Report to Congress on
National Coverage Determinations
For Fiscal Year 2011

Kathleen Sebelius
Secretary of Health and Human Services
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This is the eleventh 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), CMS reports the amount of time it took to complete and implement all NCDs (including NCDs for items and services not previously covered as a benefit) made between October 1, 2010, and September 30, 2011. In fiscal year (FY) 2011, we achieved an average time of just over 6 months from the date of a formal request to the date of publication of the proposed decisions memorandum (DM) which aligns with the timeframes set by section 731(a) of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (codified at section 1862(l) of the Act). It took an average of 87 days from date of publication of the proposed DM to the final DM[i]. There was an average of an additional 72 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 fits within a statutory benefit category, is not specifically excluded from coverage, and in most circumstances, that the item or service is "reasonable and necessary" for Medicare beneficiaries. 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 or treatment of illness or injury or to improve the functioning of a malformed body member...." For more than 36 years CMS has exercised these authorities to make coverage determinations regarding whether specific items or services fit within 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 Act, an NCD entails a determination by the Secretary with respect to whether or not a particular item or service is covered under 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, Medicare Administrative Contractors, Quality Improvement Organizations, Qualified Independent Contractors, Administrative Law Judges, and the Medicare Appeals Council.

Since multiple contractors process and pay claims for more than 44 million Medicare beneficiaries, it takes time to communicate precisely how to implement these uniform national policies, once a decision is made. Implementation may include technical, localized computer systems changes, and/or changes to multiple shared computer systems that involve all Medicare contractors and system maintainers. Beneficiaries are protected by the NCD's effective date when an NCD expands coverage, even if computer system edits are delayed. Medicare instructions include an effective date that establishes when items and services will be covered (or not covered) as well as an implementation date indicating the last day contractors have to complete all required system edits.

In FY 2011, 11 NCDs were implemented.

Statutory timeframes for completing NCDs

- **6 months:** From a formal request to publication of the proposed DM (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 proposed DM to release of a final DM.

- Table 1 below presents the details of each NCD implemented in FY 2011, including the outcome of CMS review and the completion times.

Table 1: NCDs implemented in FY 2011

	NCA type/result	Proposed DM [1]	Final DM[2]	NCD implemented[3]
Decisions initiated in FY 2010 and implemented in FY 2011				
Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome	New, coverage with evidence development	<6	90	98
Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer*	New, covered	9	92[4]	39
Counseling to Prevent Tobacco Use	New, covered	6	89	131
Erythropoiesis Stimulating Agents (ESAs) for Treatment of Anemia in Adults with CKD Including Patients on Dialysis and Patients not on Dialysis *	New, Contractor discretion	9	92	N/A[5]
Home Use of Oxygen to Treat Cluster Headache	1st Reconsideration, expanded coverage with evidence development	6	88	42
Intensive Cardiac Rehabilitation (ICR) Program – Dr. Ornish's Program for Reversing Heart Disease	New, Added to list of covered programs	<6	90	74

[1] Months elapsed from date of opening coverage analysis to date of proposed DM posted on CMS Website.
[2] Days elapsed from date of proposed DM 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 CMS website (i.e., policy effective date) to date of implementation instructions.
[4] The due date announced on the CMS website was met. However, when calculated, that due date was 2 days over the statutory due date.
[5] Given the totality of the currently available evidence CMS decided it would not issue a national coverage determination at this time for Erythropoiesis Stimulating Agents (ESAs) for Treatment of Anemia in Adults with CKD Including Patients on Dialysis and Patients not on Dialysis (CAG-00413N).

Intensive Cardiac Rehabilitation (ICR) Program – Pritikin Program	New, Added to list of covered programs	<6	90	74
Magnetic Resonance Imaging (MRI)	2nd Reconsideration, expanded coverage with study participation	<6	85	39
Positron Emission Tomography for Initial Treatment Strategy in Solid Tumors and Myeloma	3rd Reconsideration, expanded contractor discretion	<6	90	82
Ventricular Assist Device as Destination Therapy	2nd Reconsideration, expanded coverage with conditions	<6	82	58
Decisions initiated in FY 2011 and implemented in FY 2011				
Magnetic Resonance Imaging (MRI)	3rd Reconsideration, expanded coverage	<6	73	81
AVERAGE		6.5	87	72

* TA and MEDCAC

Factors CMS Considers in Commissioning External Technology Assessments

During the NCD process CMS may determine that it needs assistance in evaluating the evidence. In many cases this will occur following the opening of an NCD (See guidance document on factors we consider in opening an NCD, which is available on the CMS coverage website at the following address: www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html?redirect=/center/coverage.asp). In other cases we may determine that we need an external Technology Assessment (TA) to evaluate the available evidence prior to deciding on the need for an NCD. There could also be instances where an external TA will help inform us on the status of the evidence on certain topics of interest to the Agency.

CMS explains the factors we consider in commissioning an external TA in a guidance document, which is also available on the CMS coverage website at the following address: www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html?redirect=/center/coverage.asp

CMS 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).
- 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 a guidance document, which is available on the CMS coverage website: www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html?redirect=/center/coverage.asp

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 vary 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.
- 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.

[i]The effective date for an NCD coincides with the date the final decision memorandum is published consistent with section 1862(a)(1)(A) and 1862(l) of the Act.