within the Medicare program.

Sanofi-aventis is pleased to offer the following comments in the areas described above. In general, we believe that the coverage process documents, while a useful opening step, require further development in the following areas:

1. Delineation of Agency responsibilities vis-à-vis FDA;
2. Informal discussions versus formal review in coverage determinations;
3. Handling and release of certain proprietary information;
4. Clarification that the NCD process will not disrupt the existing local coverage process; and
5. Policies applicable to MCAC referrals and external technology assessment.

First, CMS should clearly differentiate its mission and objectives under the Medicare program relative to those of the Food and Drug Administration (FDA), especially with respect to the safety and efficacy of drugs and biologicals. In its process documents, CMS only tangentially refers to and acknowledges the important mission and role of the FDA, and never fully clarifies its working relationship with FDA or what consideration is given in the initiation of Medicare coverage determinations to FDA approval and labeling of products. In addition, CMS does not clearly explain the intersection of a Medicare coverage determination, including referrals for MCAC review or external technology assessment, with data secured under FDA prescribed pre-market clinical trials, or post-market studies or surveillance. CMS' concern over lack of safety and efficacy data for therapies specifically in the Medicare population could be more properly addressed by the FDA given its existing mission and broader scientific and clinical resources. We respectfully recommend that CMS exclude "safety and efficacy" concerns from its definition of "reasonable and necessary," and not include such concerns as a criteria for conducting a national coverage determination.

Second, we recommend that CMS clarify the process of internally engaging with manufacturers and other stakeholders, compared to the actions that occur under a formally initiated review. It is unclear whether seeking informal advice from CMS or informally providing information to CMS will automatically trigger the national coverage process, even if the manufacturer or other stakeholder may conclude that a national determination is not necessary or appropriate at that time. CMS should indicate at what stage during initial, informal discussions it will begin to consider launching the national process, and how other stakeholders may be informed of this consideration before the national process is launched. Also, CMS should allow requestors to withdraw the request for a national coverage determination and permit current policy to continue.

Third, we urge CMS to explain its policies on the handling and release of information obtained during informal contacts, and formally initiated coverage determinations. CMS should delineate what information it considers to be proprietary and its policies to protect proprietary information, and how manufacturers and other stakeholders can inform the agency regarding the proprietary or confidential nature of particular information. This includes the question of staging, i.e. certain data may be treated as proprietary at one stage, but not in a later stage. For example, if a manufacturer, prior to FDA approval of a drug, provides CMS with clinical data not yet in the public realm, such data may not be confidential post-FDA approval. Another example is the handling of pre-publication manuscripts prepared by clinical investigators that have been submitted to peer-reviewed journals for potential publication. Most journals will not publish material that has been made public already, even inadvertently. Failure by CMS to clearly protect the confidentiality of such material at

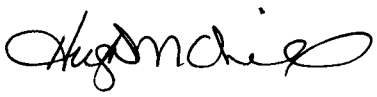
the right stages will have a chilling effect on researchers' willingness to share their work with the Agency.

Fourth, we urge CMS not reduce beneficiary access to necessary care by infringing upon local carriers' authority to cover medically accepted therapies. In the draft Guidance, CMS states it may open a NCD when there is concern about local variation in coverage. We are concerned about how, and under what circumstances, that determination will be made.

Finally, we recommend CMS clarify its policies around referrals to the MCAC and for external technology assessment. We seek clarification around the threshold standards involving clinical data deficiencies or other concerns that serve as triggers for such referrals. CMS should address the role it assigns to existing external review organizations and guidelines in the coverage determination process. For instance, practicing oncologists rely upon carefully reviewed, consensus guidelines on cancer therapies published by external organizations. CMS should clarify the role, if any, it ascribes in its coverage determination and technology assessment process to such established, highly regarded organizations, as well as to drug compendia and peer-reviewed journals. CMS should also clarify the role it envisions for major medical societies or other professional organizations that have the potential for making significant contributions to the Agency's stated goal of determining what products and therapies contribute the most clinical value and improve health outcomes for Medicare beneficiaries. For example, these organizations and other experts should be involved in the key steps of the MCAC process, including framing the questions posed to the MCAC, providing and assessing relevant information to be considered by the MCAC, having adequate opportunity to comment and interact with the MCAC during the public meeting, and an opportunity to submit additional information to CMS following the MCAC meeting. Finally, in recent months, CMS has convened MCAC meetings for certain broad categories of treatment that are not the subject of pending national coverage determinations. Given the agency's limited resources for convening such meetings, the criteria for initiating MCAC or technology assessments that are not part of a formal national coverage determination should be clarified.

Sanofi-aventis thanks CMS for its consideration of our comments. We are committed to the objectives of evidence-based medicine and look forward to continuing to work constructively with CMS on meeting those shared objectives. If you have any questions, please feel free to contact me.

