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Draft Guidance for the Public, Industry and CMS Staff

Factors CMS Considers in Opening a National Coverage Determination

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For questions regarding specific National Coverage Determinations, please call the Coverage and Analysis Group's main number, at (410) 786-2281.

For questions regarding the National Coverage Determination Process, please contact Vadim Lubarsky, at (410) 786-0840.

Public Comment: Electronic comments may be submitted to CAGInquiries@cms.hhs.gov. Alternatively, written comments may be submitted to the Coverage and Analysis Group, Centers for Medicare & Medicaid Services, Mail Stop: C1-12-28, 7500 Security Blvd. Baltimore, Md. 21244. When submitting comments, please refer to this guidance document. In order to ensure consideration, comments must be received by May 8, 2005.

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This guidance represents the Centers for Medicare & Medicaid Services' (CMS's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind CMS or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, we encourage you to contact CMS staff listed on the title page of this guidance.

I. Purpose of this Guidance Document

The purpose of this guidance document is to relate the factors CMS considers for opening a National Coverage Determination (NCD). This guidance document details: 1) the initial portion of the NCD process; and 2) what CMS considers a complete, formal request necessary to start the formal review process.

II. Background

This is the first in a series of guidance documents required under section 731 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which requires the Secretary to make available to the public the factors considered in making national coverage determinations (NCDs) of whether an item or service is reasonable and necessary. For additional information on the background of the Medicare program or on the overall coverage process, please consult the September 26, 2003 Federal Register Notice on the Process for Making Medicare National Coverage Determinations.

III. Prior to Initiation

The NCD process consists of three major steps: 1) initiation, 2) review, and 3) completion. CMS initiates the NCD process by "opening" the NCD. This is announced to the public by posting a "tracking sheet" on the CMS coverage website (http://cms.hhs.gov/coverage). Development of a complete, formal request for an NCD can be initiated either by an outside party or internally by CMS staff. Though requestors and other interested parties are encouraged to provide additional information, clarify issues, and engage in dialogue as questions arise during the development of an NCD, the NCD is likely to be developed and completed in the most timely manner when relevant information is provided with the initial request. One key goal of publishing a series of guidance documents is to help describe and define the relevant information on which an efficient NCD rests. Although CMS relies on generally accepted principles of evidence-based medicine to evaluate the clinical research literature, we plan to issue in the near

future specific guidance describing our approach to evaluating the scientific information submitted and what constitutes adequate evidence to support NCD development.

A. Informal contacts and inquiries

The public frequently raises general questions about the coverage of items and services to us by telephone, mail, or in person. These questions may include, but are not limited to, asking us to explain the current coverage of a particular item or service, or requesting assistance with, or advice about, possible submission of a formal request for an NCD. We consider all of these contacts to be informal and will not announce the substance of these contacts on our web site.

If requested, CMS will advise interested parties on how to request an NCD, the implications of such a request, and explain what is needed for us to consider a submission to be a complete, formal request. We will offer suggestions to the requestor to clarify the amount and kind of information necessary for us to evaluate whether an item or service is "reasonable and necessary" under the Act, and in some instances, we may provide assistance to the requestor in meeting this threshold.

B. Preliminary meetings

Preliminary discussions are encouraged for requestors to discuss issues that may affect review of their requests. These meetings, either in person or by teleconference, are useful to conserve both industry and government resources in avoiding duplicative work and to assure that all relevant evidence is submitted in a timely manner. Requestors may use this time to:

- 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.

CMS, in turn, may:

- Discuss components and concepts of the NCD process, including but not limited to, benefit category determination, the NCD timeline, evidence-based medicine, local vs. national coverage determinations, FDA and CMS relationships, and other items;
- Provide initial evaluation of supporting documentation presented by the requestor;
- Provide initial information on the likely scope of the review and assessment questions;
- Provide initial opinions on the applicability of the item or service in question to the Medicare population; and
- Provide information on the complete NCD process.

