

**GUIDING PRINCIPLES FOR WHEN NATIONAL COVERAGE
DETERMINATION TOPICS ARE REFERRED FOR EXTERNAL EXPERTISE
VIA A TECHNOLOGY ASSESSMENT AND/OR THE MEDICARE COVERAGE
ADVISORY COMMITTEE
DRAFT GUIDANCE --- NOT FOR IMPLEMENTATION**

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This draft guidance represents the preliminary views of the Coverage and Analysis Group (CAG), Office of Clinical Standards and Quality (OCSQ), Centers for Medicare & Medicaid Services, Department of Health and Human Services (DHHS), concerning referrals of national coverage determination (NCD) topics for additional, external expertise via the Technology Assessment (TA) process through the Agency for Health Care Research and Quality (AHRQ) and/or the Medicare Coverage Advisory Committee (MCAC). It does not create or confer any rights for or on any person and does not operate to bind CMS or the public. We are interested in considering alternative approaches that may be used in referring topics for a TA or for MCAC review. After considering any public comments, CMS plans to publish a general statement of policy.

Comments and suggestions regarding this draft document should be submitted to DHHS, CMS, OCSQ, CAG, 7500 Security Blvd., Mail Stop C1-09-06, Woodlawn, MD 21244. For questions regarding this draft document, contact Patricia Brocato-Simons, (410) 786-0261, or pbrocatosimons@cms.hhs.gov

Background

CMS has made NCDs according to a process detailed in a Federal Register Notice dated April 27, 1999 (64 FR 22619). The process was designed to make it more open, understandable, and predictable to all interested parties. We have received several public inquiries over time seeking clarification on when CMS will refer a topic for external TA assistance, MCAC review, or in some cases, both. The remainder of this document describes our view of the TA process and the circumstances when we will generally request external assistance and/or MCAC consideration. We invite your comments and suggestions on this draft guidance document.

The TA Process

The process of comprehensively evaluating technologies and making coverage determinations is a continuum of TA activities and policy considerations. Depending on the item or service being reviewed, the TA activities may include:

- development of pertinent background information;
- development of an analytic framework;
- specification of assessment questions;
- choice and description of methods;

- critical appraisal of the evidence; and
- development of methods to summarize and discuss the results of the critical appraisal.

In general:

- 1) All NCDs will include the TA activities described above and will be the responsibility of the CAG staff;
- 2) For selected NCDs, external assistance on one or more of the assessment activities will be requested. External assistance will be provided by AHRQ and its evidence-based practice centers (EPCs) or external contractors;
- 3) For a subset of NCDs, assessment activities will be referred to MCAC for review;
- 4) MCAC provides an unbiased, external evaluation of the evidence in a public forum. Specific areas of assistance for the TA/NCD process include: expert clinical and technical review regarding TA methods and conclusions about the net health outcomes of the technology under consideration; expert advice on factors not directly related to evidence review but important to the NCD; and, a forum for formal public input and advice. At selected times, MCAC will also provide general methodological advice not related to a specific NCD.

REQUESTING EXTERNAL TA ASSISTANCE

An external TA might be requested when:

- 1) The scope and magnitude of one or more of the TA activities are too extensive to be reviewed internally within a reasonable timeframe; or,
- 2) The complexity of one or more of the TA activities requires external assistance to supplement CAG staff. Such assistance might be in specific clinical or sub-clinical areas or methodology-related in developing analytic frameworks, applying systematic review methods, and/or in utilizing specific methods such as meta-analyses or Markov modeling.

REFERRAL OF NCD-RELATED TA ACTIVITIES TO MCAC FOR REVIEW AND ADVICE

CMS generally utilizes MCAC to allow for additional expert and public input on coverage topics, including those that are highly complex, have a major potential impact on the health of beneficiaries and/or the Medicare program itself, raise important social, legal or ethical issues, and/or are sensitive Congressional and/or constituent topics. Issues related to specific NCDs may be referred to MCAC when:

- 1) The TA questions are numerous and/or complex, there are complex and/or controversial clinical issues involved, or specialized methods (such as modeling) are employed; or,
- 2) There are potentially relevant factors (such as the potential for better research) that are not directly related to the evidence review but would provide important information for making a coverage determination; or,
- 3) There are competing and/or conflicting TAs or other evaluation controversies from various external sources providing data, or general debate over conclusions. Further impartial input from a diverse group of experts is then sought; or,
- 4) Formal public input on TA methods and data sources (internal or external), or other issues, will be particularly important.

ISSUES NOT RELATED TO A SPECIFIC, CURRENT NCD MAY BE REFERRED TO MCAC AT THE DISCRETION OF CMS WHEN:

- 1) Presentation, public discussion and clarification of a general methodological issue and/or approach would be beneficial for future NCDs or;
- 2) A group of related coverage issues or topics arise over time for which a common evaluation approach might be beneficial.