May 18, 2017

International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Special Task Force for the Initiative on Value Assessment Frameworks

Dear Sirs,

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to submit comments on the May 4th Draft Report, A Health Economics Approach to US Value Assessment Frameworks.” 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 specifically focused on establishing value for medical technologies and diagnostics that will help these stakeholders assess value and define the many ways medical technologies and diagnostics can improve patient care outcomes. As the Special Task Force notes in its draft report, assessing value properly is critical for sending signals to healthcare technology manufacturers that they should continue to allocate resources to research and development to support continued innovation and medical progress for the benefit of both patients and society. We certainly agree with that goal.

We submit for your consideration the following suite of products, just released on May 15th, that we believe provides a comprehensive approach for assessing the value of a specific medical technology or diagnostic across the spectrum of health care stakeholders.

- A Framework for Comprehensive Assessment of Medical Technologies
- A Framework for Comprehensive Assessment of the Value of Diagnostic Tests
- Understanding Evidence on the Value of Medical Technologies

Bringing innovation to patient care worldwide
Application of the Medtech Value Assessment Framework:

- Cymedica’s e-vive™ System
- Siemens Coronary Computed Tomography Angiography (CCTA)
- Rotation Medical’s Bioinductive Implant

Application of the Value of Diagnostic Technologies Assessment Framework:

- Abbott’s 4th Generation ARCHITECT HIV Antigen/Antibody Combo Test
- Abbott’s Vysis ALK Break Apart FISH Probe Kit Test
- Exact Sciences Cologuard Multi-target sDNA Test

The purpose of our initiative has been to drive the discussion on how to determine objectively the value of a medical technology or diagnostic and what evidence is necessary to support its use. Our aim has been to help our industry demonstrate the value of technologies and diagnostics in a consistent and effective fashion and to offer guidance to patients, providers, and payers in assessing our member companies’ technologies. Each of our specific frameworks for medical technologies and diagnostics take into account a broad range of “value drivers” that have impact on the quality and cost of care and that we believe should be incorporated into any assessment process for medical technologies and diagnostics, especially as the U.S health care system increasingly emphasizes patient preference, personalized medicine, and population health: clinical factors; non-clinical factors important to patients or caregivers; care delivery economics (e.g. the impact of the technology on revenues and costs for a provider or payer as well as impact on clinical workflow); and societal impacts. These frameworks recognize that each stakeholder will view value of each technology and diagnostic differently and will assign weights to these value drivers often in different ways depending on their perspectives. Above all, our frameworks are not designed to be a one-size-fits-all or a formula approach, but are intended to be flexible and promote understanding that technologies will and do offer value in different ways.

You will find perspectives in our frameworks to be similar to many of the observations and recommendations in the ISPOR draft report.

We do, however, want to use this letter to offer several comments for your consideration and ask that you consider these for the final version of the report:

- The draft report does not address the unique characteristics of medical technologies and diagnostics nor discuss the special challenges posed by these technologies for value assessments. The frame of reference for the ISPOR analysis is prescription drugs and we believe that any value assessment for medical technologies should be very different from that used for biopharmaceutical products. Among those most basic differences between medical technologies and pharmaceuticals are: (1) the diversity of medical technologies ranging from implantable orthopedic and cardiovascular devices, to minimally invasive surgical instruments, to imaging and radiation therapy equipment, to diagnostic tests require that value assessments be flexible enough to take into account the unique nature of technology or diagnostic; (2) the ways in which medical technologies are embedded in
complex processes of patient care, such as in surgical procedures, should recognize that any evaluation of the medical device will be complicated; (3) the rapid evolution of devices once they come to market, and clinician and patient learning curves in use of the device can quickly make an initial assessment of its value out-of-date with product improvements and with greater experience in its use; and (4) diagnostic and imaging technologies present their own analytic challenges since their value lies in how they enable improved clinical decision-making and therapy selection, which is distinct from the value of the underlying therapeutic intervention itself.

- As a corollary to these observations about the uniqueness of medical technologies and diagnostics, AdvaMed believes that evidence standards applied to the assessment of these technologies need to reflect different medical technologies’ clinical use, level of complexity and risk, innovation time-cycle, the feasibility of data collections, and ultimately the aspects of value important to specific stakeholders. The basic principle should be that value assessment should utilize an appropriate range of available evidence, and the type of evidence and assessment methodology should be based on the technology type and the potential risk to patients. We have submitted for your review a paper on Understanding Evidence on the Value of Medical Technologies that makes the case for recognizing a broad range of evidence types that should be used in assessment methodologies to ensure that high value technologies reach patients in a timely fashion.

- The draft report recognizes both the advantages and limitations of health system allocation decisions based on QALY analysis. AdvaMed argues, however, that QALY analysis is generally inappropriate for evaluating medical devices. The heterogeneity of medical devices makes it exceedingly difficult to obtain an absolute measure of value added, especially through randomized controlled trials as discussed in our Evidence paper. Multiple studies have already shown that QALY is an inaccurate, imprecise, and potentially misleading way of measuring the value for medical devices. In a study of the sensitivity of cost-effectiveness to changes over time as measured by QALYs, David Cutler and Robert Huckman found that the cost-effectiveness of angioplasty in New York State changed from a net cost in each of the first three years 1982-1983 to a net benefit of $18,000 per patient per year by 2000.1 A case study on drug-eluting stents in the United Kingdom concluded: “Undue reliance on the ICER [incremental cost effectiveness ratio]/QALY methodology can lead to premature rejection of a promising technology… If payers overzealously use flawed ICER/QALY methodology… important opportunities to improve health outcomes will be lost, and innovation in this field may be halted in its tracks.”2 As argued above, many medical devices interact with health care providers experience and go through iterative improvements, complicating the estimation of incremental benefits of a medical technology in terms of QALY at any one point in time. Moreover, QALY must be continually recalculated per adopted innovation (and be

subject to the thresholds described above). In addition, for devices that provide an iterative benefit, or potentially build upon a platform already laid by existing innovations, what is the expenditure to be calculated, and how is the improvement in quality to be measured? Recent medical devices are increasingly relying upon smart technologies that provide software-as-a-service solutions for healthcare. Medical devices with embedded and updatable software may not become fully effective until after the software has been fully developed, raising further concerns on how QALY for such devices can be measured. QALYs also disproportionately favor procedures and devices that confer survival benefits over those that provide improvement of life. For example, hip replacements confer substantial quality-of-life benefits even at a slight increase of a probability of death; however, these will not be weighted as high using QALY when compared with procedures that improve life expectancy. QALY analysis, therefore, does not address the underweighting of products that improve quality of life without increasing expected lifespan. Ultimately, even when a QALY can be appropriately calculated, it should be considered only a part of the total value equation.

- The timeframes over which a technology provides impact are important to consider and document in value assessment. For many medical technologies, impact should be assessed beyond traditionally relevant health system timeframes, such as an acute care episode or a 90-day bundled episode of care. In many cases, the value of a technology to the patient accumulates over a much longer period of time, and this should be considered in the value assessment. This is particularly relevant in today’s value-based models, in which payers and providers take on more risk, serve populations for longer time periods, and are given incentives linked to longer-term outcomes.

We thank you for this opportunity to offer comments on the draft report. We would be pleased to be counted among the stakeholders to have an opportunity to offer input for revisions that may be contemplated for the final version of the report.

Sincerely,

Donald May
Executive Vice President,
Payment and Health Care Delivery