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

November 30, 2009

The Honorable Joseph R. Biden, Jr.
President of the Senate
Washington, DC 20510

Dear Mr. President:

I am respectfully submitting the enclosed report entitled, "National Coverage Determinations." This report is required by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000.

As you know, Medicare provides coverage for items and services for over 43 million beneficiaries. The vast majority of Medicare coverage determinations are made at the local level by contractors that pay Medicare claims, with input from clinicians that the contractors employ. However, in certain cases, Medicare deems it appropriate to develop a national coverage determination (NCD) for an item or service to be applied on a national basis for all Medicare beneficiaries meeting the criteria for coverage.

This report includes a list of all NCDs made in fiscal year 2007 for medical items and services not previously covered as a benefit by the Medicare program. In addition, it also details the time it took to complete and fully implement these NCDs, including the time it took to make and implement the coverage, coding, and payment determinations necessary to implement each of the determinations.

I hope you find this report useful. I am also sending an identical copy of this report to the Speaker of the House of Representatives. Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

Kathleen Sebelius

Enclosure

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

November 30, 2009

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

Dear Madam Speaker:

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Sincerely,

Kathleen Sebelius

Enclosure

Report to Congress on
National Coverage Determinations
For Fiscal Year 2007

Kathleen Sebelius
Secretary of Health and Human Services
2009

This is the seventh 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, 2006 and September 30, 2007. In fiscal year (FY) 2007, 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 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 87 days from date of publication of the Proposed Decision Memorandum (PDM) to the final decision. There was an average of an additional 110 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 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, CMS has 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)

As defined in section 1862(1) of the Social Security Act, a national coverage determination 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 40 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. However, beneficiaries are protected by the NCD's effective date, even if computer system edits are not completed for some time. Medicare instructions typically include an effective date that is earlier than the implementation date for contractors.

In FY 2007, there were 26 NCDs either initiated or implemented. In 7 of the NCDs described in Table 1, benefits were expanded beyond what was previously covered under Medicare.

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 2006 to be implemented in FY 2007				
Blood Brain Barrier Disruption (BBBD) Chemotherapy	New, noncovered	<6	83	131
Extracorporeal Photopheresis	Reconsideration, coverage expanded with conditions	6	76	104
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	<6	90	48
Ultrasound Diagnostic Procedures*	Reconsideration, coverage expanded with conditions	6	85	22
Electrical Bioimpedance for Cardiac Output Monitoring	Reconsideration, unchanged, local contractor discretion	<6	88	57
Infrared Therapy Devices	New, noncovered	6	90	84
Cavernous Nerves by Electrical Stimulation with Penile Plethsmography	New, noncovered	6	76	131
Clinical Trial Policy (1st Reconsideration)**	Reconsideration, coverage expanded	9	90	92
Intracranial Stenting and Angioplasty	Reconsideration with conditions, covered	6	89	91
Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting	Reconsideration, no change to coverage	6	90	88
Serum Iron Studies (Addition of Restless Leg Syndrome as a Covered Indication)	Reconsideration, unchanged, local contractor discretion	6	89	89
Independence iBOT 4000 Mobility System[4]	Does not meet BCD definition of DME			250

[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 to date of implementation instructions.
[4] Benefit Category Determination (BCD) NCD

Decisions initiated in FY 2007 and implemented in FY 2008				
Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions[5]	New, noncoverage or covered with conditions	<6	77	252
Nebulized Beta Adrenergic Agonist Therapy for Lung Diseases[6]	New, contractor discretion	6	82	134
Lumbar Artificial Disc Replacement	Reconsideration, noncovered all devices	<6	81	48
Prothrombin Time (INR) Monitor for anticoagulation Management	Reconsideration, coverage expanded	<6	90	159
Blood Derived Products for Chronic Non-Healing Wounds	New, noncovered	<6	90	75
Computed Tomography 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
Microvolt T-Wave Alternans	Reconsideration, coverage unchanged	6	88	105
PET for Infection and Inflammation	Reconsideration, coverage remains the same	6	90	131
Artificial Hearts[7]	Reconsideration, covered with conditions	6	90	214
Percutaneous Transluminal Angioplasty (PTA) and stenting of the Renal Arteries**	Reconsideration, no change to coverage	<9	88	86
Screening DNA Stool test for Colorectal Cancer	New, noncovered	6	87	119
Pulmonary Rehabilitation[8]	New, no NCD issued	6	90	104
AVERAGE		**6**	**86**	**114**

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

[5] In view of the intense public interest in the NCD after its publication, CMS wanted to make certain no reconsideration of the NCD was to occur during the initial implementation. Despite the delayed implementation date, the effective date of the NCD was unchanged.

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

[7] Implementation required a change to the hospital claims processing system (GROUPER) that is only updated once per year.

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

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 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: https://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 Technology Assessment (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 the following address: 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 (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: 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.