THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAR 20 2008

The Honorable Richard B. Cheney
President of the Senate
Washington, D.C. 20510

Dear Mr. President:

I am respectfully submitting the enclosed report entitled, "National Coverage Determinations." This report is being submitted to Congress in response to requirements of section 522(a) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000, Public Law 106-554.

The report includes a compilation of the actual time periods necessary for the Department of Health and Human Services to complete and fully implement national coverage determinations made in fiscal year 2006 for medical items and services not previously covered as a benefit by the Medicare program. This report also details the time it took to make and implement the necessary coverage, coding, and payment determinations, including the time required to complete each significant step in the process of making and implementing each of the determinations.

I am also sending an identical copy of this report to the Speaker of the House of Representatives.

Sincerely,

Michael O. Leavitt

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

MAR 20 2008

The Honorable Nancy Pelosi
Speaker of the House of Representatives
Washington, D.C. 20515

Dear Madam Speaker:

I am respectfully submitting the enclosed report entitled, "National Coverage Determinations." This report is being submitted to Congress in response to requirements of section 522(a) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000, Public Law 106-554.

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Sincerely,

Michael O. Leavitt

Enclosure

Report to Congress on National Coverage Determinations For Fiscal Year 2006

Michael O. Leavitt
Secretary of Health and Human Services
2008

This is the sixth annual report to Congress on Medicare National Coverage Determinations (NCDs) for the Centers for Medicare & Medicaid Services (CMS). Consistent with section 1869(f)(7) of the Social Security Act (the Act), we report time to complete and implement all NCDs (including items, services and devices not previously covered as a benefit) made between October 1, 2005 and September 30, 2006. In fiscal year (FY) 2006, we continued to meet the deadlines set by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, with an average time of just under 6 months from date of formal request and publication of the Proposed Decision Memorandum (PDM) and 85 days from publication of the PDM to the Final Decision Memorandum (DM) release. There was an average of an additional 81 days to fully implement the payment and coding changes for decisions to cover an items or service (coding changes occur on a fixed quarterly cycle).

Medicare payment is contingent on a determination that a service meets a benefit category, is not specifically excluded from coverage, and in most circumstances, that the item or service is "reasonable and necessary." Section 1862(a)(1)(A) of the Act states that subject to certain limited exceptions, no payment may be made for any expenses incurred for items or services that are not "reasonable and necessary" for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member. For over 30 years, we have exercised these authorities to make a coverage determination regarding whether a specific item or service meets one of the broadly defined benefit categories and can be covered under the Medicare program.

National Coverage Determinations (NCDs)

An NCD is a national policy statement granting, limiting, or excluding Medicare coverage for a specific medical item or service. An NCD is usually written in terms of a particular patient population that may receive (or not receive) Medicare reimbursement for a particular item or service. NCDs are binding on all Medicare Carriers, Fiscal Intermediaries (FIs), Medicare Administrative Contractors, quality improvement organizations (QIOs), Qualified Independent Contractors (QICs), Administrative Law Judges (ALJs), and the Medicare Appeals Council (MAC).

We completed 23 NCDs for FY 2006. Two of the 23 NCDs were initiated and implemented within FY 2006 and the remaining NCDs were either initiated or implemented in FY 2006. In 13 of the NCDs described in Table 1, benefits were expanded beyond what was previously covered under Medicare.

Statutory timeframes for completing NCDs

- **6 months:** formal request date to publication of the PDM: (9 months if there is a Technology Assessment (TA) or a Medicare Evidence Development & Coverage Advisory Committee (MedCAC) meeting).

- **90 days:** Date of publication to release of the final DM

Table 1 below presents the details of each NCO, including the outcome of the NCD and the completion times.

Table 1
Report to Congress on National Coverage Determinations for Fiscal Year 2006

