Paths to Medicare Coverage

Title VIII of the Social Security Act authorizes Medicare beneficiaries to obtain health services from any institution, agency, or person qualified to participate in the Medicare program. The statute lists categories of items and services eligible for Medicare coverage and specifies that no payment may be made for services that are not "reasonable and necessary for the diagnosis treatment of illness or injury or to improve the functioning of a malformed body member" (Social Security Act, Title XVIII, Section 1862(a)(1) (A)).

Until recently, CMS also considered the cost of items and services. This policy is called a "least costly alternative" (LCA) determination. Although there is no statutory provision giving specific authority or prohibiting the application of LCAs, CMS is no longer using LCA determinations. This is because *Hays v. Leavitt* in the U.S. District Court for the District of Columbia held that the Secretary of Health and Human Services lacked the authority to apply the LCA policy under the applicable statute.

The LCA determination policy could be reinstated statutorily through Congressional action. Given Congressional efforts to move Medicare towards paying for performance (as opposed to volume), there have been some discussions to reinstate LCA, but large drug and device manufacturers oppose it.

National Coverage Determinations

National coverage determinations (NCDs) are made through an evidence-based process, with opportunities for public participation. The NCD process is usually reserved for those items or services that have the potential to affect a large number of beneficiaries and that have the greatest impact on Medicare. Over the past 30 years, CMS has made about 300 national coverage decisions. In contrast, Medicare contractors have made about 9,000 local coverage decisions (note: 2003 data).[1] (see a discussion of LCDs below)

CMS strongly encourages those wishing to request an NCD (e.g. industry, beneficiaries, or others) to make contact informally prior to the formal request to learn more about the process. In "Factors CMS Considers in Opening a National Coverage Determination,[2]" CMS suggests informal contacts and preliminary meetings with the agency.

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[1] "An Introduction to How Medicare Makes a Coverage Determination," Medicare Payment Advisory Commission, March 2003, page 246.

[2] "Factors CMS Considers in Opening a National Coverage Determination," CMS, 4/11/2006, http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=6&McdName=Factors+CMS+Considers+in+Opening+a+National+Coverage+Determination&mcdtypename=Guidance+Documents&MCDIndexType=1&bc=BAAIAAAAAAAA&

- Informal contacts and inquiries to CMS to:
    - Raise general questions about the coverage of items and services, which may include, but are not limited to:
        - the current coverage of a particular item or service,
        - requesting assistance with, or advice about, possible submission of a formal request for an NCD.
    - Seek advice from CMS on how to request an NCD, the implications of such a request, and what is needed for CMS to consider a submission to be a complete, formal request.
    - Seek clarification from CMS regarding the amount and kind of information necessary to evaluate whether an item or service is "reasonable and necessary", and
    - Request CMS assistance in meeting this threshold by assisting requestors in locating relevant evidence.
- Preliminary meetings
    - CMS encourages preliminary discussions for requestors to discuss issues that may affect review of their requests.
        - Suggested topics that requestors may wish to discuss at these meetings:
            - Supporting documentation related to the request;
            - Clinical trial data;
            - Short- and long-term action items that stakeholders may adopt;
            - Expectations of evidence in the process; and
            - Information on the applicability of the item or service in question to the Medicare population.
        - CMS 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.

While meetings with stakeholders are not confidential, CMS will attempt to protect the confidentiality of any documents submitted during these meetings to the extent permitted by law, and will not post the substance of preliminary meetings.

It has been suggested that companies build reimbursement-driven data capture into their clinical trials and voluntarily authorize FDA to share data with CMS.

NCD Coverage with Evidence Development (CED)

Coverage with evidence development (CED) is a Medicare policy through which CMS provides conditional payment for items and services while generating clinical data to demonstrate their impact on health outcomes, such as a registry or clinical trials. CED is incorporated into the formal NCD process. The decision to consider a CED option is entirely within CMS's discretion. Since finalizing the CED guidance in 2006, CMS has issued 52 NCDs, 15% of which included CED[3].

