September 25, 2015

Steven D. Pearson, MD, MSc, FRCP
President, Institute For Clinical and Economic Review
One State Street
Suite 1050
Boston, MA 02109 USA

Sent via Email: ctaf@icer-review.org

RE: ICER Draft Report on CardioMEMS and Entresto for Management of Congestive Heart Failure

Dear Dr. Pearson

The Advanced Medical Technology Association (AdvaMed) is pleased to submit the following comments on the ICER Draft Report on CardioMEMS and Entresto for Management of Congestive Heart Failure and the Questions for Deliberation which were released by CTAF for the October 29, 2015 Public Meeting.

AdvaMed member companies produce the 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. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

AdvaMed wishes to provide comments on the following topics: (1) General Procedural Issues related to the ICER Draft Report on CardioMEMS and Entresto for Management of Congestive Heart Failure; and (2) Issues related to the CTAF Questions for Deliberations for the October 29, 2015 Public Meeting. Our comments specifically relate to the CardioMEMS device, and do not represent an opinion on Entresto.

I. General Procedural Issues related to the ICER Draft Report on CardioMEMS and Entresto for Management of Congestive Heart Failure

   A. The New ICER Value Framework Has Not Been Sufficiently Vetted

   The ICER Framework on assessing value has only recently been finalized. Thus, we believe there has not been sufficient time for stakeholder and public comment and it has not gone through any vigorous
vetting process to date. It is unclear how the framework assesses the clinical and economic impact of medical technologies/devices on health systems. Although ICER has previously evaluated drugs, it does not seem to have significant experience in evaluating medical technologies/devices. Medical devices account for only a small portion of health care spending. Additionally, advances in medical technology can increase efficiencies in care and have been demonstrated to lower health care costs over the long term.

Emphasizing short-term cost savings may create barriers to using innovative treatments that represent improvements in care but deliver their cost savings over a longer period of time. Applying the value framework to new technologies with limited time on the market may be a source of inherent bias, as there is insufficient time for physician and patient experience to evolve and be adequately captured. Importantly, this short time frame does not adequately capture the longer-term patient outcomes that factor into the cost/value equation.

**B. ICER Lacks Sufficient Clinical Expertise/Participation in the Evidence Review Process**

We note that two of the ICER Report’s physician authors, who are not directly associated with ICER, are employees of the VA Palo Alto Health Care System and do not appear to have on-going specialty experience or certification in managing patients in the critical care setting or interventional cardiology, where devices like CardioMEMS would be most likely considered and utilized. AdvaMed is concerned that there is insufficient clinical representation on the ICER panel by clinician(s) with first-hand, practical clinical experience with the technology under review.

The patients that would require a device such as CardioMEMS tend, by definition, to have more advanced stages of CHF (NYHA Class III patients with a hospitalization in the previous 12 months). Therefore, the data analysis should be conducted by practicing clinicians with the appropriate background and experience to opine in this area. AdvaMed recommends that the ICER authors include a rotating clinical expert position that varies according to the technology being reviewed. Establishing such a position on the ICER panel would ensure representation by a clinician with direct experience with a reviewed technology, and provide ICER with invaluable insight into the practical application of the technology and its value in clinical practice. Inclusion of such clinical expertise will provide real-world input regarding the implications of a coverage and reimbursement determination during the ICER/CTAF deliberation process. The lead medical society for each technology should nominate or select the clinician, or when there is no agreement on a lead society, relevant state and national medical societies should be invited to recommend the candidates for this position.

**C. ICER Should Provide Additional Transparency in the Proceedings**

We also believe that transparency in the ICER evidence review process could be improved by requiring contracted research organizations to meet with interested parties prior to providing their draft reports. Such a meeting would promote the discussion of specific topics relevant to the contracted research organization’s review and evaluation of submitted information and existing research. The contracted organization would have an opportunity to ask questions requiring technical expertise. Interested parties would have the opportunity to discuss the interpretation of peer-reviewed literature and provide the contractor with completed clinical research not yet in the public space. Furthermore, this meeting would ensure that the contractor understood all relevant research—thereby improving Evidence Report accuracy and obviating the need for the immediate re-review of an assessment due to newly published research.
ICER focuses heavily on the opinions expressed by the 2013 FDA Advisory Panel Committee in the CHF Draft Report. However, the ICER report does not include relevant findings made by the FDA, including the Agency’s disagreement with the Advisory Panel and ultimate decision to grant CardioMEMS FDA approval. The report also fails to include relevant information, such as CMS’ approval of increased payments for the technology under the new technology add-on payment (NTAP) policy (inpatient setting) and under the transitional pass-through payment policy (outpatient setting). Full disclosure of such supplemental material and events is essential in allowing the public to provide comprehensive comments on this issue.

II. CTAF “Questions for Deliberation” (October 29, 2015, Public Meeting)

The CTAF CHF “Questions for Deliberation” for the October 29, 2015 public meeting are posed in a manner that assumes the totality of evidence for CardioMEMS has been adequately presented. This may not be the case. For example, regarding alternative management strategies for CardioMEMS, we are aware that several important, large, randomized controlled studies concerning implantable device-based impedance monitoring were not included in the ICER Report. These implantable device studies should have been considered as potential alternate management strategies, and would have been more appropriate than considering “non-pharmacologic interventions” such as structured telephone support, tele-monitoring, and patient education to make indirect effectiveness comparisons for contextual purposes.

The assumption that the evidence presented in the Draft Report is complete introduces significant bias in the questions for deliberation and interferes with the validity of the responses. The questions should include a response option indicating that the responder does not have adequate information based on the Draft Report to come to a conclusion. Therefore, AdvaMed recommends that CTAF include the following fourth choice (d) for each of the questions evaluating care value/provisional health system value:

(d) Unable to Determine/Inadequate Evidence Presented

We also recommend that each question indicate that the available evidence being queried is based on the evidence specifically provided in the September 11, 2015 Draft Report.

We would be pleased to answer any questions regarding these comments. Please contact Steven J. Brotman, MD, JD, Senior Vice President, Payment and Health Care Delivery Policy, at (202) 434-7207, if we can be of further assistance.

Sincerely,

/s/

Don May
Executive Vice President,
Payment and Health Care Delivery