Sincerely,



Hugh O'Neill
Vice President, Integrated Healthcare Markets

Commenter: Mitchell G. Scott, Ph.D.
Organization: American Association for Clinical Chemistry

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) draft guidance "Factors CMS Considers in Opening a National Coverage Determination." We strongly support the agency's decision to develop guidance in this and other policy areas. A more transparent, interactive policy process is likely to result in better and clearer policy decisions and greater regulatory compliance.

Currently, Medicare and each of its local payers determine on its own what level of evidence is necessary to justify coverage of a test. Unfortunately, this patchwork process requires medical device manufacturers and clinical laboratories to duplicate efforts when seeking local coverage determinations from the 36 carriers and fiscal intermediaries. Since each of these contactors has its own process for making these determinations, the result is often inconsistent and conflicting coverage decisions among contractors.

AACC suggests that CMS establish a mechanism whereby a test is automatically forwarded for a national coverage decision (NCD) once it has been approved by a certain number of contractors, possibly one-third. This new process would eliminate disparities of coverage and reduce the burden on the health care entities pursuing coverage decisions, while preserving the local entry option for new technologies. We look forward to working with you on this and other coverage decisions.

By way of background, AACC is the principal association of professional laboratory scientists--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and work in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and its application to health care.

Commenter: Richard Smith
Organization: Pharmaceutical Research and Manufacturer of America

(Comment on next page)

Richard I. Smith
Senior Vice President
Policy, Research and Strategic Planning

PhRMA

May 6, 2005

Steve Phurrough, MD
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Re: **Draft Guidance Document on "Factors CMS Considers in Opening a National Coverage Determination"**

Dear Dr. Phurrough:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this opportunity to comment on a draft guidance released March 9 by the Centers for Medicare and Medicaid Services (CMS) on factors CMS considers in opening a Medicare national coverage determination (the "draft guidance").

PhRMA is a voluntary, nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies. Our members are devoted to discovering new medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA's biotechnology and pharmaceutical research member companies invested $38.8 billion in research and development on medicines in 2004. Through this investment, PhRMA's member companies play a leading role in discovery of new therapies and advancement of scientific and clinical knowledge.

PhRMA appreciates the steps CMS has taken since 1999 to improve the transparency and predictability of its national coverage process. These steps are especially important as coverage policies can have a significant impact on patients' access to medicines and also influence biomedical innovation. We believe the national coverage process should be patient-focused and evidence-based and we look forward to continue working with CMS to further enhance agency procedures in this area.

The three guidance documents released on March 9 address key points in the coverage decision-making process – when CMS will initiate internally a national coverage analysis, when a decision will be referred to the Medicare Coverage Advisory

Committee, and when an external technology assessment will be requested. Our comments focus on the draft guidance on internally generated coverage analyses, and suggest several changes to further improve the clarity, predictability and timeliness of the national coverage process. These three factors are important for providing beneficiary access to medically appropriate care, and also to supporting continued medical innovation. We also make two recommendations regarding the scope of the draft guidance, as described in detail below, and several recommendations regarding CMS' establishment of good guidance practices.

Clarity:

1) Objective Criteria:

The draft guidance seeks to describe situations in which CMS will initiate an internally generated national coverage analysis by providing a list of illustrative examples. However, these examples do not provide needed predictability to help manufacturers and other stakeholders determine whether CMS is likely to initiate a national coverage analysis for a particular item or service. The draft guidance would be improved by inclusion of a set of objective criteria that describe factors that would or would not result in initiation of a national coverage analysis. These criteria should be based on providing patients access to care. The predominant means to do so is through the local coverage process. The NCD criteria should provide an alternative means to access in the uncommon event that the local coverage process is unable to establish coverage. We believe that establishing such criteria would help CMS further its goal of ensuring beneficiary access to appropriate care and improved health care quality.

We propose that CMS should internally generate NCDs only if:

a) Significant controversy exists about the scope of covered items or services and local coverage processes are unlikely to resolve or address these concerns;

b) Documented program integrity concerns have arisen under existing local or national policies, and local coverage processes are unlikely to resolve or address these concerns; or

c) New peer-reviewed evidence indicates that changes may be warranted in current policies for the kinds of reasons described above and local coverage processes are unlikely to resolve or address these concerns.

CMS should not internally generate NCDs if:

a) The majority of local contractors already provide coverage for the item or service, or;
b) The item or service is a newly approved drug or biologic and has not had adequate time for full dissemination through the local coverage process.

2) Relationship to Previous Pronouncements:

Several points raised in the draft guidance touch on issues addressed in prior *Federal Register* Notices.

CMS should improve the clarity of the draft guidance and its consistency with prior policy statements by explaining how the procedures it describes relate to prior notices on national coverage determinations.

For example, the draft guidance describes new thresholds for initiation of an internal coverage analysis that diverge from those described in an April 1999 *Federal Register* Notice[1] on the national coverage process. Whereas the draft guidance cites "significant questions about. . . safety, effectiveness, or obsolescence" raised by providers, patients, or other members of the public," the prior Notice cites the need for "substantial controversy among medical experts."[2] A threshold of having "questions raised" is more and subjective, and thus reduces clarity and predictability. The previous language conveys a standard that is more reasonable and objective. We recommend that CMS modify the guidance document to return to the "significant controversy" language used in the 1999 Notice.

