



August 26, 2011

Donald M Berwick, M.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1577-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Durable Medical Equipment and Definition of “Durable” in Proposed Rule for Medicare Program: Changes to the End-Stage Renal Disease Prospective Payment System for CY 2012

Dear. Dr. Berwick:

The Advanced Medical Technology Association (AdvaMed) submits the following comments on the proposed definition for “durable” for purposes of coverage of durable medical equipment (DME) under Part B of the Medicare program, as included in CMS-1577-P. Specifically, the rule establishes a definition regarding how long equipment must withstand repeated use to be considered DME and proposes ways to implement this definition.

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.

3-Year Minimum Lifetime Requirement Establishes Arbitrary Coverage Criterion That Will Deter Innovation

The proposed rule would establish a 3-year minimum lifetime requirement that DME must meet in order for equipment to be considered “durable” and potentially eligible for coverage under the Medicare program. AdvaMed believes that this proposal establishes an arbitrary threshold for the following reasons. While the proposed rule cites Merriam Webster, the Department of

Commerce, and economics dictionaries to justify its proposal, CMS does not offer clinical, health care, or quality of care evidence to explain why it has proposed the definition of “durable” or how it determined that “3-years” was an appropriate requirement. This “one-size fits all” approach to DME classification fails to recognize the significantly wide array of DME products now covered under Medicare and the impact innovation will have on product availability in the future.

Under the proposed definition for “durable,” equipment determined to withstand repeated use for 2 years and 11 months, but which also meets other tests for coverage (e.g. home use, medically necessary and reasonable, etc.) and improves patient care outcomes, mobility, and functioning, would not be eligible for coverage. In this regard, the rule discourages advances in medical progress and innovation that improves quality of care, leads to more rapid recovery, and enhances the functional ability of elderly and disabled beneficiaries. The proposed definition would also lock into place a standard of care that exists at a given point in time. Furthermore, the technology improvement that in this case does not meet the 3-year durability test could also result in cost savings, which the program would not capture because of the arbitrary definitional threshold. With consequences such as these, the proposed rule fails to achieve your triple aim goals of improving care for individuals, improving the health of populations, and delivering care as efficiently as possible.

Determining Whether Equipment Meets 3-Year Minimum Lifetime Requirement Will Result in New Regulatory Burdens/No Appeals Process

While proposing to establish a 3-year minimum lifetime requirement for DME, the proposed rule does not identify the agency’s process for determining which products meet this test. The proposed rule states that in cases where it is not clear that the equipment can meet the 3-year minimum lifetime requirement, CMS and its contractors would review additional information and evidence, including but not limited to a HCPCS request form, pre-market clearance documents from FDA, product warranty documents, product website, product marketing materials, subject matter expert reviews, and other sources. The proposed rule, however, is silent on the process for certifying a product as “durable” in instances when it is clear that equipment would meet the 3-year minimum test and how that decision would be made. In either situation, AdvaMed is concerned that the process and requirements will further lengthen an already extended process for securing coverage under Medicare for new products, and in so doing, create significant new disincentives for manufacturers to innovate. In addition, the rule fails to address the need for an appeals process that would allow manufacturers and other stakeholders to contest decisions made by CMS not to cover a device because it fails meet the 3-year minimum lifetime standard.

Applying Definition Prospectively Could Lead to Inconsistent Coverage Policy for Beneficiaries with Negative Impact on Medical Progress

In the proposed rule, CMS indicates that the 3-year lifetime requirement would be applied prospectively only and would not apply to equipment already covered as DME once the new definition is implemented. Prospective applicability of this definition raises questions about how

the proposed rule would affect products which are introduced in a modified form with improved functionality. Would CMS consider the modified product a new product subject to the 3-year minimum lifetime requirement, even when the predicate product was not subject to this standard and was covered by Medicare as DME? Specifically, the proposed rule fails to discuss whether the prospective application of the proposed policy would differ if a new generation product did or did not receive a HCPCS code different from the predicate device now covered by Medicare as DME, or if the predicate device did or did not meet the minimum lifetime requirement. If CMS requires the modified product to meet the new standard and the product fails to meet the 3-year test, what impact will the rule have on medical progress and beneficiary health, and what message will that send to Medicare beneficiaries and to manufacturers about the program providing access to new and improved products? In addition, the proposed new standard can lead to inconsistent coverage policy, with Medicare covering a predicate device simply because it has been “grandfathered” under the rule, and not another improved version of the product introduced at a later point in time, which could enhance patient care outcomes for Medicare beneficiaries. While this “one size fits all” policy is inappropriate, AdvaMed is in no way suggesting that the solution is to apply such policies retrospectively to existing products

Application of the 3-Year Minimum Lifetime Criteria to Multi-Component Devices Will Create Significant Problems

The rule proposes to consider ways to apply the 3-year minimum lifetime standard to the component of a multi-component device that performs the medically necessary function of the device and specifically offers three methods to do so. The rule does not propose or discuss a process that CMS would use for determining which products would be considered multi-component devices for purposes of application of the standard to these devices, or how CMS proposes to distinguish between “components” and “supplies” and accessories.” Nor does it discuss the process CMS would use for defining which component might perform the medically necessary function or the “vital” part of the device, or how it would address the issues when a multi-component product has more than one medically necessary function. AdvaMed is concerned that application of any single, inflexible policy for handling multi-component devices/systems will be unworkable. Further, as noted above, AdvaMed is concerned that application of the standard will further lengthen an already extended process for securing coverage under Medicare for new equipment, and in so doing, create significant new disincentives for our member companies to innovate. This delay could be especially significant in the case of multi-component products where the analytic challenges of determining which component performs the medically necessary function could be particularly complex.

Recommendations/Conclusion

AdvaMed does not support the proposal to establish a 3-year minimum lifetime requirement for DME and believes that CMS should withdraw the proposed definition. The proposed definition would establish a “one-size fits all” approach to DME classification that fails to recognize the significantly wide and complex array of DME products now covered under Medicare. Furthermore, the rule fails to consider and discuss many of the implications of the proposed policy change, particularly the negative impact it will have on medical progress and

beneficiaries' access to innovative and improved products in the future as well as its potential burden on developers and manufacturers.

Given the issues the proposed definition raises, AdvaMed recommends the following:

First, CMS should convene a study panel to allow stakeholders to collaborate with CMS to:

- Develop a definition of “durable” which takes into consideration clinical, health care, and quality of care evidence; and
- determine whether and how to apply this definition to the wide array of DME, including multi-component devices; and

Second, CMS should address least burdensome approaches to applying this definition prospectively, including ways to:

- minimize the risk of creating unduly burdensome requirements on manufacturers at FDA and at CMS; and
- eliminate the risk of inconsistent coverage policies that negatively impact beneficiary access to DME.

AdvaMed stands ready and willing to work with CMS to establish this panel and resolve these issues.

If you have any questions, please contact Richard Price at rprice@advamed.org or (202)434-7227.

Sincerely,



Ann-Marie Lynch
Executive Vice President
Payment and Health Care Delivery Policy