December 9, 2011

Marilyn Tavenner  
Principal Deputy Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attn: CMS-4157-P  
Mail Stop C4-26-05  
7500 Security Blvd.  
Baltimore, MD 21244-1850

Re: Clarifying Coverage of Durable Medical Equipment in Proposed Rule for Medicare Program: Proposed Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs for Contract Year 2013

Dear Ms. Tavenner,

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to submit the following comments on a proposed rule clarifying coverage of durable medical equipment (DME) for beneficiaries enrolled in Medicare Advantage (MA) plans, as included in a larger proposed rule, CMS-4157-P.

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.

AdvaMed does not support the proposed rule’s changes that would dramatically change MA beneficiaries’ access to durable medical equipment for the sake of ensuring “that MA organizations maximize program efficiencies by driving enrollee utilization to specific DME products for which MA organizations may have negotiated bulk discounts.” Decisions about providing Medicare-covered services should be determined first and foremost by clinical criteria that ensure that beneficiaries have access to the items and services that will improve their medical conditions and enhance their health and well-being. Medicare beneficiaries choosing to enroll in a Medicare Advantage plan are entitled to receive the full array of benefits available to Medicare beneficiaries enrolled in the fee-for-service program. As such, the choice of DME appropriate for an individual patient should be determined by his or her physician. Our concerns and recommendations are discussed below.
Limiting MA Plan Coverage of DME to Specific Manufacturers or Brands Based on Price Without Adequate Patient Safeguards

The proposed rule would allow MA plans to limit their coverage of DME to products of specific manufacturers or brands on the basis of prices paid for items, rather than on the basis of their appropriateness for the medical conditions of the enrollees they serve. As noted above, the rule signals that CMS is clarifying coverage policy for DME in order to help ensure that MA plans will be able to maximize efficiencies in directing beneficiaries to products for which plans have negotiated bulk discounts.

While the proposed rule does impose conditions on plans that choose to limit coverage of DME to specific manufacturers or brands, there is no stated plan to ensure that these conditions will adequately protect patients’ access to the products they require. For example, the proposed rule would require that MA plans choosing to limit coverage to specific manufacturers’ products or brands ensure that enrollees have access to all preferred manufacturer products through their contracts with network suppliers. However, neither the preamble nor proposed rule itself indicates the criteria by which a plan may designate a product preferred. On the basis of the proposed rule’s justification for clarifying coverage policy for DME in MA plans, we must assume that the rationale that plans will use for defining preferred products will be based solely on the price of an item and not on other criteria, such as quality or medical appropriateness for a given patient, since the rule is silent on requiring plans to use other criteria such as these in defining preferred products.

The proposed rule also requires that plans provide coverage of any medically necessary DME items, including those made by non-preferred manufacturers, but appears to limit coverage to a transition period and/or links coverage to individual medical necessity determination and appeals processes. Once again, clinical considerations of the prescribing physician appear to be secondary to the price of the non-preferred product. Moreover, the amount of time that a Medicare beneficiary (or his or her physician) must wait when seeking an individual determination of medical necessity is not specified or limited.

The need for specific standards that plans should use for defining preferred products and for ensuring access to non-preferred products when medically necessary is critical for patients, since products, even those within the same product category, are seldom equivalent in terms of their appropriateness and performance when the unique needs of a patient are taken into account. For example, one strategy for ensuring MA enrollee access to appropriate products would be for CMS to establish formulary standards that require plans to meet clinical criteria and product quality requirements. Using diabetes test strips as an example, these standards could include offering a range of brands of test strips, requiring that products meet FDA Blood Glucose Meter Accuracy Standards, using a non-interfering test strip platform, and adopting patient protections.

Furthermore, allowing plans to base coverage decisions strictly or principally on price will have a negative impact on beneficiary access to innovative products, when those products that improve patient outcomes or provide other patient benefits are more expensive than older technologies.
The Fallacy of Applying Prescription Drug Therapeutic Equivalence to DME Products

The proposed rule cites an existing regulation that requires an MA-PD plan or Part D plan sponsor to provide for an appropriate transition process for enrollees transitioning from other coverage when the enrollee is currently prescribed Part D drugs not on the new Part D plan’s formulary and for whom a therapeutically substitutable formulary drug is available. The proposed rule would establish a similar transition period under which MA plans would be expected to provide one refill during a 90-day transition period before the enrollee is moved to the new product—on the assumption that a process exists for defining therapeutic equivalency for DME products, similar to that which exists for prescription drugs. In fact, no such process exists or is recognized for DME items and supplies. Rather current device category groupings under HCPCS are not based on performance or therapeutic equivalency. Physicians and their patients make decisions about specifying individual DME products on the basis of a patient’s particular and unique medical condition, home environment, and the ability to function with a given device. Further, substituting one prescription drug for another is not equivalent to providing alternative DME products which often require significant education and training in order to be able to properly use a different brand of DME.

As an example of a product that would be subject to a 90-day transition period, the proposed rule offers ostomy bags, suggesting that ostomy products are therapeutically equivalent and can easily be substituted for each other. In fact, this example actually points to the potentially negative health consequences of moving forward with a policy that would allow MA plans to substitute one product for a less expensive one, on the assumption that they are interchangeable. Ostomy products are not interchangeable and vary considerably based on brand. Most patients needing ostomy products experiment with several different systems before selecting and customizing the specific products that meet their individual needs. Specific features of products will have differing levels of importance for patients, depending on such factors as an individual’s anatomy, skin characteristics, diet, and ability to carry out activities of daily living. Without specially trained clinicians being able to customize specific ostomy systems that meet a patient’s individual and unique needs, MA enrollees face the prospect of significant negative health outcomes following ostomy surgery. We also note that Medicare law defines ostomy products as prosthetic devices, distinguishing them from DME. They should, therefore, be outside the scope of the proposed rule. And if this is not the case, we would argue that the proposed rule fails in terms of alerting stakeholders to the possibility that the proposed policy might apply to items other than DME and related supplies, and providing them with an opportunity to submit informed comments, as envisioned under the Administrative Procedure Act.

Conclusion

AdvaMed believes that the proposed rule on coverage of DME in MA plans contradicts a general Medicare Advantage policy requiring MA plans to provide all medically necessary Parts A and B covered items and services, and represents a significant departure from protections built into the traditional Medicare program. Given the significant additional patient protections that need to be considered and embodied in a policy change of this importance, AdvaMed urges CMS
not to finalize the proposed rule. CMS should first convene a study panel of physicians providing these services to Medicare beneficiaries, clinical experts, including those who develop and manufacture DME products, and patient representatives to develop recommendations setting out appropriate DME coverage policies for MA plans that have as their foundation both clinical criteria and product quality standards that will ensure Medicare beneficiaries’ access to the products that will improve their health and quality of life. In addition, CMS should provide a clear plan for oversight and beneficiary, supplier, and referral agent education activities for ensuring patients’ access to products that will improve their health.

AdvaMed stands ready and willing to work with CMS to implement the recommendations described above.

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

Sincerely,

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