3) Definitions of Key Terms:

We also recommend that CMS define key terms it uses in the draft guidance, either in the guidance itself or in a separate document. A number of these terms relate to standards of evidence for Medicare coverage. We recognize that CMS has begun the process of drafting additional guidance on evidence required for Medicare coverage. However, in order to consider the role and appropriateness of these concepts in the coverage process, it would be helpful to have them defined for purposes of this document.

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[1] Notice, "Medicare Program; Procedures for Making National Coverage Decisions," Health Care Financing Administration, 64 Fed. Reg. 22,619 (April 27, 1999).
[2] *Id.*, at 22,621.

Predictability:

We appreciate CMS' suggestion of posting on the CMS Web site a list items and services for which it may initiate national coverage analysis. PhRMA supports this concept, and we recommend several changes to make it more useful to the public:

1) Post all items under consideration, not just some of them;
2) For each item, briefly explain which criteria CMS believes are relevant to its consideration of an internal request;
3) Keep the list current. Specifically, we recommend that an item or service should be kept on the list for a set period of time (for example, 60 to 90 days), after which the agency would either initiate a request or remove the item from the list. This would enhance predictability by avoiding situations in which the status of items or services remains uncertain for an extended period of time because of their continued presence on the list. Such uncertainty would be detrimental to providers who use items or services covered by Medicare, patients who benefit from these tests and treatments, and the companies that develop them.

CMS' September 2003 *Federal Register* Notice on the national coverage process describes elements that must be included in an external request for coverage in order for it to be considered "complete."[3] The current draft guidance should at a minimum reference these elements.

We also ask CMS to develop clear, evidence-based procedures for agency reviewers to follow when they believe the agency needs to deviate from the criteria for determining when a request is complete. PhRMA is concerned that some coverage decisions have been delayed as a result of requests for additional information that fell outside of the elements defined by the agency in its prior *Federal Register* Notices.

FDA has established procedures for its reviewers to follow when they want to make a decision that would deviate from the requirements of an FDA guidance document.[4] These procedures were developed as part of the agency's good guidance practices procedures. As described in greater detail below, the provision of the Medicare Modernization Act requiring development of guidance on Medicare national coverage

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[3] Notice, "Medicare Program; Revised Process for Making Medicare National Coverage Determinations," Centers for Medicare and Medicaid Services, 68 Fed. Reg. 55,634, (Sept. 26, 2003) (hereinafter "September 2003 Federal Register Notice").

[4] 21 C.F.R. §10.115(d) (3) allows FDA employees to "depart from guidance documents only with appropriate justification and supervisory concurrence."

requirements directs the agency to follow procedures similar to those used to develop FDA's good guidance practices.[5]

Timeliness:

We appreciate CMS' continued efforts to ensure timely completion of national coverage decisions. We recommend several changes to the guidance related to the timeliness and predictability of national coverage decision-making.

1) Performance tracking:

In the draft guidance, CMS describes current agency policy regarding the early phase of a formal external request of coverage – the time between initial submission of a request and CMS considering it complete and "received."

The draft guidance contains helpful suggestions concerning the steps an external requester may wish to take once a request has been submitted -- e.g., scheduling a preliminary meeting with CMS at which the requester may "submit clinical trial protocols for review." We believe it is important for the agency to describe a clear, objective and timely process for this important phase of the national coverage decision-making process.

We also recommend that CMS record the time periods elapsed between submission of external requests and their "receipt," then include these data in required annual reports to Congress on national coverage determinations.[6]

2) Prioritizing external requests:

In the draft guidance, CMS says it will re-prioritize coverage reviews if it has "a large volume of NCD requests to review at once," and that it will "prioritize these requests based on the magnitude of the impact on the Medicare program and beneficiaries."

We believe the predictability and accountability of the national coverage process would be strengthened through a "first in, first reviewed" approach similar to that used by FDA. We support CMS' goal of ensuring that the agency give "priority attention to those requests that have potential for significant impact" on beneficiaries. This goal could be effectively achieved within a predictable,

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[5] Social Security Act, §1862(l)(1) (42 U.S.C. §1395y(l)(1)).
[6] *See* Social Security Act §1869(f)(7) (42 U.S.C. §1395ff(f)(7)).

accountable framework by establishing a "priority" track for requests deemed high-priority based on established criteria.

Scope:

1) Consideration of safety in national coverage policy:

   CMS for the first time in this draft guidance proposes consideration of safety as a factor in initiating coverage decisions. PhRMA is dedicated to regulatory policies that provide strong assurance of product safety, and we believe that regulatory responsibility for this issue rests squarely with the Food and Drug Administration. In its September 2003 *Federal Register* Notice on the national coverage process, CMS notes that the agency "adopts FDA determinations of safety and effectiveness."[7] To the extent that CMS would like to explore steps to support FDA in its safety mission, we recommend it do so via formal rulemaking consistent with FDA's statutory authority and through collaboration with FDA and non-governmental stakeholders.