CMS seeks comments on how to make this critical interactive process in NCD development occur as efficiently as possible.

IV. Who Can Request an NCD

Development of a complete, formal request for an NCD can be initiated either by an outside party or by internal Agency personnel.

A. Requests by external parties

A request to make an NCD can be received from an individual or entity who identifies an item or service as a potential benefit (or to prevent potential harm) to Medicare beneficiaries. A requestor may be a Medicare beneficiary, manufacturer, provider, supplier, medical professional association, health plan, or other party who requests our consideration of a particular issue for an NCD.

B. Requests by aggrieved parties

Section 1869(f)(4) of the Social Security Act permits certain aggrieved persons to make a request that the Secretary issue a national coverage or noncoverage determination with respect to a particular type or class of items or services, if the Secretary had not previously made a coverage or noncoverage determination. These individuals are described in section 1869(f)(5) of the Act as "individuals entitled to benefits under Part A, or enrolled under Part B, or both, who are in need of the item or service that is the subject of the coverage determination." Thus, this track can be invoked only for an initial request if we have not issued a coverage or noncoverage NCD.

We realize that in these very rare instances related to requests made by aggrieved parties, we may need to expedite timeframes; we will notify the requestors when these situations arise.

C. Requests initiated internally

One of the key provisions of the Social Security Act is section 1862 (a)(1)(A) which provides, in pertinent part, that no payments be made for items or services that are not reasonable and necessary. While there is no statutory or regulatory definition of the term, the agency has generally interpreted "reasonable and necessary" to include the meaning that the item or service should improve health outcomes overall for Medicare beneficiaries. We may thus internally generate in certain instances a request to develop an NCD in the interest of the general health and safety of Medicare beneficiaries. Generally, once initiated, this process is similar to the externally generated request process. The following are circumstances that may prompt CMS to generate an internal NCD request on an existing technology already in use:

- Providers, patients or other members of the public have raised significant questions about the safety, effectiveness, or obsolescence of currently covered items or services. Similarly, significant concerns may have been raised about the safe and effective use of a therapy in Medicare beneficiaries (e.g., off-label use of drugs) or the appropriateness of a treatment given other available treatment options in the Medicare patient population receiving the service; or
- Interpretation of new evidence or re-interpretation of previously available evidence indicates that changes may be warranted in current policies for the kinds of reasons described above;
- Local coverage policies are inconsistent or conflict with each other to the detriment of Medicare beneficiaries. For instance, the noted variation is not related to local differences in the capabilities of health care providers to use the technology effectively which can be resolved over time, but rather is causing significant disparities in the care available to Medicare beneficiaries that are unlikely to be addressed effectively through provider training and education or through the local coverage process;
- Program integrity concerns have arisen under existing local or national policies, that is, there is significant evidence of wide variation in billing practices not related to variation in clinical need, or of potential for fraud under existing policies.

An internally-generated NCD may also be considered for a new item or service, an existing item or service that has been substantially modified, or for a proposed new use of a covered product if:

- 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;
- More rapid diffusion of the technology is likely to have a significant programmatic impact on Medicare and on other Medicare-related public policies (e.g., reduction in health inequalities);
- Significant uncertainty exists concerning the safety and effectiveness, patient selection, or appropriate facility and staffing requirements for the new technology. The presence of significant uncertainty about benefits and risks is of particular concern when rapid diffusion of the item or service is likely;
- Use of the new item or service likely conflicts with existing NCDs; or
- Available evidence suggests that local variation is not warranted.

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. CMS is particularly interested in comments on the criteria for opening an NCD, especially, on the general criteria described above and on ways in which further useful details of the criteria could be specified. CMS also seeks comment on the most effective

consultative process for alerting interested parties to potential NCD openings under consideration and eliciting their input, keeping in mind resource limitations and the goal of completing the NCD process in a timely manner. CMS expects that public input and discussion of these criteria and the NCD process will help assure the transparency and effectiveness of the NCD process. We also expect that public comments and discussion in response to a future guidance document focused on the types of evidence most relevant to Medicare coverage decision making will provide further clarity for product developers, researchers, and other stakeholders.

