February 24, 2011

Danielle Moon, Director
Medicare Drug & Health Plan Contract Administration Group
and
Russell Hendel
Centers for Medicare & Medicaid Services
Department of Health and Human Services
OA/CPC/MCAG/DPAP
Mail Stop C4-22-04
Baltimore, MD 21244

Dear Ms. Moon and Mr. Hendel,

The Advanced Medical Technology Association (AdvaMed) would like to comment on proposed revisions to Chapter 4 of the Medicare Managed Care Manual, “Benefits and Beneficiary Protections.” 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.

We would specifically like to comment on a proposed revision in Section 10.2 which would allow Medicare Advantage (MA) plans to restrict access for covered durable medical equipment (DME) items to certain manufacturers of those items. We are submitting this letter, in addition to comments through the spreadsheet accompanying the notice of the revisions, because we believe such a major change in policy requires thorough discussion of its implications for beneficiary health.

The Proposed Revision Allowing MA Plans to Restrict Access for Covered DME to Certain Manufacturers of Those Items.

A revised draft of Chapter 4 of the Medicare Managed Care Manual, submitted for public comments February 10, 2011, would allow MA plans to restrict access for covered DME items to certain manufacturers of those items, provided these DME items are accessible to plan enrollees through all contracted network providers. The actual policy of restricting access is established in an example provided under a bullet labeled “Access.” AdvaMed
recommends deleting all of this explanatory material (from “For example” to “providers;”).

The revised policy fails to include criteria for defining the parameters that would apply to MA plans restricting beneficiary access to certain manufacturers’ DME products. The result is that it appears that managed care plans would be able to restrict access to DME products strictly on the basis price, regardless of the quality of the item or its appropriateness for a particular patient’s condition, and regardless of the clinical judgment of the physician treating the patient or the patient’s preferences. In effect, the proposed policy includes no safeguards for Medicare beneficiaries and would give MA plans wide latitude to adopt objectionable coverage polices that could have a seriously negative impact on their health.

The proposed change contradicts a general Medicare managed care policy that requires MA plans to provide or pay for all medically necessary Parts A and B covered items and services. With the proposed change, beneficiaries and the physicians who treat them could face a severely diminished set of covered DME benefits and product choices as a result of the policy change.

The Medicare Advantage policy change represents a significant departure from protections built into the traditional Medicare program. As recently as last year, CMS proposed for Medicare’s durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program, and subsequently finalized an “anti-switching rule” to prevent suppliers from influencing beneficiaries with diabetes from switching blood glucose monitors and testing supplies that they and/or their physicians had previously selected. This rule is intended to complement another protection, known as the 50 percent rule, built into the competitive bidding program by Congress to require DME suppliers to furnish a sufficient number of different types of testing strip products that, in the aggregate and taking into account volume for the different products, account for at least 50 percent of all such types of products on the market. In addition, the Medicare DMEPOS competitive bidding program provides a general mechanism, a physician or treating practitioner authorization, through which a Medicare beneficiary can be confident of obtaining the specific brand or mode of delivery required to avoid an adverse medical outcome. In contrast, the proposed policy offers no similar or equivalent beneficiary protections.

Allowing managed care plans to restrict access of covered DME to certain manufacturers’ products without allowing physicians to select the appropriate product to meet their patient’s needs exacerbates problems that already exist within the Healthcare Common Procedure Coding System (HCPCS). Under HCPCS, a single code is often used to describe a wide range of DME products with varying functionalities of importance to patients. In addition, products in a single code may not be interchangeable. If plans decide to make decisions about restricting access by codes, they may force beneficiaries
to change to products which are not appropriate for their care needs or will not result in quality outcomes of care desired by their treating physicians.

Conclusion

AdvaMed appreciates the opportunity to submit these comments on a significant policy change in the Medicare Managed Care Manual that would allow plans to restrict access to certain manufacturers’ DME products. The policy change may have a significant, negative impact on beneficiary health and well-being because it appears to allow plans to restrict access, without any consideration given to a patient’s particular medical condition or the clinical judgment of the prescribing physician. **For this reason, AdvaMed recommends deleting in Section 10.2 of the draft revised Manual, under the bullet labeled “Access” all of the explanatory material (from “For example” to “providers;”).**

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

cc: Jonathan Blum
    Deputy Administrator and Director
    Center for Medicare