2) Scope of coverage decisions:

   In the draft guidance, CMS describes important elements of the process for initiating national coverage decisions, but does not explicitly address a requested NCD's permissible scope. The pertinent provision of the Medicare statute defines an NCD as a determination "with respect to whether or not a *particular* item or service is covered nationally . . ."[8] PhRMA requests that CMS include in the guidance a clear affirmation that an NCD pertains to review of particular items and services to determine whether they meet criteria for Medicare coverage.

Guidance development process:

PhRMA appreciates the steps CMS has taken to develop guidance documents through an open process that provides for stakeholder input. Nevertheless, we are concerned, that the agency has provided very little guidance on its good guidance

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[7] September 2003 Federal Register Notice, at 55,636.
[8] Social Security Act §1862(l)(6)(A) ((42 U.S.C. §395y(l)(6)(A)) (emphasis supplied). *See also* 42 CFR §400.202.

practices. As you know, Section 731 of the Medicare Modernization Act requires CMS to issue guidance to the public setting forth "the factors considered" in determining whether an item or service is "reasonable and necessary" for purposes of national coverage determinations. CMS must issue this guidance "in a manner similar to the development of guidance documents" under section 701(h) of the Food, Drug, and Cosmetic Act (FDCA), governing FDA's "good guidance practices" (GGPs).

CMS issued a notice in the Federal Register on September 24, 2004 which included a very limited set of principles for its guidance process, i.e., reflects current thinking, non-binding, opportunity to comment, and comments taken on a continuous basis. Yet, Section 701(h) of the FDCA is quite detailed with respect to FDA's GGPs. CMS should provide further details about its good guidance practices in order to improve the transparency and guidance that Congress sought to provide in enacting Section 731 of MMA. At this point the process seems very amorphous and subject to constant change.

For example, Section 701(h) of the FDCA requires (1) the Secretary to develop guidance documents with public participation; (2) FDA employees not to deviate from guidances without appropriate justification and supervisory concurrence; (3) prior public participation in most instances before guidance documents which change any existing policy interpretation are finalized; (4) uniform nomenclature and uniform approval processes; (5) periodic publication of list of guidances in the Federal Register and periodic review of those guidance documents and revision or withdrawal as appropriate; (6) availability of comments in a public docket; and (7) publication of rule regarding GGPs. Public participation requires meaningful opportunity to comment and consideration of the comments. Comments should be readily accessible as they are in FDA. Moreover, clarity in guidance documents is critical to their effectiveness.

Section 701(h) also instructs FDA to ensure "an effective appeals mechanism" to address complaints that the agency is not developing and using guidance documents in accordance with the legal requirements. CMS should create an effective appeals process which includes a mechanism to resolve disputes when someone believes a guidance document is not being followed or misapplied and also to dispute the substance of the guidance document.

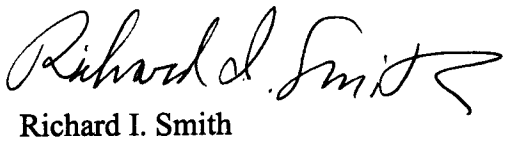
Finally, CMS should specify what pronouncements will be subject to notice and comment rulemaking under the Administrative Procedure Act and what pronouncements will be subject to its guidance procedures. Congress did not intend that all policy development occur through less formal guidance process when rulemaking is otherwise required. Specifying all of these procedures provides the public with certainty about the process and a means to hold CMS accountable.

We appreciate that the process of establishing complete, effective good guidance practices could be time-consuming, but we urge the agency to continue this important effort.

Conclusion:

PhRMA appreciates this opportunity to comment on CMS' draft guidance on opening a national coverage determination. We look forward to working with the agency to bring increased clarity and predictability to this and other elements of the national coverage process.

Sincerely;



Richard I. Smith

Commenter: Bradley Merrill Thompson
Organization: Indiana Medical Device Manufacturers Council
Baker & Daniels

The Indiana Medical Device Manufacturers Council (IMDMC) appreciates the opportunity to submit these comments on the three draft guidance documents referenced above.

IMDMC is an association that represents Indiana-based manufacturers of medical devices and diagnostics products. One key objective of IMDMC is to improve the access of Medicare beneficiaries to innovative, high-quality health care. Medicare's national coverage process can bear directly on this objective. We therefore commend CMS for taking steps – such as the release of these draft guidances – to make the national coverage process more transparent, participatory, and predictable.

Before offering its specific comments, IMDMC would like to urge CMS, as a general approach, to use the guidance-development process to chart for Medicare beneficiaries a direct, expeditious route to quality-improving new services and technologies. We commend to the attention of CMS the use by FDA of the "least burdensome" concept – the concept of employing the least burdensome requirements and processes necessary to ensure public health. In the Medicare context, this same approach could be applied to the requirements and processes associated with ensuring that an item or service is "reasonable and necessary." Through such an approach, CMS could sharpen the coverage process into the straight line that is indeed the shortest distance between beneficiaries and the care they need.