	NCD type/result	Proposed DM[1]	Final DM[2]	NCD implemented[3]
Decisions initiated and implemented in FY 2006				
Infrared Therapy Devices*	New, noncovered	6	90	84
Intracranial Stenting and Angioplasty	Reconsideration, coverage expanded with conditions	6	89	91
Decisions initiated in FY 2005 and implemented in FY 2006				
Bariatric Surgery for the treatment of morbid obesity***	Reconsideration, coverage expanded with conditions, noncovered >65 of age	6	90	98
Cardiac Rehabilitation Programs***	Reconsideration, coverage expanded with conditions	5.9	90	91
Cavernous Nerves Electrical Stimulation with Penile Plethysmography	New, noncovered	6	76	137
Clinical Trial Policy**	Reconsideration, coverage clarified	9	90	92
External Counterpulsation (ECP)	Reconsideration, unchanged	6	90	14
Home Use of Oxygen	New, coverage expanded to patients in clinical trial	4.2	90	197
Intestinal and Multi-visceral Transplantation	Reconsideration, unchanged	6	90	46
Lumbar Artificial Disc Replacement***	New, noncovered for >60 yrs of age	6	90	62
Lung Volume Reduction Surgery	Reconsideration, patients in registry covered	6	91	105
Microvolt T-wave Alternans	New, coverage expanded with conditions	5.6	90	13
Nesiritide for Treatment of Heart Failure	New, noncovered	5.2	90	81
Decisions initiated in FY 2005 and implemented in FY 2006				
Non-Autologous Blood Derived Products for Chronic Non-Healing Wounds	Reconsideration, noncovered	4.6	73	74
Pancreas Transplants	Reconsideration, coverage expanded with conditions	6	90	68
Stem Cell Transplantation	Reconsideration, coverage expanded with conditions	4.4	90	63
Tumor Antigen by Immunoassay CA 125 (Addition of Primary Peritoneal Adenocarcinoma as a Covered Indication)	Reconsideration, coverage expanded	2.9	46	63
Decisions initiated in FY 2006 to be implemented in FY 2007				
Blood Brain Barrier Disruption (BBBD)	New, noncovered	5.6	83	131

Chemotherapy				
Extracorporeal Photopheresis	Reconsideration, coverage expanded with conditions	6	76	104
Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting	Reconsideration, coverage expanded with conditions	6	88	91
Vagus Nerve Stimulation for Treatment of Resistant Depression TRD	Reconsideration, noncovered	6	88	80
Ventricular Assist Devices as Destination Therapy	Reconsideration, coverage expanded with conditions, patients in registry covered	5.6	90	48
Ultrasound Diagnostic Procedures	Reconsideration, coverage expanded with conditions	6	85	22
AVERAGE		**5.7 MONTHS**	**85 DAYS**	**81 DAYS**

• Technology assessment
**MedCAC
******* Technology assessment and MedCAC

[1]Months elapsed from date ofacceptance ofrequest to date ofproposed decision memorandum. (DM) posted on CMS website. [2]Days elapsed from date of proposed DM on website to date offmal decision memorandum (DM). (MMA requires that the frnal DM include changes made as a result of the 30-day comment period).
[3]Days elapsed from date of fmal DM posted on website to date of implementation of instructions.

Factors CMS Considers in Commissioning External Technology Assessments

During the NCD process, we may determine that we need assistance in evaluating the evidence. In many cases, this will be following the opening of an NCD (see Guidance Document on Opening an NCD). In other cases, we may determine that we need a TA to evaluate the available evidence prior to deciding on the need for an NCD. Also, there may be instances where a TA will help inform us on the status of the evidence on certain topics of interest to the Agency.

We explain the factors we consider in commissioning an external technology assessment in our guidance document, which is available on the CMS coverage website at: https://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=7.

In general, we may request an external TA if one of the following conditions applies:

- The body of evidence to review is extensive, making it difficult to complete an internal technology assessment by CMS within the 6-month statutory timeframe;
- An independent formulation of the appropriate assessment questions and methodological approach to an issue is desirable given the complexity or conflicting nature of the medical and scientific literature available;
- Significant differences in opinion among experts concerning the relevant evidence or in the interpretation of data suggest that an independent analysis of all relevant literature will be of value;
- The review requires unique technical and/or clinical expertise not available within CMS at the time of the review;
- The review calls for specialized methods (e.g., decision modeling, meta-analysis) in health technology assessment;
- The topic under consideration will be referred for consideration to the MedCAC; or
- Relevant non-proprietary but unpublished data could be collected and analyzed.

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

We explain the factors we consider in referring a topic to the MedCAC in our guidance document, which is available on the CMS coverage website at: https://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=10.

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

- There is significant controversy among experts. The opinions of clinical and scientific experts about the medical benefit of the item or service, the level of competence of providers, the requirements of facilities, or some other significant consideration that would affect whether the item or service is "reasonable and necessary" under the Social Security Act;
- The existing published studies contain potentially significant methodological flaws such as flawed design, inappropriate data analysis or small sample size;
- The available research has not addressed policy relevant questions;

- The available research has not addressed diseases and conditions or the special needs of the elderly in the Medicare population;
- The existing published studies show conflicting results;
- CMS would like additional expert review of the methods used in external TAs, particularly when there were questions about a TA, complex clinical issues, or specialized methods such as decision modeling;
- CMS would like greater public input by receiving and considering comments on the effectiveness of an item or service that could be subject to varying interpretations. Obtaining the perspective of affected patients and caregivers (e.g., the degree of perceived benefit, subjective assessment of risk, or burden of side effects) through public comments and voting representatives on the panel may be relevant;
- 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 technical review, a preferred methodological approach, or a clinical management issue would benefit future NCDs;
- Dissemination of a technology may have a major impact on the Medicare program, the Medicare population, or the clinical care for specific beneficiary groups;
- 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.