There are two types of CED:

- Coverage With Appropriateness Determination (CAD)
  - Additional clinical data is required that is not routinely available on claims forms to ensure that the item or service is being provided to appropriate beneficiaries according to the clinical criteria described in the NCD.
    - For example, an NCD with CAD could be issued if the technology should be restricted to specific patients or providers, or if there is a concern of inappropriate utilization.
- Coverage With Study Participation (CSP)
  - Existing evidence is inadequate to determine whether the "reasonable and necessary" standard is met, but beneficiaries may be enrolled in a clinical trial that is expected to generate sufficient data in a clinical trial registry to allow CMS to make a final coverage determination.
    - For example, an NCD with CSP could be issued if evidence is available but it is not relevant to Medicare beneficiaries.

CMS currently lists six NCDs that are subject to CED:

National Coverage Determination	CED	Paraphrased Language from Decision Memo
Cochlear Implantation	None scheduled at present	Medicare coverage is provided only for those patients who meet all of the selection guidelines only when the provider is participating in, and patients are enrolled in clinical trial.
Chemotherapy for Colorectal Cancer	NCI: Clinical Trials Covered Under the Medicare Anti-Cancer Drug National Coverage Decision	CMS will cover the use of these three drugs in clinical trials identified by CMS and sponsored by the National Cancer Institute (NCI).
PET (FDG) for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung, and	National Oncologic PET Registry	CMS has determined that there is sufficient evidence to conclude that an FDG PET scan for the detection of pre-treatment metastases (i.e., staging) in

[3] "Analysis of CMS CED Comment Solicitation," Avalere, March 2012, page 4.

Testicular Cancers		newly diagnosed cervical cancer. For all other indications in this decision memorandum, CMS has determined that the evidence is sufficient to conclude that an FDG PET scan is reasonable and necessary only when the provider is participating in and patients are enrolled in a prospective clinical study.
Implantable Cardioverter Defibrillators	American College of Cardiology-National Cardiovascular Data Registry	CMS determines that the evidence is adequate to conclude that an implantable defibrillator is reasonable and necessary for patients with certain characteristics, but not all patients.
PET (FDG) for Dementia and Neurodegenerative Diseases	Medicare-Approved PET for Dementia Trial	CMS indicated that an FDG-PET scan is considered reasonable and necessary in patients with mild cognitive impairment or early dementia only in the context of an approved clinical trial that contains patient safeguards and protections to ensure proper administration, use and evaluation of the FDG-PET scan.
Long term oxygen treatment	NHLBI	CMS will cover the home use of oxygen for certain beneficiaries when they are enrolled in clinical trials approved by CMS and sponsored by the NHLBI.
Complete decision memos available on http://www.cms.gov/CoverageGenInfo/03_CED.asp		

Reviewing CED: From November 2011 to January 2012, CMS collected comments regarding ways to improve the CED process. CMS sought comments on:

- Implementation of CED through the national coverage determination (NCD) or other avenues under Part A and Part B,
- Potential impact of CED on the Medicare program and its beneficiaries, and
- Suggested approach to CED to maximize benefit to Medicare beneficiaries.

Most respondents agreed that CED should only be applied within the NCD process and suggested CMS release the criteria they use to determine when to issue a CED.

Mark McClellan, Director of Brookings Institution's Engelberg Center for Health Care Reform (and former CMS Administrator) submitted comments reflecting discussions at a

roundtable in December 2011.[4] The Engelberg Center convened the roundtable to engage experts representing broad segments of the health care system, including public and private payers, regulatory authorities, academia, patient and consumer advocacy organizations, medical product developers, and other organizations. The roundtable suggested four broad areas to improve the application of CED:

1. More comprehensive approach to prioritization and initiation of CED,
2. More systematic strategy and infrastructure for collection and analysis of observational data generated as part of routine delivery of care,
3. Greater clarity about the evidentiary standards and methods to be addressed by CED, and
4. More careful focus on issues of costs and funding for CED, both for the coverage involved and the infrastructure required to develop the data and conduct the analyses.

Currently, CED following the 2006 guidance remains in place as CMS evaluates the comments and drafts a new guidance document. The CMS Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) is holding a meeting on May 16, 2012 to "review desirable characteristics of evidence appropriate for Coverage with Evidence Development (CED)." However, the timeline to finalize new guidance is unclear -- CMS first used CED in 1996, but the CED guidance was not finalized until 2006.