Draft Guidance: "Factors CMS Considers in Opening a National Coverage Determination"

- "Local Variation"

  The draft guidance identifies a number of circumstances that may lead CMS to initiate a national coverage review. One such circumstance is variation in local coverage policies.

  IMDMC believes that the local coverage process is an important and vital means for ensuring access of Medicare beneficiaries to life-saving and life-improving innovations. Coverage policies developed by Medicare's contractors can more readily reflect local medical practice, as well as the individual needs of beneficiaries. We therefore urge CMS, at a minimum, to exercise caution and balance in relying on local variation as the basis for a national coverage review.

  Our principal recommendation is that CMS internally generate a national review only when actions by local contractors are unable to adequately address a coverage issue, such as a risk to the health of beneficiaries. Adequacy of local actions should be a threshold test – one applied before CMS reaches (if at all) consideration of the other circumstances identified in the draft, including the circumstances on which we comment below.

- "Programmatic Impact"

  The draft guidance says that a circumstance that may prompt a CMS-initiated national review is when "[m]ore rapid diffusion of [a new] technology is likely to have a significant programmatic impact on Medicare and other Medicare-related public policies . . ."

  IMDMC is concerned that this language is overly broad and may be interpreted to encompass economic-related impacts. While IMDMC supports steps to make Medicare more cost-conscious, we believe that coverage determinations are properly focused on the quality of the care accessible to beneficiaries.

- "Re-interpretation of Previously Available Evidence"

  The draft guidance also identifies "re-interpretation of previously available evidence" as a circumstance that may warrant a CMS-generated coverage review of an existing service or technology.

  We believe that this language could be interpreted to subject covered services and technologies to abrupt changes in evidentiary standards. While it is important to remain open and sensitive to evolving medical information, the language in the draft implies the application of new standards to the same information – a result that would undermine predictability by putting a coverage decision's duration in doubt.

- "Safety and Effectiveness"

  In several passages, the draft guidance cites "safety and effectiveness" as the basis for a CMS-initiated coverage review. For example, the draft states that such a review may be undertaken "in the interest of the general health and safety of Medicare beneficiaries." Separately, the draft says that a coverage review may be initiated when questions are raised by providers, patients, or the public concerning the safety or effectiveness of a previously covered service or technology.

  IMDMC submits that FDA holds exclusive responsibility within the Department of Health and Human Services for ensuring the safety of products subject to FDA regulation. We recognize that "effectiveness" may have different meanings in the regulatory and reimbursement contexts. We urge CMS to use the draft guidance as a means for explaining more precisely the "effectiveness" questions that may precipitate a Medicare coverage review.

- Advance Notice of Potential Coverage Topics

  In the draft guidance, CMS says that it may announce on its Web site topics that are under consideration for internally generated coverage requests.

  This approach is a helpful means for making the coverage process transparent to stakeholders at an earlier stage. We suggest that the agency make these announcements a matter of routine by posting to the Web *all* topics under

consideration for a CMS-generated coverage request. Moreover, while the agency indicates that it may consult stakeholders in connection with consideration of coverage topics, we believe the draft guidance should delineate clear, structured opportunities for eliciting feedback on all such topics.

Draft Guidance: "Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee"

- "Major Impact"

  The draft guidance identifies several circumstances in which CMS may refer a coverage topic to the Medicare Coverage Advisory Committee (MCAC). One such circumstance is when dissemination of a technology "has the potential to have a major impact on . . . the Medicare program overall."

  Consistent with our comment above on "programmatic impact," IMDMC is concerned that the language on "major impact" is overly broad and could be interpreted to make a cost-related impact the basis for an MCAC referral. We support greater cost-consciousness in Medicare, but we fear that allowing economic factors to influence MCAC referrals could divert focus from helping beneficiaries secure access to high-quality care.

- "Broad, Significant Issues"

  In the draft guidance, CMS says that MCAC may be convened not only to consider coverage requests affecting specific items and services, but also "to address broad, significant issues also relevant to coverage policy development."

  We note that these broader issues will almost certainly affect a broader array of stakeholders. As a consequence, IMDMC suggests that CMS offer special opportunities for stakeholder participation. For example, the agency might ensure that MCAC meetings on broader topics are of sufficient length to permit stakeholder to make more detailed oral comments. Similarly, each such MCAC meeting might hold open its "record" for a specified period, during which written comments could be submitted.

Draft Guidance: "Factors CMS Considers in Commissioning External Technology Assessments"

- "Economic Impacts"

  The draft guidance notes that a technology assessment "can involve the evaluation of a technology's . . . economic impacts."

