April 3, 2017

Steven D. Pearson, MD, MSc, FRCP
President
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

Re: Call for Stakeholder Input for Revised ICER Value Framework for 2017-2019

Dear Dr. Pearson,

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to comment on the Institute for Clinical and Economic Review’s (ICER) updated value assessment framework released in February. AdvaMed is the national association of manufacturers of medical devices and diagnostics. Our member companies develop and manufacture 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. 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 supports initiatives that will move the delivery of health care in the nation from a volume-based system to a value-based system that improves quality of care, is more patient-centered, and slows healthcare cost growth. We are also committed to a rigorous value-based system that will accomplish these goals and enable high-value care for all patients.

To this end, we have been engaged with patients, providers, and payers in developing a comprehensive value framework that is designed specifically to help these stakeholders assess value and determine the range of ways medical technologies and diagnostics can drive value and improve patient care outcomes.

We were pleased to read ICER’s recognition in the updated framework that devices and diagnostics require different approaches to evidence generation and analysis, including consideration of evidence for medical technologies that is very different from biopharmaceutical products, and that evaluations of long-term cost-effectiveness of medical technologies are challenging for a number of different reasons, including the rapid evolution of a device, clinician and patient learning curve, and types of patients treated. At the same time, however, ICER’s
updated framework states that devices and tests will continue to be evaluated using the overall conceptual approach of the ICER value framework, with modifications.

After carefully reviewing the updated ICER value framework, we hope that, with additional changes, it will reflect more accurately the particular characteristics of medical devices and diagnostics and the complications those characteristics create for value propositions. Therefore, since it was noted that ICER would continue to refine its framework even during the 2017-2019 timeframe, we recommend that ICER directly engage the medical technology industry to develop more customized approaches that more appropriately assess different categories of medical technology and diagnostic products. We also urge that ICER not review medical technologies and diagnostics until the refinements with the input of our industry are incorporated in a revised framework.

In addition to our comments below, we have attached a letter from Hal Singer, Ph.D., a Principal at Economists Incorporated, an Adjunct Professor at Georgetown University’s McDonough School of Business, and a Senior Fellow at George Washington University’s Institute for Public Policy. Last September, we submitted an independent analysis by Dr. Singer of ICER’s original framework. We asked Dr. Singer to consider the updated framework and we are submitting his new analysis as part of our comments and recommendations for amending the updated framework.

**ICER’s value framework incorrectly assumes that device spending and device prices are major drivers of increases in national health care expenditures**

ICER’s conceptual approach for its value framework is based on an incorrect assumption that spending for technology and increasing prices for those technologies are driving increases in national health care expenditures—and are inappropriately doing so. With its general focus on prescription drugs, the ICER value framework may base its assumption on experience with prescription drug spending and prices. However, data analysis for the device industry demonstrates that spending and prices for devices and diagnostics are not major contributors to increases in national health spending growth as may be the case for other health care service categories.

A June 2015 study done for AdvaMed by Guy King, a former head actuary of the Health Care Financing Administration, and Gerald Donahoe, formerly an economist with the Department of Commerce, shows that for the period 1989 through 2013, device spending has been a small and constant share of total national health care expenditures at approximately 6%. In addition, device prices have grown at a much lower rate than CPI and medical care CPI (MC-CPI) over the same period. Device prices grew at an average annual rate that was about one-third the rate of growth in CPI (0.9% compared to 2.7% for CPI) and at about one-fifth the rate of growth of prices for MS-CPI (0.9% compared to 4.5% for MC-CPI). This study was an update of previous studies done for AdvaMed on the subject, and each showed virtually identical trends in device spending as a small and constant percent of national health spending and very low average annual rates of growth in device prices compared to CPI and MC-CPI.
The study findings on device prices were validated by two other studies commissioned by AdvaMed that demonstrated significant declines in both nominal and inflation-adjusted prices for major categories of implantable devices. Analysis Group, Inc. looked at *Average Price Trends for Implantable Medical Devices* for two periods—2007-2011 and 2011-2015. Analysis Group obtained average pricing data from the Millennium Research Group, Inc., an independent third-party provider of proprietary survey data of average selling prices, for the following seven categories of implantable medical devices: cardiac resynchronization therapy defibrillators (CRTDs), implantable cardioverter defibrillators (ICDs), pacemakers, artificial hips, artificial knees, drug-eluting stents, and bare metal stents. During the period 2007-2011, the analysis found significant declines in average prices paid by hospitals across each of the categories of implantable devices both in terms of nominal as well as inflation-adjusted prices. Across the seven categories of implantable technologies, average nominal price declines over the period ranged from 5% to 25% and average inflation-adjusted price declines ranged from 13% to 31%. An update of this study for the period 2011-2015 (not yet formally released) found similar declines in both nominal and inflation-adjusted prices for the same seven categories of implantables, with average nominal price declines across the seven categories ranging from 8% to 20%, and inflation-adjusted price declines ranging from 18% to 28%.

