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

JUN 18 2007

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 detailed 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 2005 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

JUN 1 8 2007

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

Dear Madam Speaker:

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Sincerely,

Michael O. Leavitt

Enclosure

Report to Congress on National Coverage Determinations For Fiscal Year 2005

Michael O. Leavitt
Secretary of Health and Human Services
2007

This report, along with the attachments, constitutes the fifth annual report to Congress on Medicare National Coverage Determinations (NCDs) for the Centers for Medicare & Medicaid Services (CMS). As required by Section 1869(f)(7) of the Social Security Act, we are reporting on the time required to complete and hlly implement NCDs in the previous fiscal year for medical items and services that expand1 coverage under the Medicare program. In fact, every decision, including a non-coverage NCD, made between October 1, 2004 and September 30, 2005 is included in this report. Attachment I elaborates on the report by presenting a table format of the detailed compilation and time required (including a summary of the time required to make and implement the necessary coverage, coding, and payment determinations) to complete NCDs. While claims are paid once a new policy is effective, we are reporting the additional time required to filly implement the coding changes as required by law. Attachment 2 provides a summary of the NCD process, and the legislative and regulatory changes impacting the process. This report, similar to the 2004 report, distinguishes between NCDs developed before the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 took effect, and those after the MMA changed the timeframes for NCD development.

This report includes 16 NCDs for Fiscal Year (FY) 2005; 15 of which expanded coverage for medical items and services under the Medicare program and one that upholds a non-coverage policy. However, only two were initiated and fully implemented within FY 2005, one of which is a reconsideration that expanded coverage to an additional population for an already covered device. The other 14 NCDs were either initiated or implemented in FY 2005, but not both, and one of these NCD was initiated in FY 2003. Eight of the NCDs mentioned in this report were carried over from FY 2004; they were initiated in FY 2004 but did not become fully operational until FY 2005. Five NCDs were initiated in FY 2005 but were not published until the beginning of FY 2006.

As reported in the FY 2004 report, the average time needed to issue and implement an NCD in FY 2004 was 327 days for NCDs initiated pre-MMA and 282 days for NCDs initiated post-MMA. In FY 2005, we continue to meet the deadlines set by MMA, with an average time of 248 days for making NCDs effective and another 73 days to fully implement the payment and coding changes, which occur on a prescheduled quarterly cycle. The timeframe averages below reflect not only the straightforward determinations, but also determinations that may have required an external technology assessment (TA) referral, a Medicare Coverage Advisory Committee (MCAC) recommendation or both. The chart below demonstrates the significant reductions in the time to develop an NCD from FY 2003 to FY 2005, measured in calendar days.

Average Timeframes for National Coverage Development

	AVERAGE TIME FY 2003 Report (in days)	**AVERAGE TIME FY 2004 Report Pre-MMA (in days)**	**AVERAGE TIME FY 2004 Report Post-MMA (in days)**	**AVERAGE TIME FY 2005 Report Post-MMA (in days)**
Overall days from acceptance to implementation	353	327	282	248

[1] Expansion of coverage includes NCDs that expand coverage for new populations and reconsider previous favorable coverage determinations.

In FY 2004, under the MMA process, the timeframe to develop and implement NCDs was reduced to 282 days, compared to 327 days for non-MMA NCDs in FY 2004 and 353 days for NCDs issued in FY 2003. In FY 2005, we have continued to meet the timeframes legislated in the MMA, with an average time of 248 days from acceptance of the request to release of a final decision memorandum. (An additional 73 days, on average, were needed to fully implement the coding and payment changes). One outlier to the reduction in timeframes is the PET for Cancers NCD; because of the complex nature of the issue, the previous lack of evidence, and the rigorous review of the policy, we were not able to fully review and implement the NCD until FY 2005. However, it should be noted that this NCD was initiated before the MMA changes, and that all of the NCDs initiated under the MMA process were developed within legislated timeframes.