  IMDMC understands this passage to be descriptive of technology assessments *in general*. As such, the statement is certainly true, and it conveys a message that IMDMC supports – that technology assessments may appropriately evaluate a variety of factors. However, we urge CMS to clarify that technology assessments performed

in connection with Medicare coverage decisions are properly focused on the clinical factors pertinent to beneficiaries' quality of care.

IMDMC very much appreciates the opportunity to submit these comments. We look forward to continuing to work with CMS as the agency develops these and future guidance documents on Medicare's national coverage process.

Commenter: Mark Wanda
Organization: Sepracor

(Comment on next page)

May 6, 2005

Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mail Stop: C1-12-28
7500 Security Blvd.
Baltimore, MD 21244

Re: Draft Guidance on Factors CMS Considers in Opening a National Coverage Determination
Draft Guidance on Factors CMS Considers in Commissioning External Technology Assessments
Draft Guidance on Factors CMS Considers in Referring Topics to the Medicare Coverage Advisory Committee

Dear Sir/Madam:

Sepracor Inc., a research based manufacturer, submits these comments in response to the proposed three guidance documents the Centers for Medicare and Medicaid Services ("CMS") has opened for public comments on March 9, 2005: a guidance on the factors used in opening a National Coverage Determination ("NCD"); a guidance on the factors used in commissioning External Technology Assessments ("TAs"); and a guidance on referring topics to the Medicare Coverage Advisory Committee ("MCAC").

We applaud CMS's efforts to develop a clear and transparent process for making national coverage determinations for medical products. CMS has identified and incorporated into its proposed procedures factors that are both appropriate and essential to reaching an informed and accurate determination of whether to cover a particular medical drug under the Medicare program. Our comments seek to clarify what factors are appropriate to consider in the NCD process, to enhance public participation in the process, and to ensure the integrity of the process. We therefore offer two sets of suggestions, designed to do the following: (1) to clarify that the NCD process is concerned exclusively with clinical considerations; and (2) to increase input of the community medical opinion.

The NCD Process Should be Focused Solely on Clinical Considerations

The statutory and regulatory basis for CMS's authority to issue NCDs make clear that the NCD's determination of when a particular medical item or service is "reasonable and necessary" must be based exclusively on clinical factors and may not include economic considerations, such as the cost of the item or service. *See* 42 U.S.C. § 1395ff(f)(1)(B) ("[T]he term 'national

coverage determination' means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title but does not include . . . a determination with respect to the amount of payment made for a particular item or service so covered."); 42 C.F.R. § 400.202 ("National coverage determination (NCD) means a decision that CMS makes regarding whether to cover a particular service nationally under title XVIII of the Act. An NCD does not include . . . a determination with respect to the amount of payment to be made for the service.").

Given these rules, the factors which may be considered in the course of the NCD review are, accordingly, clinical evidence about the drug's therapeutic ability, safety and effectiveness of use, the advantages of the drug over those competitors within the same therapeutic category, and the opinions of qualified physicians who have prescribed or administered the drug and can testify to its medical benefits and risks. The NCD review must not address drug reimbursement issues. Those determinations should be made by others at CMS with appropriate expertise in accordance with the statute. We do note that, moreover, that the NCD process is ill-suited for the consideration of economic issues.

Overall, the proposed guidance documents faithfully reflect the NCD's clinical character. There are a few instances, however, where the proposed documents depart from this understanding, suggesting instead that economic features of a drug or medical service may be an appropriate consideration. Once again, while Sepracor strongly supports efforts to protect the integrity of the Medicare Trust Fund and eliminate medically unnecessary services, such efforts must be undertaken in a manner consistent with the statute and regulations. We therefore suggest the following changes:

First, the last bullet point on page 5 of the proposed Guidance Document on Opening a National Coverage Determination discusses, as one of the circumstances which may prompt CMS to generate an internal NCD request on an existing technology already in use, the concern with program integrity of existing local or national policies, and refers to "significant evidence of wide variation in billing practices not related to variation in clinical need, or of potential for fraud under existing policies." While we fully appreciate CMS's concern about the integrity of the Medicare program, we do not believe that the NCD process is an optimal vehicle for resolving those concerns. How will the NCD process, which is intended to address clinical issues, resolve questions of Medicare integrity or diverging billing practices? Other mechanisms exist, or should be modified to address these legitimate concerns.

Second, the last paragraph on page 2 of the proposed Guidance Document on Commissioning External Technology Assessments states that a TA may involve the evaluation of a health technology's "economic impacts." For reasons stated above, a TA is not an appropriate mechanism to consider economic factors of a particular health care technology. As CMS has previously stated, an external TA is designed to "provide an independent analysis of all scientific and clinical evidence available on a particular health care technology." *CMS, Revised Process for Making Medicare National Coverage Determinations*, 68 Fed. Reg. 55634, 55639 (Sept. 26, 2003). A TA is a process designed to provide an independent analysis where "there is a conflict or complex medical and scientific literature available." *Id.* Being focused on an analysis of scientific and medical opinion regarding a particular drug or service under review,

how would the TA involve economic considerations? These considerations require a different type of inquiry, one capable both of analyzing the appropriate economic factors and of assessing the policy considerations involved.

