



March 28, 2016

The Clinical Episode Payment (CEP) Work Group
Health Care Payment Learning & Action Network

Re: Comments on draft white paper, Accelerating and Aligning Clinical Episode Payment Models: Elective Joint Replacement

Clinical Episode Payment Work Group, HCP-LAN:

The Advanced Medical Technology Association (AdvaMed) is pleased to offer comments on LAN's recommendations contained in the February 26th draft white paper, Accelerating and Aligning Clinical Episode Payment Models: Elective Joint Replacement. AdvaMed has been a strong supporter of delivery reform models, such as bundled payments and episode based payments since their inception in the Affordable Care Act. We recognize the importance of the goals of these payment models for improving both the efficiency and quality of health care through enhanced care coordination, greater provider investment in infrastructure and redesigned care processes for higher quality care, and incentives to provide higher value care across the acute and post-acute care continuum of services covered by Medicare.

Our members' technologies play a critical role in assisting providers to achieve each of these goals—especially in the context of the broad spectrum of services related to elective joint replacement. Our member companies' products and services improve patient care quality and outcomes and many improve efficiency by reducing the lengths of stay of patients in health care facilities, enhancing perioperative productivity and reducing costs, allowing procedures to be performed in less intensive and less costly settings, providing early detection of disease and infections, and improving the ability of providers to monitor care, among other benefits.

Total joint replacement is one of the major success stories of American medicine. Total joint replacement procedures have been shown to restore mobility, relieve pain, and help patients with osteoarthritis return to normal lives and functioning. Medicare patients receiving total hip and knee replacement show nearly half the risk of death after seven years compared to osteoarthritis patients not receiving total joint replacement.¹ In addition, total knee replacement has been found

¹ Lovald, ST, et al., "Mortality, Cost, and Health Outcomes of Total Knee Arthroplasty in Medicare Patients," Journal of Arthroplasty, November 2012. Lovald, ST, et al., "Mortality, Cost, and Downstream Disease of Total Hip Arthroplasty Patients in the Medicare Population," Journal of Arthroplasty, May 2013.

to be cost saving. One study has found that total knee replacement surgery generates a net societal savings of approximately \$19,000 per patient lifetime, due to reduced disability costs and improved productivity.² This study found that in 2009 alone, savings in the U.S. were an estimated \$12 billion.

We have organized our comments for the CEP Work Group's recommendations in the order in which they appear in the draft paper.

1. Episode Definition

Elective: Many providers participating in the Bundled Payment for Care Improvement (BPCI) initiative implemented by the Center for Medicare & Medicaid Innovation (Innovation Center) and the Comprehensive Care for Joint Replacement (CJR) bundled payment model already use or will be using Medicare DRGs for defining their bundles. AdvaMed recommends that future episode payment models for elective joint replacement also be based on DRGs, in order to simplify administration for providers. This would mean, however, creating additional target prices for fractures, as was done for the CJR, since these procedures have higher costs.

Appropriate: The white paper recommends that an ideal episode payment model for elective joint replacement should support appropriateness of the episode and optimal quality, and should have a set price that supports high quality care delivery.

We urge the CEP Work Group to consider that high quality care delivery should encompass evaluation of patient access to the full range of devices appropriate for a specific individual's medical conditions and life-style. One of our overarching concerns with episode-based payments is their focus on short-term costs incurred during a relatively short period of time that can lead to stinting on care. Stinting in this instance can take the form of selecting only lower utility devices without proven track records of safety and durability. It can also mean compromised patient access to innovative technologies when these are more expensive than previous generations of devices. The Work Group should also consider how to structure policy options that would encourage use of joint implants associated with reduced revision rates. Lower joint replacement revision rates significantly lower Medicare spending outside the 90-day episode of care window, and translate to fewer beneficiaries undergoing costly and invasive revision surgery. Too much emphasis on short-term savings could compromise patient access to technologies that perhaps cost slightly more in the short term, but save much more long-term by reducing the need for revision surgeries.

