ST. JUDE MEDICAL
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St. Jude Medical
One St. Jude Medical Drive
St. Paul, MN 55117 USA
Tel 800 328 9634
Tel 651 756 2000
Fax 651 756 3301

Submitted Electronically

April 16, 2012

Maria Ellis
Executive Secretary, MEDCAC
Coverage and Analysis Group
Office of Clinical Standards and Quality
Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mail Stop S3-02-01
7500 Security Boulevard
Baltimore, MD 21244

RE: May 16, 2012 MEDCAC Meeting on Evidentiary Characteristics for Coverage with Evidence Development (CED)

Dear Ms. Ellis:

St. Jude Medical, Inc. has prepared the following comments for the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) Panel that will meet on May 16, 2012 to discuss Evidentiary Characteristics for Coverage with Evidence Development (CED). We appreciate the opportunity to share our views on this very important matter that impacts beneficiary access to cutting-edge medical interventions.

St. Jude Medical develops medical technology and services that focus on putting more control into the hands of those who treat cardiac, neurological and chronic pain patients worldwide. The company is dedicated to advancing the practice of medicine by reducing risk wherever possible and contributing to successful outcomes for every patient.

St. Jude Medical Comments

St. Jude Medical supports the continued use by Medicare of Coverage with Evidence Development (CED) as a means to provide beneficiaries with access to promising medical services and procedures while supporting evidence generation efforts that can inform national coverage decision-making. The use of CED by CMS in national Medicare coverage decision-making is a significant development. By permitting more than a "yes/no" determination with respect to a matter that is under review for national coverage, CED has provided CMS with the ability to cover new technologies on a conditional basis—affording beneficiaries with access to cutting-edge

medical interventions in return for collection of information that can add to our understanding of these promising new medical services and procedures.

- *The range of CED efforts to date indicates the strength of the program.* A number of CED efforts have been initiated since the program was begun in the mid-2000s, including studies for the following technologies: implantable cardioverter defibrillators for primary prevention; off-label uses of drugs approved for colorectal cancer; FDG-PET scanning for specific solid tumor cancer indications; home use of oxygen; and the artificial heart.

  In addition to the CED efforts that have been initiated, CMS has suggested its willingness to provide conditional coverage under CED for a number of other services that have been the subject of national Medicare coverage decision-making. These CED topics include a wide range of technologies and procedures, and they vary widely in the study approaches that have been considered and used. We view the variety of medical procedures that have been considered for CED studies, as well as the differing study approaches that have been used, to be a strength of the program.

- *CED studies should be cooperative ventures in which CMS fully engages relevant stakeholders.* In recent months, CMS has announced that it is considering revisions to the Guidance Document that it posted in 2006 for CED, and it has taken a more prescriptive approach toward CED, specifying in proposed national coverage determinations the study design that will be acceptable for a CED study. This approach runs counter to the 2006 CMS Guidance Document for CED that was developed with significant stakeholder input.

  We believe that CMS actions that are not consistent with the guiding principles set forth in the 2006 CED Guidance Document, if continued, will weaken the CED program. A regulatory and prescriptive approach by CMS toward CED will dampen stakeholder interest in evidence generation through this mechanism, and it will foster an adversarial, instead of a cooperative, relationship between CMS and stakeholders.

- *Administering CED requires sensitivity to the unique context surrounding a new technology, and these studies should be limited to unique opportunities in national coverage decision-making, where coverage can be provided to study participants in order to generate needed information.* Managing a CED program presents a number of challenges. It involves considerable judgment in determining which national coverage determinations are best suited for CED, it requires substantial administrative skill and resources given the complexity of the matters under investigation, and it entails sensitivity to the views of stakeholders who will gather the information needed to inform coverage through CED studies. We do not think that pre-set evidentiary thresholds or formulas—the subject of this MEDCAC panel meeting—can replace good judgment.

  A careful examination of the available evidence on almost any new item or service being considered for national Medicare coverage can be expected to raise additional questions concerning the impact of the medical intervention. Even in cases where the benefits of a new medical procedure or service can be judged to outweigh the risks involved, some matters will typically remain unanswered by the available evidence. Although some might be of the opinion that CED should be used in each and every instance where conclusive evidence is absent, we disagree with this approach.

  We believe that CED should be used with restraint, and applied only in those situations where beneficiaries have the most to gain in terms of access to a promising technology, and where Medicare participation in a CED study can be of most value. We recognize that these are matters of judgment, and we believe that

each use of CED should be governed by the specific context surrounding a particular medical technology or procedure. We do not believe that an absolute evidentiary threshold should exist for CED studies. Further we believe that medical technologies that have been found by the FDA to be safe and effective through the PMA approval process should rarely be the subject of CED.

CED should not be used to reconsider questions about the impact of medical interventions for which a national Medicare coverage determination has already been made prior to the availability of CED. In one recent instance, CMS, on its own initiative, reopened a national Medicare coverage determination, found the published evidence wanting, and proposed to cover the medical service only within the context of a CED clinical trial. The previous national coverage determination had based coverage on a physician determination of the effectiveness of the service for the individual patient, and the determination was made prior to the more-recent CMS practice of determining medical effectiveness through systematic reviews of medical literature.

- *We believe that CED should not be used in these situations, because coverage would be eliminated for those currently covered and restricted to those patients participating in a CED study.* Our view is that, in these instances, where national coverage has been granted before CED was put in place, and where CMS would like to see additional studies, existing coverage should remain intact while new studies are conducted that could be used to inform a new coverage determination. We think that a subset of covered patients could be studied closely to gather the evidence bearing on effectiveness of the service—but CMS should not revoke existing coverage for beneficiaries absent clear results from a study documenting it to be ineffective.

- *We also believe that CED studies conducted under Coverage with Appropriateness Determination (where the medical intervention is found to be "reasonable and necessary," but covered only for patients participating in a study), should have clear study endpoints.* These CED study endpoints should determine whether the study continues to be needed to ensure the proper protections for Medicare beneficiaries.

St. Jude Medical supports a CED program that is marked by stakeholder collaboration and involvement. In our view, the stance CMS takes in managing CED will determine whether the twin goals of accelerated beneficiary access to promising medical services and the generation of evidence on the impact these services have on beneficiary outcomes in real-world settings can be achieved. If CMS chooses to reverse the position it took in the 2006 CED Guidance Document and approach CED in a regulatory vein—with overly prescriptive requirements on the type of evidence that should be generated, we believe that an opportunity to fill in significant gaps in our understanding of promising new technologies will have been missed. Certain recent national coverage determinations have been marked by this approach, where CMS has unilaterally ruled out certain data gathering approaches for CED. We believe that this approach is short-sighted.

We understand that some might favor a more directive and prescriptive approach toward CED, where CMS specifies the details of study design. In our view, broad stakeholder participation in CED matters not only adds legitimacy to the process, but it also ensures that the right research questions are asked, that patient views about outcomes are taken into account, that practical data collection matters are fully addressed, and that the studies are performed economically. We believe that the positive features associated with full stakeholder engagement in the design, operational features, and funding issues associated with CED studies far outweigh any inconveniences associated with this effort.

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Thank you for considering these comments on CED evidentiary characteristics. If you have any questions, please contact me directly at 651-756-2153 or at pchristianson@sjm.com.

Sincerely,

Patricia A. Christianson
Senior Manager, Health Policy and Reimbursement