Finally, we point to a study from July 2014 by the Milken Institute, Health Savings: Medical Technology and the Economic Burden of Disease. We mention this study also because of comments we make in the next section of this letter that medical technology assessment should encompass multiple dimensions of value if it is to accurately reflect value of medical technologies and diagnostics.

The Milken study estimates the full costs and broader economic benefits (e.g., impact on GDP from increases in productivity) of certain medical technologies used to address four prevalent causes of death and disability in the nation: diabetes, heart disease, musculoskeletal disease, and colorectal cancer. The study estimates that the net annual benefit from these technologies was $23.6 billion in 2010. The study also constructs three alternative trajectories through 2035 for continued technology innovation for each of the four diseases: (1) reduced incentives to invest in improvement and adoption and resulting reduced technological progress; (2) continuation of the historical incentive level; and (3) enhanced incentives. The study finds a cumulative $1.4 trillion gain (in 2010 dollars) over a 25-year period in the increased incentives scenario relative to the persistence of continued incentives and a cumulative $3.4 trillion loss (in 2010 dollars) over a 25-year period in the decreased incentives scenario relative to increased incentives. The impact of value frameworks (such as ICER’s framework as proposed without modifications) that do not consider the multi-dimensional nature of the value of medical technologies can, therefore, have a consequential negative impact on the costs of disease, innovation in the medical device industry, and the nation’s economy.

**ICER’s updated framework continues to rely too heavily for new technologies on budget impact and estimating the cost per Quality Adjusted Life Year (QALY) gained**

Based on our own work on developing a value framework for medical technologies and diagnostics, and through our discussions with multiple stakeholders outside the medical
technology industry, we have learned that different stakeholders care about and prioritize different but overlapping sets of value drivers against which they judge a medical technology’s benefits or value. Multifaceted value cannot be based predominantly on budget impact or the incremental cost per QALY achieved, as the updated ICER framework continues to embody.

AdvaMed’s experience strongly underscores that medical technology assessment should encompass multiple categories of value, which should be used in any evaluation of the value of a medical technology. Assessment of value should include clinical impact, non-clinical patient benefits, care delivery economics, and societal benefits. Each of these categories should be considered a relevant value measure, especially as the U.S. health care system is increasingly emphasizing patient preferences, patient engagement in decision-making about a specific course of treatment, personalized medicine, and broad population health metrics as major goals that patients, clinicians, and payers are seeking to incorporate into their value evaluation processes. The figure below summarizes these dimensions of a comprehensive value framework that we believe should be used for evaluating medical technologies and diagnostics.

In this context, ICER’s updated framework, with its continued strong emphasis on budget-impact analysis to attribute value to a particular medical technology through a national level assessment, continues to take too narrow a view of what determines the value of a medical technology or diagnostic. After discussion with stakeholders, ICER proposes in its updated framework that for devices and other services a net budget impact threshold of $500 million per PMA per year be used to indicate when special attention may be needed to address short-term affordability. As we noted in our prior letter to ICER, wrong conclusions about the value of new medical devices or diagnostics will be made if they must compete for revenue under a cap. Furthermore, the budget cap approach diminishes the variation in prioritization that different stakeholders will consider
for determining value drivers. We and our member companies would appreciate an opportunity to provide our expertise on this matter.

In addition, ICER’s updated framework, with its proposal to use a broader range of cost-effectiveness thresholds but not a higher threshold, continues to assume that the value of a new product is defined fundamentally by its incremental cost per QALY achieved at the time it is introduced into the marketplace—and that all new medical technologies are accompanied by high costs that need to be controlled. In addition, emphasis on incremental cost per QALY diminishes the importance of individual patient preference and physician clinical expertise about the appropriateness of a particular treatment option for patient care. As we and others have repeatedly noted, this approach can adversely compromise consideration of all appropriate treatment options for a particular patient’s condition.