Many medical devices and technologies provide benefits over a period of time spanning multiple years. The financial incentives in delivery reform models with short episode windows, together with their promise of an additional stream of income for providers, can be too compelling for providers, especially when the long-term value of more expensive care or technologies is not

² Ruiz D, et al., "The Direct and Indirect Costs to Society of Treatment for End-Stage Knee Osteoarthritis," *Journal of Bone and Joint Surgery*, 2013; 95: 1473-80.

factored in. As a result, savings on short-term costs could translate into higher costs over the long term, for example, through higher revision rates for joint replacement procedures as a result of patients not having access to devices more appropriate for their needs and lifestyles. We also note the challenges in sustaining savings, year after year, that are generated by spending reductions year after year and how the pressure to do so can challenge a provider's decision process in particular when the realization of these risks could take several years before they are expressed in a way that requires further utilization. We discuss this last point in greater detail below.

We offer a real world example of how financial incentives in delivery reform models can lead to what may be compromised patient access to appropriate devices for joint replacement. Some of our orthopedic company members have learned that certain providers participating in the Innovation Center's BPCI initiative have radically changed the type of hip and knee implants that they buy and implant in patients.

In the past, these hospitals had purchased a range of device implants—including some implants that are more basic, without newer features and with varying levels of performance characteristics that improve range of motion or impact durability (e.g., lower utility implants). Providers made implant selection decisions that corresponded to the particular lifestyle needs of patients, including life expectancy, level of activity, and medical conditions. This process is called demand matching and is an effective method in managing utilization without limiting access to technologies that best meet individual patient needs. With participation in BPCI, these providers now purchase almost exclusively lower utility implants without respect to patient needs. Matching the utility of a device to a particular patient's need is critical to ensuring a positive outcome for the patient and long-term effectiveness of the procedure. For example, an active, tennis-playing 65-year old requires a hip or knee of higher utility and performance characteristics than one that is appropriate for a sedentary 85-year old.

While it is possible that the patient mix of Medicare beneficiaries treated by the providers has changed since participation in BPCI began, it should be pointed out that lower utility devices are also initially less expensive than the higher utility devices, leading to potentially higher internal savings that can be shared in the short term. The longer term impact of using almost exclusively lower utility devices, when they may not be appropriate for the lifestyle and medical needs of individual patients, may not be known for several years, when active beneficiaries may require earlier than expected revision procedures or experience other negative outcomes. If the choice of a hip or knee device were made solely on the basis of patients' relative health, lifestyle and life expectancy, patients would be provided a device that appropriately demand matched to their unique needs with cost not being a leading driver of this decision so as to ensure the best possible outcomes and longevity.

In order to protect beneficiaries from these potential consequences of the financial incentives inherent to certain delivery reform models and to ensure that decisions about a patient's care are made solely on medical grounds, AdvaMed first recommends that participating providers be required to make available to the public on Hospital Compare or via other reporting:

- (1) whether or not the providers have participated in gainsharing, and the amount of gainsharing rewards that physicians and other providers receive from internal savings initiatives of the hospital, and
- (2) savings they earn from reconciliation payments made for a performance year.

With this information, Medicare beneficiaries will be able to ask questions about how rewards and savings will affect their care and health care outcomes and also for making decisions with their providers about the most appropriate device for their particular health and lifestyle.

Furthermore, we strongly oppose any gainsharing programs that reward providers for using products simply because they are less expensive and not appropriate for patients' needs. Internal gainsharing programs that focus on medical device savings simply drive providers to use devices because they are less expensive, even if it means higher Medicare spending in the long-run due to more frequent revision procedures in the future.

Toward that end, we oppose gainsharing that is exclusively tied to use of lower-utility medical devices not appropriately matched to patient needs. Instead, we believe that shared savings opportunities should be based on incentives that encourage providers to deliver high quality care more efficiently. In this way, higher quality and reductions in adverse patient events become the central organizing principles of care redesign, rather than incentives that lead providers to use the cheapest product to maximize a short-term gainsharing arrangement.

In addition, AdvaMed urges that episode payments be accompanied by controls that protect patients against wholesale changes in device offerings of providers participating in the payment model and to consider prohibiting gainsharing altogether when tied to the use of less expensive and lower-utility devices. We further recommend that care in participating hospitals be carefully monitored for the appropriateness of device choice for individual patients and surgeons.