V. What Constitutes a Complete, Formal Request for an NCD

There are several ways an individual or entity can contact us about NCDs. One approach involves informal contacts, as described above. The other approach involves "formal requests," and may result in the official opening of an NCD.

The latter process will only be initiated when we receive a complete, formal request. A request is considered to be “received” once certain conditions are met.

A formal request includes:

- A formal request letter and supporting documentation submitted electronically (unless there is good cause for only a hardcopy submission).
- Request identified as a "formal request for an NCD"
- 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 tests. The requestor may recommend one or more benefit categories for the item or service and submit supporting documentation justifying the recommendation. All the information needed to make a benefit category determination, (including that provided by the requestor and generated by the agency) should be in place before the request can be considered complete. In instances when ambiguity may exist, CMS will need to carefully analyze whether the item or service falls under a benefit category determination before opening an NCD in order to ensure that there is an applicable statutory category. If an item or service can fit into more than one benefit category, we have the discretion to assign it to the most appropriate one. CMS seeks comments on important areas where ambiguity may be perceived currently, and on how such ambiguity can most effectively be resolved.
- The requestor should submit adequate supporting documentation along with the formal letter, including a full compilation of the supporting medical and scientific information currently available that measures the medical benefits of the item or service. Additional information on documentation will be discussed in the guidance document on evidentiary standards.

VI. CMS Review of a Formal Request

When a requestor submits a request for an NCD, we review the materials to determine if it meets the definition of a complete, formal request. If the request lacks adequate supporting documentation to enable us to conduct our review, we notify the requestor and explain our rationale. For instance, we may advise the requestor that the quality of the evidence appears limited. However, we will not decline a request simply because the evidence presented seems insufficient.

Requestors are encouraged to schedule and complete a preliminary meeting with the appropriate Coverage and Analysis Group (CAG) personnel. At this meeting, a preliminary review of the item or service and supporting documentation can be presented by the requestor, and any additional information that might be necessary can be requested by CAG personnel. Preliminary meetings are also the appropriate place for the requestor to submit clinical trial protocols for review, if relevant.

Once the request is considered "received," we post the request on our web site under our list of pending coverage issues. Posting of the tracking sheets permits interested individuals to participate in and monitor the progress of the NCD process. This is a key element in making our NCD process more efficient, open, and accessible to the public. Once a formal request is posted, there will be an opportunity for public participation and submission of additional evidence.

We continue to expect that a requestor will submit all evidence currently available pertaining to the issue of whether the item or service is reasonable and necessary. In the absence of adequate evidence, we may conclude that the item or service is not reasonable and necessary or leave the issue for local contractor discretion. Also, if after accepting the request, we reexamine the evidence and come to the conclusion that the item or service related to the request does not fall under a benefit category, we will issue an NCD explaining that coverage cannot be granted based on the lack of an applicable benefit category rather than a determination that the item or service is not reasonable and necessary.

VII. Prioritizing Requests

In the rare event that we have a large volume of NCD requests to review at once, we retain the flexibility to prioritize these requests based on the magnitude of the impact on the Medicare program and beneficiaries. This flexibility will enable us to ensure that we can pay priority attention to those requests that have potential for significant impact on our beneficiaries – a life-saving cancer treatment, a breakthrough in cardiac pacing, etc.

VIII. Where to Submit a Complete Formal Request

Electronic requests may be submitted via www.cms.hhs.gov/coverage using the "contact us" link. Requests may also be submitted in electronic format by mail to:

Centers for Medicare and Medicaid Services; Director, Coverage and Analysis Group; 7500 Security Blvd.; Baltimore, Md. 21244.

IX. Conclusion

Proper application of the principles and procedures outlined in this guidance document can promote public health and access by speeding the development of NCDs, and can assure that NCDs are both accurate and timely.