Attachment 1 provides a tabular summary of the NCDs and related information. It charts the NCDs along with the periods of elapsed time measured in calendar days for each significant step within the coverage process. The chart contains seven columns for each completed NCD. The first two columns document time needed to obtain a TA and recommendation from an MCAC. Not all issues require an external TA or a referral to the MCAC. However, if either of these routes is chosen to assist in the NCD process, they do extend the time it takes to implement an NCD. Therefore, the columns "Days to Technology Assessment" and "Days to MCAC" represent the time elapsed from date of acceptance to either the date of receiving the TA or the date of receiving the signed MCAC recommendation. The third column represents the time elapsed from the date of acceptance to the date the decision memorandum (DM)/proposed DM was posted to our website for public display. (For NCDs developed before MMA was implemented, the term "DM" is used, and for NCDs developed after MMA, the term "proposed DM" is used.)

Attachment 1 also factors in days from acceptance to posting of the final decision and implementation. The fourth column represents the total elapsed time from date of decision memorandum (DM)/proposed DM posted on website to date of final decision. This is the effective date of the NCD for Medicare beneficiaries. The fifth column represents the total elapsed time from date of acceptance of request to date of final decision posted on website (effective date). The sixth column represents the total elapsed time from date of final decision to date of implementation of instructions. The final column describes whether the NCDs that are subject to MMA timeframes met the prescribed timelines. For decisions prior to MMA, there was a self-imposed 180-270 day timeframe to develop and issue claims processing instructions to our contractors to ensure accurate payment and consistent claims processing (contractual agreement with contractors allow 5 months lead time for any systems changes to ensure accuracy and consistency among our contractors). Before MMA, payment changes were effective within 180 calendar days of the first day of the next full calendar quarter (i.e., January, April, July, or October) that followed the date the decision memorandum was issued. However, MMA legislated that the final NCD, along with coding changes, would be completed within 90 days of the posting of the proposed DM (to include a 30-day comment period and 60 days to implement coding changes for the final decision). It is important to note that although NCDs are effective on the date we release the final decision, the implementation of coding changes for the contractor systems that process claims require additional time. Therefore, although the NCD is effective for items or services furnished on the date the final decision is released, the changes to ensure that claims are paid correctly may

not be implemented until a later date. In these cases, claims may be paid retroactively or contractors may be instructed to hold claims for payment. Regardless, all services performed on or after the NCD effective date (i.e., decision memorandum publication date) will be covered as of that date.

Attachment 2 describes the legislative and regulatory history of the NCD process. This attachment provides a synopsis of the process, overall timeframes, and how timeframes changed recently as a result of the MMA of 2003.

		Pre-decision			Post-decision			
		Days to TA[2]	Days to MCAC[3]	Days to proposed decision[4]	Days to final decision[5]	Total days overall[6]	Total Days to Implement decision[7]	Met MMA timeframe
	Decisions initiated and fully implemented in FY 2005							
1	Implantable Cardiac Defibrillators (3rd reconsideration)[8]	N/A	N/A	N/A	29	29	0	Yes
2	Mobility Assistive Equipment	N/A	N/A	50	91	141	61	No
	Decisions initiated in FY 2004 and implemented in FY 2005							
3	Abarelix for the Treatment of Prostate Cancer	N/A	N/A	178	88	266	71	Yes
4	Aprepitant for Chemotherapy Induced Emesis	N/A	N/A	184	88	272	92	Yes
5	Autologous Stem Cell Transplantation (AuSCT) for Amyloidosis	N/A	N/A	183	90	273	62	Yes
6	Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) 1st Recon **(Remain Non-Coverage)**	40	32	274	87	361	63	Yes
7	Cochlear Implantation	N/A	N/A	180	90	270	92	Yes
8	Carotid Stenting	N/A	N/A	183	89	272	110	Yes
9	Ultrasound Stimulation for Nonunion Fracture Healing	N/A	N/A	184	90	274	69	Yes
10	Smoking and Tobacco-Use Cessation Counseling	N/A	N/A	183	89	272	105	Yes
	Decisions initiated in FY 2005 and implemented in FY 2006							
11	Cardiac Rehab Programs	44	41	176	90	266	N/A	Yes
12	Home Use of Oxygen	19	N/A	126	90	216	N/A	Yes
13	Intestinal and Multi-Visceral Transplantation (reconsideration of approval criteria for transplant centers)	N/A	N/A	184	90	274	N/A	Yes
14	Lumbar Artificial Disc Replacement	N/A	N/A	184	89	273	N/A	Yes
15	Microvolt T-Wave Alternans	N/A	N/A	167	90	257	N/A	Yes
	Decisions initiated in FY 2003 and implemented in FY 2005							
16	PET for Cancers[10]	353	N/A	616	88	704	80	N/A