Furthermore, linking the value of a new product primarily to its cost per QALY does not recognize the impact the innovation can have on improved health outcomes. Nor does QALY analysis recognize that the innovative product can represent an improvement, both in terms of efficiency and quality, over the current standard of care. For example, many medical devices provide benefits that are important to practitioners and patients but are not well-measured by a QALY approach. A new technology that allows discharge of a patient from a hospital earlier than the existing standard of care and reduces the pain associated with a procedure would be unlikely to generate a high QALY score, since it would not be associated with an extension of life and the benefits are of relatively short duration. Again, this argues for the broader view of value we mentioned above and consideration of dimensions of value that go beyond clinical impact.

The result of the ICER approach to value can mean compromised patient access to innovative care, with payers translating cost into non-coverage decisions, which could lead device and diagnostic companies to invest less in innovative approaches for certain health care conditions. Furthermore, the significant economies of learning in the device industry and a typically rapid series of incremental improvements in devices after their introduction often means that a net cost of a device can become a net benefit over a short period of time.

While ICER’s updated framework recognizes that modifications will have to be made in its overall approach to reflect the particular characteristics of devices and diagnostics, it does not specify a process for making those modifications. Nor does it indicate whether device and diagnostic companies will be part of a process to modify the general approach to reflect the characteristics of their products. Just as our member companies work with payers and technology assessment organizations globally, we hope to be part of ICER’s process for modifying its updated framework, and also hope that the process is transparent for all stakeholders with an interest in improving care delivery and outcomes for all patients. We reiterate our recommendation from above that ICER not review medical technologies and diagnostics until modifications with our companies’ input are finalized.
5-year period for limit on short-term affordability is inappropriate for many medical technologies that provide value over many more years

The ICER updated framework continues to consider cost and value of an innovation only over a short timeframe—5 years. In so doing, it does not recognize that many medical devices and diagnostics have value for much longer period of time, e.g. 20 years for joint replacements, or even for the lifetime of the patient. With diagnostics, for example, long-term outcomes may depend on a variety of treatment decisions throughout a complex care pathway. With the improved negative predictive value of screening tests, such as the HPV screening assay, recommended screening intervals are being lengthened to 5 years and beyond for some screening programs. A model that limits value to 5 years would be inadequate to account for multiple 5-year intervals of screening and thus would be insufficient for public health decision-making. Therefore, applying the full price/cost of a new technology in the short term without accounting for longer term benefits creates a lower value estimate that is inappropriate for many new technologies.

ICER should be cautious that the frameworks it creates do not inadvertently reward short-term dynamics at the expense of health care value and patient care over the longer term. As we noted in our previous letter, ICER’s framework would reward a calculus that trades a higher-priced device that needs only be implanted or used once, for a lower-priced device requiring replacement at 5-years’ time. Such a choice for short-term low-price over long-term value may ultimately harm health care budgets and could harm patients as well. AdvaMed recommends that ICER consider a time-horizon for devices that considers long-term durability of the product and patient longevity.

While we appreciate the updated framework’s discussion of the tension between long-term value and short-term budget impact, we point out again that device spending is not the problem in national health care spending and that ICER’s framework needs to be modified to accommodate the long-term value of many medical devices and diagnostics.

Process for stakeholder engagement

ICER’s guides for stakeholder engagement in the technology review process acknowledge the importance of stakeholder input and the guides establish timelines for such engagement. For our companies with new technologies subject to ICER review, the process, however, has presented barriers to effective input.

For example, manufacturers and other stakeholders have only 20 business days to comment on the Draft Evidence Report. This timeframe has presented challenges for our companies, especially when an evidence report has been found to include inaccurate data or analysis that needs correction. Further, alternative points of view about data and analysis offered by our companies are never discussed as to whether they were considered by ICER and/or why they have not been incorporated into the draft report. We also recommend that the process for selecting voting panel members and invited speakers should ensure that a range of views are
represented including those supporting technological innovation and not only those focusing on reducing cost. Our companies have also found the time allotted at the public meeting for discussion of the draft report to be inadequate for thorough consideration of the report’s findings and analysis. This meeting is critical for ensuring public confidence in the panel’s familiarity with the issues raised by the technology and appropriateness of their voting decisions. Meaningful engagement by stakeholders with the voting panel is imperative, particularly where ICER assessments focus on diseases or conditions, or on specific medical technologies requiring particular knowledge or expertise.

We would be pleased to answer any questions regarding these comments and appreciate any opportunities to work with you on these important issues in the future.

Sincerely,

Don May
Executive Vice President
Payment and Health Care Delivery