Report to Congress on
Medicare National Coverage Determinations
For Fiscal Year 2017

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This is the seventeenth annual report to Congress on Medicare National Coverage Determinations (NCDs) from 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 Medicare benefits) made between October 1, 2016 and September 30, 2017. In fiscal year (FY) 2017, we achieved an average time of 6 months from the date of a formal request to the date of publication of the proposed proposed decision memorandum (DM), which aligns with the timeframes set by section 1862(l)(2) of the Act. Additionally, it took an average of 83.5 days from date of publication of the proposed (DM) to the final DM[1], which is also within the statutory timeframes. It took an average of an additional 225 days to fully implement the payment and coding changes for NCDs to cover an item or service from the date the final DM was published on the CMS website. (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…." CMS exercises 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 of the Act. 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 Administrative Contractors, Quality Improvement Organizations, Qualified Independent Contractors, Administrative Law Judges, and the Medicare Appeals Council.

Since multiple contractors' process and pay claims for 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 fee-for-service (FFS) 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

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

not covered) as well as an implementation date indicating the last day contractors have to complete all required system edits.

In FY 2017, four NCDs were implemented.

Statutory timeframes for completing NCDs

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

  Table 1 below presents the details of each NCD implemented in FY 2017, including the outcome of CMS review and the completion times.

Table 1: NCDs implemented in FY 2017

	NCA type/result	Proposed DM[2]	Final DM[3]	NCD implemented[4]
Decisions initiated in FY 2015 and implemented in FY 2017				
Stem Cell Transplantation (Multiple Myeloma, Myelofibrosis, and Sickle Cell Disease)	1st Reconsideration, CED	6.0	90	250
Decisions initiated in FY 2016 and implemented in FY 2017				
Gender Dysphoria and Gender Reassignment Surgery	New, Contractor Discretion	6.0	89	N/A[5]
Leadless Pacemakers	New, CED[6]	6.0	65	223
Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis	1st Reconsideration, CED	4.9	90	202
AVERAGE		5.7	83.5	225

[2] Months elapsed from date of opening coverage analysis to date of proposed NCD posted on CMS Website.
[3] Days elapsed from date of proposed NCD to date of final NCD. (The Social Security Act requires that the final NCD include changes made as a result of the 30-day public comment period and a summary of, and responses to, all public comments received.)
[4]Days elapsed from date of final NCD posted on CMS website (i.e., policy effective date) to date of published implementation instructions.
[5] Given the totality of the currently available evidence CMS decided it would not issue a national coverage determination at this time for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N).
[6] CED (coverage with evidence development) refers to coverage contingent on beneficiaries' participation in an approved clinical study to generate further evidence.

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 https://www.cms.gov/medicare-coverage-database/indexes/medicare-coverage-documents-index.aspx?MCDIndexType=1&mcdtypename=Guidance+Documents&bc=AgAAAAAAAAAA&

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 review. There may also be instances when 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 https://www.cms.gov/medicare-coverage-database/indexes/medicare-coverage-documents-index.aspx?MCDIndexType=1&mcdtypename=Guidance+Documents&bc=AgAAAAAAAAAA&

CMS may request an external TA if one or more 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 at https://www.cms.gov/medicare-coverage-database/indexes/medicare-coverage-documents-index.aspx?MCDIndexType=1&mcdtypename=Guidance+Documents&bc=AgAAAAAAAAAA&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, about complex clinical issues, or about 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; or it would be helpful to obtain 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.
- 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 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.