[2]Calendar days elapsed from date of request of technology assessment to date of receipt of technology assessment
[3]Calendar days elapsed from date of request of MCAC review to date of receipt of signed minutes from MCAC
[4]Calendar days elapsed from date of acceptance of request to date of proposed decision memorandum (DM) posted on CMS website. Prior to MMA, DMs were posted, after MMA, proposed DMs were posted
[5]Calendar days elapsed from datc of decision memorandum (DM)/proposed DM posted on website to date of final decision (MMA requires that the tinal decision include changes made as a result of the 30-day comment period).
[6]Calendar days elapsed from date of acceptance of request to date of final decision posted on website. (MMA requires that final decisions be made within 9 months for NCDs where no TA or MCAC is required, and 12 months for NCDs where a TA or MCAC is necessary).
[7]Calendar days elapsed from date of final decision posted on website to date of implementation of instructions.
[8]The third ICD reconsideration was opened to continue analysis of data from the Sudden Cardiac Death in Heart Failure Trial (SCD-HcFT) as part of a formal request from Medtronic Inc. to expand coverage to include the study population. This data was not publicly available before the close of the second reconsideration, and thus CMS was required by Section 73 1 of the Medicare Modernization Act to issue a final decision within the mandated 9 month timeline, which in this case occurred on December 28,2004. By reopening the reconsideration upon the SCD-HcFT publication, CMS was able to quickly complete the analysis and issue a decision in an expedited timeframe.
[9]Management inaccurately established a final due date that was incorrect **(3 m**onths vs 90 days). Staff completed and posted the final decision on that date.
[10]Due to the complex nature of this issue, the previous lack of evidence, and the rigorous review of the policy, we were not able to fully review and implement the NCD in FY 2005. However, this NCD was initiated before the MMA changes.

Attachment 2

As described in the FY 2004 report, the NCD development process was originally set forth by a Federal Register Notice published on April 27, 1999 (64 FR 22619). The 1999 Notice announced the establishment of a series of internal time frames to enhance the accountability of the NCD process, with a general 90-day timeframe to generate a decision memorandum (DM), and more complex or controversial NCDs requiring an extension of these time frames. Effective October 27, 2003 (68 FR 55634), we issued a new Federal Register Notice that revised the NCD development process in order to make the process more efficient and ensure that we had access to all relevant information to make fully informed decisions, as well as incorporating changes required by the BIPA 2000.

The NCD review process sometimes requires an external technology assessment (TA). An external TA may be requested because 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 staff 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 MCAC; or relevant non-proprietary but unpublished data could be collected and analyzed (See *Factors CMS Considers in Commissioning External Technology Assessments* Guidance Document, April 11, 2006*)*. Under the pre-MMA process, the anticipated completion date for a TA was generally 180 days. Under the MMA process, we only receive an additional 3 months to develop a proposed DM if either a TA or MCAC review is required.