Functional Assessment Tool. The white paper also recommends that providers use a standardized, validated functional status assessment tool to determine that the patient is an appropriate candidate for a surgical procedure. AdvaMed supports this recommendation as a safeguard for patient access to joint replacement procedures, especially in the context of persons receiving care through an ACO delivery model. The financial incentives in ACOs, with their emphasis on spending reductions without accompanying robust quality measures, could lead to delay in patient access to appropriate joint replacement as a response to the cost of the replacement procedures being significantly higher than alternative treatments, such as medication therapy. As a result, joint replacement procedures will have a much greater impact on an ACO's year-end spending total than medication therapy and when compared to the ACO's benchmark could result in lower shared savings available to providers in the ACO. A standardized, validated functional assessment tool will help protect patients against this form of stinting.

Decision Aids. AdvaMed strongly supports the use of decision aids as additional tools for safeguarding patients against stinting that may occur in delivery reform models. Further we recommend that the use of decision aids as part of shared decision making by patients and

providers be incorporated into a quality measure that would be required for joint replacement procedures. As discussed above, AdvaMed is concerned that some providers participating in BPCI may be shifting almost exclusively to using lower utility devices. A requirement that providers and beneficiaries share in decision-making about the particular device to be used for a procedure will help protect patients from financial incentives that may lead to less than optimal device choices.

We also believe that shared decision-making will be most effective for patients if they understand the financial incentives underpinning delivery reform models and also have available specific levels of financial rewards received by providers participating delivery reform models.

2. Episode Timing

So long as services that would be included in a look-back period of 30 days prior to surgery are related to the elective procedure, AdvaMed supports that starting point for the episode. We also support an end point of 90 days post-discharge, by which time most spending would have occurred for most patients. We also concur with the recommendation that quality measurement should include data up to 12 months post-discharge, even though the episode payment period ends 90 days post-charge. While we remain concerned with the impact financial incentives in short-term episodes can have on patient access to all appropriate treatment options and innovative technologies, we believe that tracking quality data for an entire year following discharge will counteract some of the delivery models' underlying incentives that could lead to stinting. Possible areas for 12 month post-discharge measurement include patient-reported outcomes that capture return to activities of daily living, restoration of mobility resembling pre-surgical movement, and revision rates.

3. Patient Population

AdvaMed supports the white paper's recommendation that the patient population to which the episode payment would apply should be broad and payments should be based on risk and severity adjustments to account for age and complexity. However, as we discussed in detail above, additional protections and strong monitoring programs also need to be put in place to protect patients from excessive standardization of hip and knee technologies and to ensure that they receive devices that most appropriately correspond to their lifestyles and medical conditions.

4. Services

AdvaMed agrees that the episode payment should include delivery of all services billed in the defined time period that are related to the joint replacement procedure, including physician services, skilled nursing or other rehabilitation services, home health, therapy service, etc.

We also recommend that payments cover telehealth services that are essential for maximizing the opportunity to improve the quality and efficiency of care provided under the episode payment. Given the variety of sites to which a patient can be referred following discharge from the hospital

setting and the desire for most patients to return to their homes as soon as possible, telehealth is ideally suited for allowing patients to return to the least restrictive setting for follow-up care and for monitoring their recovery and progress in regaining function. In order to incentivize the use of telehealth technologies, the episode payment for joint replacement procedures must recognize the need for coverage of services beyond restrictions and limitations that exist in public programs (see Medicare and expanded coverage for telehealth under BPCI and CJR) or private payer programs. Calculation of benchmarks and actual spending totals should not penalize providers for their desire to use these technologies, which are particularly central for these procedures to realize improvements in efficiency and quality of care.

5. Patient Engagement

As discussed above, AdvaMed strongly supports the development and deployment of rigorous decision-making tools for joint replacement procedures and we support including in these tools information enumerated in the specific recommendations of the white paper. However, we caution that shared decision-making may involve a cost to physicians not reflected in fee-for-service payments for their services and not included in benchmark calculation. We agree especially with the recommendation that patients and their family caregivers need information on how providers are being reimbursed in an episode payment model. We argue that this information should necessarily include a discussion of gainsharing rewards that a provider will receive as a result of services provided during the episode--and specifically how those rewards might affect a physician's decision about device selection for the patient. From this discussion, patients should understand that devices have a broad range of functional features designed to address individual patients' lifestyles and medical conditions, and how physician recommendations have changed over time, particularly in the context of participating in bundled payment programs. These discussions will protect patients as well as deter providers from less than optimal device choices for joint replacement procedures.