Opining on economic issues in the NCD process may cause other problems as well. For example, who would be responsible for considering the economic value of a service or a drug? Would it be CMS or an outside entity? Would the TA involve a study to examine current payment levels for a product in the marketplace and compare those payment levels to its competitors? Could that economic analysis even be undertaken if all of the competitor services or drugs are not also subject to an NCD? How would a TA weight the clinical differences that exist between competitor products in economic terms? All of these questions will need to be addressed by CMS and Congress before any economic considerations are brought into a clinical process staffed by clinical personnel.

Third, the second and last bullet points on page 4 of the proposed Guidance Document on Referring Topics to the Medicare Coverage Advisory Committee mention, as some of the circumstances under which CMS may refer a topic to the MCAC, the instances where (1) existing published studies "have not addressed policy relevant questions," and (2) "CMS determines that the NCD process would be better informed by deliberation that incorporates the viewpoint of patient advocates as well as a broad societal perspective of factors not directly related to the scientific review of the evidence but nevertheless relevant to the decision." With respect to the first reference, it is not altogether clear what the proposed guidance document means by "policy relevant questions." We suggest clarifying that these are policy questions related to the drug's clinical use. With respect to the second reference, we likewise suggest clarifying that the relevant factors should be related to medical considerations. The MCAC's basic mission is to "provide independent, expert advice and assistance to [CMS] in making sound coverage decisions based upon the reasoned application of scientific evidence." 68 Fed. Reg. at 55640. The MCAC is not suited to evaluate considerations which are not related to the questions of the drug's clinical properties or its use by the members of the medical profession.

We do welcome CMS's willingness to incorporate the viewpoint of patient advocates and other community representatives into the MCAC review process. As we explain in the following section, we believe that their views, along with the view of physicians who prescribe and administer the drug under review, should be strongly considered, both by the MCAC and at earlier stages in the NCD process.

The NCD Process Should Strongly Factor in Community Medical Opinion

We applaud CMS's effort to involve community medical opinion in the NCD process, and believe that this effort should be made more extensive. We note that CMS indicated that, before deciding whether to generate an NCD, it "may consult with the relevant beneficiary groups, professional bodies and/or manufacturers of the technologies in question." *Proposed Guidance Document on Opening a National Coverage Determination* at 5. CMS should make these consultations mandatory. Moreover, they should include national professional bodies and local associations of physicians who prescribe or administer the technology under review. In this

way, CMS will be in a position to benefit directly from the opinion of physicians who actually use the drug or service under review.

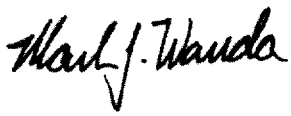
For the same reasons, we suggest having an institutionalized process for soliciting the opinions of these bodies during the public participation part of the NCD review process. *See id.* at 7. The comments of national and local societies of physicians concerning the use of the drug or service, and the appropriate dosage, scripts, and utilization criteria, would then enable CMS to make a more informed decision on whether to commission an external TA and/or refer the request to the MCAC. We are mindful, as is CMS, of the fact that these two additional procedures, while providing the agency with valuable scientific and clinical information, can also slow down the process of preparing an NCD. Therefore, it is important to solicit input from medical professionals familiar with the drug or service under review at the early stages of the process, in order to be in a better position to determine whether these additional steps are necessary. CMS may wish to formalize a process that solicits these comments during the first 30 days of any review period.

Finally, as CMS revises these guidance documents, Sepracor strongly supports policies that will promote public confidence in the NCD process. Accordingly, CMS should mandate that all physician organizations and patient advocacy groups submitting NCD comments be required to disclose any financial support they may be receiving from manufacturers or organizations that are subject to an NCD. While comments from clinical and patient groups will be critical in determining the clinical effectiveness of a particular product or service, the public should know whether these organizations have financial interests involved in the outcome. Sepracor believes that an open and transparent process will yield the best results for patients, stakeholders in the NCD process and the Medicare program.

* * *

Sepracor appreciates your consideration of these positions and welcomes the opportunity to meaningfully contribute to the development of the final guidance documents.

Sincerely,



Mark Wanda
Vice President, Legal Affairs

Commenter: Bonnie Washington
Organization: Novartis Pharmaceuticals Corporation

On behalf of Novartis Pharmaceuticals Corporation ("Novartis"), I am pleased to submit these comments on the above referenced guidance documents recently released by the Centers for Medicare and Medicaid Services (CMS). Novartis Pharmaceuticals Corporation is part of the Novartis Group of Companies, a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye care, and animal health.

Novartis believes CMS's development of these coverage guidance documents is an important step in ensuring openness and public accountability in the national coverage determination (NCD) process. We have had extensive past experience with NCDs and are encouraged by CMS' efforts to provide greater clarity to each step of the process.

