

Report to Congress on  
National Coverage Determinations  
For Fiscal Year 2004

Michael O. Leavitt  
Secretary of Health and Human Services  
2006

This report, along with the attachment, constitutes the fourth annual report to Congress on Medicare National Coverage Determinations (NCDs) for the Centers for Medicare & Medicaid Services (CMS). As required by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA 2000), we are reporting on the time required to complete and fully implement NCDs in the previous fiscal year for medical items and services not previously covered by the Medicare program. Attachment 1 elaborates on the report by presenting a table format of the detailed compilation and time required to complete and fully implement NCDs made between October 1, 2003 and September 30, 2004 (including a summary of the time required to make and implement the necessary coverage, coding, and payment determinations).

This report, unlike the 2003 report, distinguishes between NCDs developed before the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 took effect, and those after the Law changed the timeframes for NCD development. Specifically, seven of the NCDs included in this year's report have been completed under the newly revised NCD process established by Section 731 of the MMA, effective January 1, 2004. Based on our own internal improvements, and through the implementation of the MMA, we have significantly reduced the time to complete an NCD.

This report includes fourteen NCDs for Fiscal Year (FY) 2004 that expanded coverage for medical items and services not previously covered by the Medicare program. However, only two were initiated and fully implemented within FY 2004. The remaining twelve were either initiated or implemented in FY 2004, but not both. Six of the NCDs mentioned in this report were carried over from FY 2003; they were initiated in FY 2003 but did not become fully operational until FY 2004. The remaining six NCDs were initiated in FY 2004 but were not published until the beginning of FY 2005. As reported in the FY 2003 report, the average time needed to issue and implement an NCD in FY 2003 was 460 days. In FY 2004, prior to the MMA implementation, we substantially reduced that time to 370 days. Once the changes in the MMA were implemented, we were able to reduce the time even further to 273 days. Where appropriate, these averages 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 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 timeframes 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 timeframes. Effective October 27, 2003 (68 FR 55634), we issued a new Notice that revised the NCD development process in order to make the process more efficient and to ensure that we had access to all relevant information to make fully informed decisions. This notice also incorporated changes required by the BIPA of 2000.

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 comprised 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. The recommendations are then forwarded to us for consideration in making a national coverage determination.

The NCD review process often requires an external technology assessment (TA). An external TA is requested if the scope and magnitude of the subject are too extensive to be reviewed internally. TAs are typically used to assist in the evidence review during the NCD process and in some cases, to identify those areas that need further evidence development. Under the pre-MMA process, the anticipated completion date for a TA was generally 180 days. Under the MMA process, we have only three additional months to develop a draft decision if either a TA or MCAC review is required.

The MMA, effective January 1, 2004, changed various timeframes affecting 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 (TA) or referral to the Medicare Coverage Advisory Committee (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 Federal Register notices) and after MMA implementation.

### Significant Steps in the Completion of a NCD

	Pre-MMA	Post-MMA
<b>Determination without TA or MCAC</b>	90 Days (3 MOS.)	Proposed DM <sup>1</sup> = 6 MOS. Final DM= Addt'l 90 Days
<b>Determination with TA or MCAC</b>	TA: Addt. 180 Days (6 MOS.) MCAC: Addt. 180 Days (6 MOS.)	Proposed DM= 9 MOS. Final DM= Addt'l 90 Days
<b>Days to Implement Decision</b>	180-270 Days (From Date of Decision Memorandum) (6 – 9 MOS.)	*Coincides with Final DM* w/o TA or MCAC= 6 MOS + Addt'l 90 Days. w/TA or MCAC= 9 MOS.+ Addt'l 90 Days
<b>Total Days Overall (from date of initial request to date of implementation)</b>	450 Days (15 MOS.)	9-12 MOS.

<sup>1</sup> Decision Memorandum

The timelines for completing an NCD prior to MMA were self-imposed, and as stated earlier, were established in the 1999 and 2003 Notices. The target time for a determination not requiring a TA and/or 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 decision memorandum (DM) within 60 days of receiving the final report from a TA or MCAC review. The DM merely announced our intention to issue an NCD.

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 DM was issued. Not all NCDs required systems changes. However, if system changes were necessary, this added to the time required to implement an NCD.

Section 731 of the MMA altered our procedures for making national coverage determinations. 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 coverage decisions are made public via our website within six 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 coverage decision must be made public within nine 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 a final decision coincide. Therefore, through the implementation of MMA, the time to complete an NCD has been reduced significantly. The chart below demonstrates the significant reductions in the time to develop an NCD from FY 2003 to FY 2004, measured in calendar days.