Local Coverage Decisions

If an NCD does not specifically exclude or limit an indication or circumstance, or if the item or service is not mentioned at all in an NCD or in a Medicare manual, an item or service may be covered at the discretion of the Medicare contractors, based on a local coverage determination (LCD). An LCD is a decision made by a Medicare Administrative Contractor (MAC) whether to cover a particular service on an MAC-wide basis.

Contractors develop LCDs by considering medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community. In order of preference, LCDs should be based on:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies,
- General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
    - Scientific data or research studies published in peer-reviewed medical journals
    - Consensus of expert medical opinion (i.e., recognized authorities in the field)
- Medical opinion derived from consultations with medical associations or other health care experts.

[4] "Comments on Opportunities to Improve Coverage with Evidence Development for Medicare Beneficiaries," Mark McClellan, Director, Engelberg Center for Health Care Reform, January 20, 2012, https://www.cms.gov/medicare-coverage-database/staticpages/public-comment.aspx?commentID=1141&ReportType=mcd

Because each MAC develops its own LCDs, a company should review the list of LCDs to determine if a similar product is currently covered in a MAC jurisdiction. A list of the current LCDs by jurisdiction is available on CMS's Medicare Coverage website.[5]

If a similar product is covered, but the company's product does not meet the specifications, LCD reconsideration may be requested**.** The whole LCD or any part/section of the LCD may be reconsidered, such as the Benefit Category Provisions, Utilization Guidelines, and Covered ICD-9 Codes. The LCD reconsideration process requires the same level of evidence required in development of a new LCD. LCDs must be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LCDs. The reconsideration process for Medicare LCDs is open to beneficiaries and providers in the district, and MACs may consider requests from other parties doing business in the jurisdiction.

Parallel Review Pilot for Medical Devices

The two-year Parallel Review pilot is a collaborative effort in which the Centers for Medicare and Medicaid Services (CMS) will begin its National Coverage Decision (NCD) related review process while the Food and Drug Administration (FDA) is completing its premarket review. The sponsor/requestor of the parallel review will gain timely insight to the information needs of CMS to determine whether the product is reasonable and necessary for the Medicare population and obtain early knowledge of any evidence gaps. CMS can address these gaps by implementing coverage with evidence development (CED) (see CED discussion above).

The pilot program expects to accept no more than 3 to 5 candidates a year. Participation in the pilot program is voluntary, will not be revealed, and will not affect the review standards for FDA or for a coverage determination by CMS. The sponsor/requestor, FDA and CMS terminate the parallel review up until CMS posts the NCD tracking sheet.

Appropriate medical devices for the parallel review pilot meet <u>one</u> of the following criteria:

1. New technologies for which the sponsor/requester has a pre-investigational device exemption (IDE) or an approved IDE application designation.
2. New technologies that would require an original or supplemental application for premarket approval (PMA) or a petition for de novo review.
3. New technologies that fall within the scope of a Part A or Part B Medicare benefit category and are not subject to a national coverage decision (NCD).

Example*: GenomeWeb Daily News* reported that molecular diagnostics firm Exact Sciences would utilize the FDA/CMS parallel review process for Cologuard, a stool-

[5] http://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx and http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

based DNA colon cancer screening test based on a biomarker and platform technology licensed from MDxHealth. Exact planned to file a premarket approval application for the test with the FDA in the fourth quarter of 2012, at which point CMS will conduct its national coverage assessment for the test.

Comments: "CMS will need to be able to assess probability of successful market entry before allocating scarce resource to a parallel review, meaningful clinical data will be required. For drugs and biologics that probably means, at minimum, extremely robust phase 2 data, and may mean initial analyses of phase 3 data. For devices, data from a pivotal clinical trial will likely be required. Product developers seeking parallel review will need to do a lot of preparatory work with no guarantee of acceptance until pretty far along the regulatory pathway." *Edward Berger, MassDevice.com*

CMS and FDA encourage any interested sponsors who believe their devices are appropriate candidates and would like to explore the use of the pilot program to contact FDA via email at parallel-review@fda.hhs.gov.