In our comments below, we have identified several issues CMS should consider clarifying in its coverage documents to promote beneficiary access to appropriate technologies and maintain a publicly accountable process. These include: maintaining the confidentiality of any preliminary discussions manufacturers may have with CMS; providing more information on the existing collaboration between CMS and the Food and Drug Administration (FDA) for parties interested in opening an NCD; increasing the level of public input in the development of external health technology assessments by the Agency for Healthcare Research and Quality (AHRQ); and clarifying when topics referred to the Medicare Coverage Advisory Committee (MCAC) relate to a specific NCD.

Confidentiality of Preliminary Discussions

Novartis recognizes CMS's 1862(a)(1)(A) authority to review new and existing items and services to determine whether they are "reasonable and necessary" for coverage and payment by CMS. On numerous occasions, CMS has publicly urged manufacturers to meet with the agency concerning the potential need to initiate an NCD for a product and the type of evidence the agency may seek when deciding whether to cover it. This invitation to manufacturers was reiterated in the draft guidance document "Factors CMS Considers in Opening a National Coverage Decision" in the section that discusses preliminary meetings. The draft guidance document, however, does not state whether such meetings would be kept confidential by CMS.

We have appreciated the opportunity to meet with CMS staff regarding our interest to meet the evidentiary needs of the agency and have found these meetings helpful in understanding CMS' perspective. To further promote this level of collaboration, Novartis urges CMS to consider all such meetings confidential and to add such language to the draft coverage document. Specifically, we would be opposed to any decision to publicize when preliminary meetings have taken place between CMS and interested parties or any information on what transpired during such meetings. The posting of preliminary meetings with drug companies—whether during the pre-market or post-market phase—could put the manufacturer at a competitive disadvantage. Additionally, we believe that the disclosure of such meetings would be a disincentive for manufacturers to meet with CMS to

discuss their products and would discourage open dialogue between CMS and the pharmaceutical industry.

Information on Collaboration between CMS and FDA

In the preliminary meeting section of the draft guidance, CMS also lists a number of issues that may be discussed by the requestor and CMS. We appreciate the listing of the types of information that may be addressed during these meetings because we believe that NCD requestors should be able to anticipate what information may be of interest to the agency and what they may gain by proactively choosing to meet with CMS.

One of the topics listed as a potential subject for discussion is any relationship CMS is engaged in with FDA. In all cases when a manufacturer has a preliminary meeting with CMS, we believe CMS must disclose to the manufacturer the relationship they have with FDA regarding the technology in question. It is important for manufacturers to understand whether there has been any data on the product shared between the agencies.

In addition, we strongly believe that manufacturers should be included in any discussions between FDA and CMS regarding their product. While there may be circumstances under which it is appropriate for FDA and CMS to share information (e.g., during a manufacturer-requested parallel approval and coverage review), the potential implications of information-sharing between the agencies are significant. Therefore, such sharing should be limited to cases in which the manufacturer has either consented to or explicitly requests collaboration between the agencies.

Increasing Public Input in the Development of Technology Assessments

The draft guidance describes steps taken by AHRQ and CMS when developing a technology assessment (TA). Novartis believes that there are opportunities for CMS to enhance the openness and transparency of the TA process while meeting its mandated timeframes for decision making.

Specifically, we recommend that when CMS requests an external TA from AHRQ, that CMS' assessment questions are open for public comment via posting on the website, though an open door forum, or at a town hall meeting.

As CMS understands, the formulation of the key questions is an instrumental part of a TA; indeed, the outcome of a TA is often predicated in large part on the questions asked. Public input into the key questions would help to ensure that the TA is framed to answer the most important issues relative to the coverage policy. Allowing public input into the TA process also increases its transparency. At a minimum, we would recommend that CMS solicit input on the assessment questions from the NCD requestor and, when appropriate, the manufacturer of the product.

CMS could also increase public participation by publishing the draft report with the evidence tables for public comment. Doing so would ensure that the comprehensiveness of evidence on a technology is considered and would further allow the manufacturer to submit additional evidence available for consideration in the TA process.

We realize that CMS is statutorily required to issue a draft national coverage determination within nine moths of accepting the request in cases where an external TA is needed. We acknowledge that opening the assessment questions and draft of an external TA for public comment may present a challenge in meeting that deadline. Nonetheless, we believe the agency can still meet the deadline and accommodate the comment period. That approach would yield a significant benefit: a greater degree of transparency in the coverage process, ultimately enabling the formulation of stronger public policy.

Purpose of MCAC Referral

As CMS notes in its draft guidance, CMS may refer topics to the MCAC not only in relation to a specific NCD, but "…to address broad, significant issues also relevant to coverage policy development." When CMS publishes notices of upcoming MCAC meetings, we suggest that CMS indicate the purpose of the meeting, specifically whether the agency is seeking information to internally generate an NCD and how the agency will use the MCAC's recommendations. We believe clarifying the purpose of MCAC meetings is an additional step in bringing more clarity and openness to the coverage process.

We appreciate the opportunity to comment on these instructive and important guidance documents.