Report to Congress on
National Coverage Determinations
For Fiscal Year 2008

Kathleen Sebelius
Secretary of Health and Human Services
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This is the eighth 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 the amount of time it takes to complete and implement all NCDs (including NCDs for items, services and devices not previously covered as a benefit) made between October 1, 2007, and September 30, 2008. In fiscal year (FY) 2008, 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 6 months from the date of a formal request to the date of publication of the Final Decision Memorandum (DM). Within those six months, it took an average of 78 days from the date of publication of the Proposed Decision Memorandum (PDM) to the final decision. There was an average of an additional 126 days to fully implement the payment and coding changes for decisions to cover an item or service (coding changes occur on a fixed quarterly cycle).

Medicare payment is contingent on a determination that an item or 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 35 years, CMS has exercised these authorities to make coverage determinations regarding whether specific items or services meet one of the broadly defined benefit categories and can be covered under the Medicare program.

National Coverage Determinations (NCDs)

As defined in section 1862(1) of the Social Security Act, an NCD means a determination by the Secretary with respect to whether or not a particular item or service is covered under this title [XVIII]. In general, an NCD is a national policy statement granting, limiting, or excluding Medicare coverage for a particular medical item or service. An NCD is usually written in terms of a specific patient population that may receive (or not receive) Medicare payment 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).

Since multiple contractors process and pay claims for more than 43 million beneficiaries, it takes some time to communicate precisely how to implement these uniform national policies. Implementation may include technical computer systems changes or changes to multiple systems. Beneficiaries are protected by the NCD's effective date, however, even if computer system edits are not completed for some time. Medicare instructions include an effective date that is earlier than the implementation date for contractors.

In FY 2008, there were 20 NCDs either initiated or implemented. In two of the NCDs described in Table 1, benefits were expanded beyond what was previously covered under Medicare. CMS

initiated an NCD in 2007 for Artificial Hearts that was not implemented in time for inclusion in this report. It will be noted in the report for the fiscal year in which it is implemented.

Statutory timeframes for completing NCDs

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

- **90 days:** From the date of publication of a PDM to release of the final DM

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

	Potential NCD type/result	Proposed DM[1]	Final DM[2]	NCD implemented[3]
Decisions initiated in FY 2007 and implemented in FY 2008				
Autologous Blood Derived Products for Chronic Non-Healing Wounds	New, not covered	<6	90	75
Computed Tomographic Angiography	New, coverage remains the same	6	90	138
Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) ***	Reconsideration, coverage expanded	9	90	144
Erythropoiesis Stimulating Agents (ESAs) for non-renal disease indications	New, noncoverage or covered with conditions	<6	77	252
Intracranial Stenting and Angioplasty	Reconsideration, coverage remains the same	<6	88	91
Lumbar Artificial Disc Replacement (LADR)	Reconsideration, not covered all devices	<6	81	48
Microvolt T-wave Alternans	Reconsideration, coverage remains the same	6	88	105
Nebulized Beta Adrenergic Agonist Therapy for Lung Diseases[4]	New, contractor discretion	6	82	134
Percutaneous Transluminal Angioplasty (PTA) and Stenting of the Renal Arteries **	Reconsideration, coverage remains the same	<9	86	81
Positron Emission Tomography (FDG) for Infection and Inflammation	New, contractor discretion	<6	90	131
Prothrombin Time (INR) Monitor for Home Anticoagulation Management	Reconsideration, coverage expanded	<6	90	159

[1] Months elapsed from date of acceptance of request to date of PDM posted on CMS website.

[2] Days elapsed from date of PDM on website to date of final DM. (MMA requires that the final DM include changes made as a result of the 30-day comment period.)

[3] Days elapsed from date of final DM posted on website, i.e. (policy effective date), to date of implementation instructions.

[4] Although CMS completed an NCA for this topic the agency determined that no NCD was appropriate at the time.

Pulmonary Rehabilitation[5]	New, no NCD issued	6	90	104
Screening DNA Stool Test for Colorectal Cancer	New, not covered	6	87	119
[redacted]				
Heartsbreath Test for Heart Transplant Rejection	New, not covered	<6	70	119
Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting	Reconsideration, covered with conditions	6	75	104
Surgery for Diabetes	New, covered with conditions	6	87	95
Surgery on the Wrong Body Part	New, not covered	<6	44	172
Surgery on the Wrong Patient	New, not covered	<6	44	172
Thermal Intradiscal Procedures	New, not covered	6	76	98
Wrong Surgery Performed on a Patient	New, not covered	<6	44	172
[redacted]				

* Technology Assessment, **MEDCAC, *** Technology Assessment and MEDCAC

[5] Although CMS completed a National Coverage Analysis for this topic the agency determined that no NCD was appropriate at the time.

Factors CMS Considers in Commissioning External Technology Assessments

During the National Coverage Determination (NCD) process, CMS may determine that it needs assistance in evaluating the evidence. In many cases, this will be following the opening of an NCD (see Guidance Document on Opening an NCD, which is available on the CMS coverage website at the following address: www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=7). In other cases, we may determine that we need an external TA to evaluate the available evidence prior to deciding on the need for an NCD. Also, there may be instances where an external 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 TA in our guidance document, which is available on the CMS coverage website at the following address: 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 TA 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 Medicare Evidence Development & Coverage Advisory Committee (MEDCAC); or
- Relevant non-proprietary but unpublished data could be collected and analyzed.

Factors CMS Considers in Referring Topics to the MEDCAC

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 the following address: 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 are 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;
- 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; or
- 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.