June 29, 2017

Tamara Syrek Jensen, JD
Director, Coverage & Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Mailstop C1-09-06
7500 Security Blvd
Baltimore MD 21244

RE: Medicare National Coverage Analysis (NCA) for Implantable Cardioverter Defibrillators (CAG-00157R4)

Dear Ms. Syrek Jensen:

The Advanced Medical Technology Association (AdvaMed) offers the following comments on the Centers for Medicare & Medicaid Services’ (CMS) National Coverage Analysis (NCA) for implantable cardioverter defibrillators (ICDs). CMS states in the NCA announcement that it is re-opening the current National Coverage Determination (NCD) to reconsider coverage indications for ICDs.

AdvaMed’s member companies produce the life-saving and life-enhancing medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed appreciates the opportunity to comment on the re-opening of the ICD NCD, which was last reconsidered in 2005. Our comments below relate to assuring patient access to ICDs consistent with the current evidence, as well as to CMS’ use of coverage with evidence development (CED).

Assuring Patient Access to ICDs Consistent with Current Clinical Evidence

In the years since the last reconsideration of the ICD NCD, considerable evidence has been developed supporting clinical use of ICDs. In 2013, a group of medical societies published a consensus report on appropriate use criteria for Implantable Cardioverter Defibrillators and Cardiac Resynchronization Therapy. In 2014, several medical societies produced an expert consensus document on the use of ICD therapy for patients who are not included or not well represented in clinical trials, but still merit consideration for treatment.

As CMS reviews the current ICD policy and reconsiders coverage indications, AdvaMed recommends that the agency ensure alignment with the clinical evidence and guidelines that have been issued in the years since the last reconsideration of the ICD NCD in 2005. Our goal is to assure that the new NCD provides access to ICDs to all appropriate patient populations consistent with the findings of the evidence and guidelines.

Coverage with Evidence Development

The ICD NCD in 2005 was one of the first CMS coverage determinations to incorporate the concept of coverage with evidence development, or CED. AdvaMed supports the use of rigorous evidence to inform medical practice. We recognize that CMS may require the use of CED to generate additional evidence in certain cases where the agency believes the available evidence regarding a promising medical technology or procedure is not sufficient to support broad, national coverage. Where appropriate in such instances, coverage contingent on the development of additional evidence may provide beneficiaries access to innovative medical treatments, particularly when the alternative is non-coverage.

At the same time, it is important to consider when enough data have been collected to address the evidence questions raised by CMS to make a definitive coverage determination, and when it may be appropriate to reconsider the level and type of information that is being collected, including discontinuing CED when the evidence questions raised by CMS have been addressed.

References:


AdvaMed has previously submitted comments to CMS regarding CED generally and regarding specific NCDs incorporating CED. We have stated in the past that when Medicare coverage is contingent on the collection of additional clinical or scientific evidence (beyond FDA requirements for safety and efficacy), CMS should:

1) collaborate with stakeholders to clearly identify the data collection objectives;
2) consider the minimum data necessary to achieve those objectives;
3) clearly identify, with input from interested stakeholders, scientifically supported study endpoints and the duration of data collection in advance (including clear stopping rules for data collection under CED); and
4) identify an appropriate mechanism to ensure continuous coverage of an item or service after a study ends, to avoid disruption in coverage and continue to allow Medicare beneficiaries to benefit from important FDA-approved technologies and services until a new or revised coverage determination is issued.

As CED generates evidence supporting the use of a new innovation or services, Medicare’s coverage policies should reflect these outcomes while minimizing additional administrative burdens and simplifying program requirements where possible. In the context of the ICD NCA, the American College of Cardiology’s National Cardiovascular Data Registry (ACC-NCDR) ICD Registry has been in place for over 12 years and has collected data for more than one million patients. It is critical that CMS reassess the rationale for this data collection requirement in the 2005 NCD and make a determination based on the evidence collected to date under that requirement regarding whether such data collection should be ended.

We look forward to responding to the proposed NCD when it is published later this year. In the meantime, if you have questions regarding these comments or if you require additional information, please contact me or Chandra Branham, JD, Vice President, Payment and Health Care Delivery Policy, at (202) 434-7219 or cbranham@AdvaMed.org.

Sincerely,

Donald May
Executive Vice President
Payment and Health Care Delivery Policy