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Draft Guidance for the Public, Industry, and CMS Staff

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

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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 and Medicaid Services; Mail Stop: C1-12-28; 7500 Security Blvd.; Baltimore, Maryland 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

This guidance document relates the factors CMS considers in referring issues to the Medicare Coverage Advisory Committee (MCAC). It details the function, structure, process and role of MCAC in the National Coverage Determination (NCD) process.

II. Background

This document describes certain steps in the national coverage determination (NCD) process concerning CMS's determination of whether an item or service is reasonable and necessary. The MCAC can be an integral part of the NCD process and its involvement affects the overall timeline for completing NCDs. Specifically, the statutorily mandated timeframe for releasing a proposed decision is six (6) months after the formal request date. If CMS requests recommendations from the MCAC, that timeframe is nine (9) months.

Topics for deliberation are referred to the MCAC when CMS needs independent, expert advice and assistance in making decisions based upon the reasoned application of scientific evidence. In addition to instances where scientific questions pertaining to specific requests for an NCD are raised, CMS may convene the MCAC to address broad, significant issues also relevant to coverage policy development. For example, the MCAC may assist CMS in considering the appropriateness of a framework for the evaluation of diagnostic tests, in assessing the strength of the evidence for multi-factorial, non-invasive, "lifestyle" modifying interventions to treat cardiac disease, or in clarifying what constitutes the standard of care in wound therapy.

On December 14, 1998, we published a notice in the Federal Register (63 FR 68780) announcing the establishment of the MCAC and soliciting nominations for membership. The MCAC was established to provide independent guidance and expert advice to CMS on specific clinical topics. The MCAC operates under a 2-year charter. The current MCAC charter is available on our website http://www.cms.hhs.gov/mcac.

III. Function

The MCAC reviews and evaluates medical literature and technology assessments, and examines other available data and information on the effectiveness and appropriateness of medical items and services that are under evaluation at CMS. The MCAC meets in an open forum to review the submitted evidence, listen to testimony, deliberate and, after arriving at a considered judgment, provide CMS with recommendations as to the strength of the evidence reviewed.

IV. Structure

The MCAC consists of a maximum of 100 appointed members. Members are selected by the Secretary from among authorities in clinical and administrative medicine, biologic and physical sciences, public health administration, patient advocacy, health care data and information management and analysis, health care economics, medical ethics, and other related professions. A maximum of 88 members are at-large standing members, 6 represent consumer interests, and 6 represent industry interests. A Chair and Vice-Chair are appointed from among the pool of at-large members. The Secretary has designated the Director of the Office of Clinical Standards and Quality (OCSQ) as the appointing authority.

At-large members have voting rights and must possess the competence commensurate with the purpose of the MCAC. The consumer and industry representatives are non-voting members who bring the perspectives of beneficiaries and product developers, respectively, to the MCAC discussions. The Chair presides at and conducts the meeting in a manner designed to ensure that the MCAC provides a balanced discussion of the issues. Members are invited to serve a 2-year term with the option of a maximum 2-year extension. The Chair and Vice-Chair serve 1-year terms and may not serve more than 2 consecutive years in their respective capacities.

All MCAC meetings are held in public. The MCAC is scheduled to conduct four to six meetings per year. No more than 15 members can serve at any one meeting, including one consumer representative and one industry representative. Members are selected for meetings based on clinical relevancy and experience related to the specific topic under review. CMS may select subject matter and methodological experts to serve as non-voting, guest MCAC members to provide additional input to panel members. CMS may also invite experts to make formal presentations to the MCAC for a particular meeting.

Primary and secondary reviewers are chosen from the at-large pool to serve as technical experts for each meeting. The reviewers assist the Chair in facilitating effective technical consideration of the meeting topic, bringing specific expertise to the topic under review.

V. Criteria for Referral to the MCAC

In general, CMS may refer a topic to the MCAC under any of the following circumstances:

- It is the subject of significant 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 the 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.

VI. Process

Once a coverage issue is referred to the MCAC, a public meeting is scheduled to discuss the coverage issue under consideration. We will publish a notice in the Federal Register generally 30 days before holding an MCAC meeting. The notice will include the time and place of the meeting, and instructions for public participation so that all interested persons will have ample notification.

There is time allotted for public comment during the course of each meeting. 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. Public testimony pertains to the specific questions being addressed by the MCAC regarding the coverage issue. In general, there are approximately 2 hours devoted to public testimony. The amount of time assigned to each presenter is dependent on the number of requests and the time allotted.

The meetings usually follow the same agenda structure. The CMS Medical Officer or Lead Analyst assigned to the topic under discussion gives a brief presentation to summarize the current coverage, coverage request (if any), and present the questions being addressed. There is also a presentation of any external technology assessment performed regarding the issue under review. Following the CMS presentation and public testimony, MCAC members deliberate openly on the issue. The public may observe the deliberations, but the MCAC generally will not hear further comments during this time except at the request of the chairperson. The MCAC also allows a brief unscheduled open public session for any attendee to address issues specific to the topic. The interested parties sign up during the morning session to request time during this allotted time on the agenda. During the deliberation, the MCAC has the opportunity to question the presenters for further clarification. Based on their considered judgment at the conclusion of the day, the MCAC members make recommendations to CMS on the strength (quality) of the evidence reviewed.

Once we receive the official transcript and executive summary of the meeting, we will post it to our website. We expect these documents to post as expeditiously as possible, usually within 30 days of the meeting.

VII. Review Material

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. The material may include any external health technology assessment (TA) conducted by the Agency for Healthcare Research and Quality or an Evidence-based Practice Center under contract with that agency; any other relevant TA's; an evidence summary prepared by CMS staff; copies of the relevant articles reviewed by CMS; written testimony; FDA documents pertinent to the issue; public testimony and slide presentations submitted by interested parties; voting questions; and any other relevant

material specific to the topic under review. In most cases, all materials distributed to the MCAC are made available to the public.

VIII. How to Access CMS's Home Page

Users can access our home page by entering http://www.cms.hhs.gov. To access information about the MCAC, select "Coverage", then select "Home Page" listed under the Medicare Coverage Advisory Committee heading or www.cms.hhs.gov/mcac.