### **Significant Steps for Issuing a Final Decision**

	<b>AVERAGE TIME FY 2003 Report (in days)</b>	<b>AVERAGE TIME FY 2004 Report Pre-MMA (in days)</b>	<b>AVERAGE TIME FY 2004 Report Post-MMA (in days)</b>
Additional Days to a Technology Assessment	122	176	172
Additional Days to MCAC recommendation	155	90	N/A
Overall days from acceptance to final decision	353	327	282

Under the MMA process, the timeframe to develop and implement NCDs was reduced to 273 days, compared to 370 days for non-MMA NCDs in FY 2004 and 460 days for NCDs issued in FY 2003.

Attachment 1 is 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 the time needed to obtain a TA and referral to the 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 decision 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 decision is used.

Attachment 1 also factors in days from acceptance to posting of the final decision and implementation. The sixth column represents the total elapsed time from the date of the decision memorandum/draft decision to the date of implementation. For decisions prior to MMA, there was a self-imposed 180 to 270-day timeframe to develop and issue claims processing instructions to our contractors to ensure accurate payment and consistent claims processing. (Our contractual agreement with the contractors allowed five months lead time for any systems changes to ensure accuracy and consistency among our contractors.) Generally, payment changes were effective within 180 calendar days of the first day of the next full calendar quarter that followed the date the NCD was issued. However, MMA legislated that the final NCD, along with system changes, would be completed within 90 days of the posting of the proposed decision (to include a 30-day comment period and 60 days to make coding changes and implement the final decision). It is important to note that although NCDs are effective on the date we release the final decision, the testing and implementation of coding changes for the contractor systems that process claims require additional time. Therefore, although the NCD is effective on the date the final decision is released, the systems changes may be not implemented until a later date. In these cases, claims may be paid retroactively or contractors may be instructed to hold claims for payment. The last column describes those NCDs subject to the MMA timeframes, and those NCDs initiated prior to MMA implementation.

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). MMA also required that NCD guidance documents be developed in a manner similar to that used for Food and Drug Administration (FDA) guidance documents. 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 proposed 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.

**Attachment 1**

	Pre-decision			Post-decision			Post MMA
	Days to TA <sup>1</sup>	Days to MCAC <sup>2</sup>	Days to proposed decision <sup>3</sup>	Days to final decision <sup>4</sup>	Days to Implement decision <sup>5</sup>	Total days overall <sup>6</sup>	
<b>Decisions initiated and fully implemented in FY 2004</b>							
Electrocardiographic Services	N/A	N/A	N/A	573	106	679	No
Positron EMISSION Tomography (FDG) and Other Neuroimaging Devices for Suspected Dementia	173	N/A	252	92	215	559	Yes
<b>Decisions initiated in FY 2003 and implemented in FY 2004</b>							
Autologous Blood-Derived Products for Chronic Non-Healing Wounds	N/A	N/A	N/A	221	221	442	No
Electrostimulation for Wounds	N/A	N/A	N/A	425	202	627	No
Ocular Photodynamic Therapy with Verteporfin for Macular Degeneration	N/A	46	N/A	187	64	251	No
Screening Immunoassay Fecal-Occult Blood Test	178	N/A	N/A	248	62	310	No
Implantable Defibrillators – Clinical Trials	N/A	N/A	N/A	214	321	535	No
Ventricular Assist Devices as Destination Therapy	N/A	133	N/A	418	0	418	No
<b>Decisions initiated in FY 2004 and implemented in FY 2005</b>							
Abarelix for the Treatment of Prostate Cancer	N/A	N/A	178	88	112	378	Yes
Aprepitant for Chemotherapy Induced Emesis	N/A	N/A	184	88	N/A	364	Yes
Autologous Stem Cell	N/A	N/A	183	90	62	335	Yes

Transplantation (AuSCT) for Amyloidosis							
Cochlear implantation	N/A	N/A	180	90	92	362	Yes
Carotid Stenting	N/A	N/A	183	89	110	382	Yes
Ultrasound Stimulation for Nonunion Fracture Healing	N/A	N/A	184	90	69	343	Yes

<sup>1</sup>Calendar days elapsed from date of request of technology assessment to date of receipt of technology assessment.

<sup>2</sup>Calendar days elapsed from date of request of MCAC review to date of receipt of signed minutes from MCAC.

<sup>3</sup>Calendar days elapsed from date of acceptance of request to date of proposed decision memorandum (DM) posted on CMS website.

<sup>4</sup>Pre-MMA decisions: Calendar days elapsed from date of acceptance to date of decision memorandum (DM) posted on website.

Post-MMA decisions: Calendar days elapsed from date of proposed decision posted on website to date of final decision (MMA requires that the final decision include changes made during a 30-day comment period and any final coding changes).

<sup>5</sup>Calendar days elapsed from date of final decision posted on website to date of implementation of instructions.

<sup>6</sup>Calendar days elapsed from date of acceptance of request to completion of decision memorandum (MMA requires that final decision be made within nine months for NCDs where no TA or MCAC is required, and twelve months for NCDs where a TA or MCAC is necessary).