The MCAC continues to be used to supplement our internal expertise and obtain public input and participation in our consideration of "state of the art" technology, science, and medicine. The MCAC is advisory in nature, with the final decision on all issues resting with us. It is chartered under the Federal Advisory Committee Act (FACA). The MCAC is composed of up to 100 members with diverse scientific and medical backgrounds. No more than fifteen members serve at any one meeting. An issue is reviewed and discussed at the MCAC meeting in a public forum. The MCAC develops specific recommendations that are then forwarded to us for consideration in making a national coverage determination.

Section 731 of the MMA, effective January 1, 2004, changed various timeframes effecting NCD development and legislated new revisions to the NCD process. However, the critical steps in the development process continue to include the length of time necessary to make a determination with and without the commission of a technology assessment or referral to the MCAC, and the time necessary to implement the final determination.

The chart below distinguishes between timelines for each significant step in the NCD process before MMA implementation (as designated in the April 1999 and October 2003 *Federal Register* Notices) and after MMA implementation.

Significant Steps in the Completion of an NCD

	Pre-MMA	**Post-MMA**
Determination W/O TA or MCAC	90 Days (3 MOS.)	Draft DM= 6 MOS. Final DM-= 9 MOS.
Determination W/ TA or MCAC	TA: Addt. 180 Days (6 MOS.) MCAC: Addt. 180 Days (6 MOS.)	Draft DM= 9 MOS. Final DM- 12 MOS.
Days to Implement Decision	180-270 Days (From Date of Decision Memorandum) (6-9 MOS.)	*Coincides with Final DM* W/O TA or MCAC= 9MOS. w/TA or MCAC= 12 MOS.
Total Days Overall (from date of initial request to date of implementation)	450 Days (15 MOS.)	9-12 MOS.

The timelines for completing an NCD prior to MMA were self-imposed and as stated earlier, established in the 1999 and 2003 Notices. The target time for a determination not requiring a TA andlor an MCAC review was 90 days. If a TA or MCAC review was required, an additional 90 days was allowed for each. It is important to note that we issued a DM within 60 days of receiving the final report from a TA or MCAC review. The DM merely announced our intention to make an NCD. The actual NCD was issued within 60 calendar days of announcing an effective1 implementation date after the release of the DM.

The target time to implement an NCD was 180 to 270 days from the date of completion of the DM. The range accounted for systems changes, if necessary. If a decision was made to cover an item or service, frequently claims processing instructions were developed and issued to our contractors to ensure accurate payment and consistent claims processing. Generally, we made payment changes effective within 180 calendar days of the first day of the next full calendar quarter that followed the date the NCD was issued. Not all NCDs required systems changes. However, if system changes were necessary, this added to the time required to implement an NCD.

Specifically, Section 73 1 of the MMA altered our procedures for making NCDs. Changes increase the opportunity for public participation by permitting comments on a proposed coverage decision. But more importantly, MMA changed the timeframes for developing NCDs. Under the MMA, proposed decision memorandums are made public via our website within 6 months of the date of the request for NCDs not requiring a TA or MCAC review. However, if the NCD requires a TA or MCAC review, the proposed DM must be made public within 9 months. Following the proposed decision, there is a 30-day public comment period,

and comments are then incorporated and a final decision implemented within 60 days of the close of the public comment period. The MMA requires that the time to develop and implement coding changes for a final decision coincide. Through the implementation of MMA, the time to complete an NCD has been reduced.

The MMA also requires the Secretary to make public the factors and timelines considered in making NCDs (i.e. whether an item or service is "reasonable and necessary" for Medicare beneficiaries. The process for issuing NCD guidance documents was issued as a *Federal Register* Notice on September 24, 2004. We have made significant strides in explaining to the public our rationale for various portions of the NCD process, and have already issued four guidance documents explaining key portions of the NCD process: 1) opening an NCD, 2) factors in commissioning a TA, 3) factors in requesting an MCAC recommendation, and 4) coverage with evidence development. We believe that these documents have considerably enhanced the communication and interaction with stakeholders, and we plan to issue other guidance documents further explaining the NCD process and incorporating public comments to make the process more open and transparent.