6. Accountable Entity

The white paper argues that the accountable entity for managing the episode should be chosen based on its ability to engineer change in the way care is delivered to the patient and its ability to accept risk for the episode. While CMS and the Innovation Center have opted to this point for hospitals to take on that role in bundled payment models, it is conceivable that certain physician practices may be able to meet both tests. AdvaMed agrees with the work group's assessment that either type of entity may be able to meet the criteria, just as both types of entities now participate in the Medicare Shared Savings Program. What will be critical is an assessment by payers of an entity's readiness to manage care across the entire continuum of settings where patients may receive care during the episode and the entity's ability to promote collaboration and coordination among multiple providers. It is also critical that the entity be able to manage gainsharing programs, to the extent they are used to foster collaboration, so that they do not result in forms of stunting discussed in detail above.

7. Payment Flow

AdvaMed supports the white paper's recommendation to use, at least for the immediate future, a retrospective reconciliation episode payment with upfront payments flowing through a fee-for-service mechanism. Given the major changes that will accompany episode payments for joint replacement and potential disruption to patient care that might occur in non-integrated systems, retrospective reconciliation based on fee-for-service payments has the advantage of being used in current episode initiatives and allowing providers to track more easily resources used in the episode—experience and information central to any transition to episodes based on prospective payments.

8. Episode Pricing

AdvaMed supports the white paper's recommendation to establish an episode price based on regional and provider-specific data, but questions have to be resolved about what is an appropriately sized region and what is the optimal blend and transition from entity specific costs to regional costs. Our concern is with any methodology for establishing price that results in ever greater pressure on efficient providers to continue to achieve savings that would pose risks to patients in the form of stinting on care and compromised patient access to appropriate treatment options and innovative technologies—risks already inherent to episode payment models. Episode payments require rigorous monitoring of patient care outcomes, including evaluation of types of devices being used by providers participating in the episode model and determination of whether incentives in the model has led to excessive standardization of devices at the expense of quality patient care.

9. Type and Level of Risk

In general, AdvaMed supports both upside and downside risk, with physicians allowed to share risk. The white paper recommends that transition periods and risk mitigation strategies should be used to encourage broader provider participation. AdvaMed argues that both of these mechanisms are needed for another purpose: to ensure that patients receive high quality care during the episode and over the long term. As noted above, the financial incentives in relatively short episode windows and the promise of gainsharing rewards that would accompany reductions in costs of care could have the effect of compromising patient access to all appropriate treatment options, especially when some of those options are more expensive than others. In many cases, providers participating in the episode payment model would not experience the consequences of inappropriate device selection since they may not become apparent until several years after the conclusion of the episode. Transition periods and risk mitigation strategies could mitigate some of negative consequences of underlying incentives in the episode payment model.

10. Quality Metrics

AdvaMed strongly supports the development of patient-reported outcomes and functional status measures for joint replacement procedures, but believe that stakeholders should agree on meaningful and measurable standard quality metrics. Today too few measures exist for joint

replacement procedures to support an assessment of quality of care received during an episode of care or meaningfully inform patients about quality they can expect from specific providers prior to a decision to undergo an elective procedure. With patient-report outcome and functional status measures, quality measurement can and should continue beyond the defined episode period and should include data up to 12 months after discharge.

11. Role and Perspectives of Stakeholders

The Work Group's white paper states that it is important to consider all stakeholder voices in the design and operation of episode payments--mentioning payers, providers, patients and consumers, and employers and purchasers—but not including manufacturers of the hip and knees technologies used in joint replacement procedures. Our member companies are, of course, expert in assisting with decision-making for matching particular design features of devices with the lifestyles of patients. In addition, they are currently developing capacities for helping providers with managing costs for the entire episode of care through services that will enhance both efficiency and quality. Manufacturers are stakeholders which should not be left out of the equation for maximizing improvements in care outcomes and controlling spending growth.

We would be pleased to answer any questions regarding these comments. Please contact Richard Price, Senior Vice President, Payment and Health Care Delivery Policy, at (202) 434-7227, if we can be of further assistance.

Sincerely,

/s/

Don May
Executive Vice President,
Payment and Health Care Delivery