DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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PROVIDER COMPLIANCE GROUP

Thomas F. Fise
Executive Director
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330 John Carlyle Street, Suite 200
Alexandria, VA 22314

APR 10 2013

Dear Mr. Fise:

I am in receipt of your organization's letter dated March 8, 2013 in which you expressed AOPA's concerns about a bulletin article published by the Jurisdiction B Durable Medical Equipment Medicare Administrative Contractor (DME MAC) entitled Documentation for K Levels for Prosthetics. The article outlines the documentation requirements to support the functional level for prosthetics billed to Medicare. You assert that Jurisdiction B is "staking out dangerous new policies" and urge CMS to improve its oversight and management of this contractor. CMS monitors the medical review activities of review contractors and it is our opinion that Jurisdiction B is making appropriate decisions in accordance with the LCD and CMS policy.

As noted in previous correspondences with your organization, section 1862(a)(1)(A) of the Social Security Act requires that Medicare only pay for items or services that are reasonable and necessary. In addition, Section 1833(e) of the Social Security Act precludes payment unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." The DME MACs recognize this statutory requirement, as well as the unique skill set and training that certified orthotists and prosthetists have in the Local Coverage Determination (LCD) for Lower Limb Prosthetics in the passage that sets out the requirement for making a functional level determination. The LCD states:

> A determination of the medical necessity for certain components/additions to the prosthesis is based on the beneficiary's potential functional abilities. Potential functional ability is based on the **reasonable expectations of the prosthetist, and treating physician**, considering factors including, but not limited to:
> - The beneficiary's past history (including prior prosthetic use if applicable); and
> - The beneficiary's current condition including the status of the residual limb and the nature of other medical problems; and
> - The beneficiary's desire to ambulate.
>
> (Emphasis added).

As noted above, the prosthetist's assessment does play a part in the selection of the functional (K) level; however, the prosthetist's assessment must be consistent with information in the

medical record from the treating physician's assessment and prognosis of overall health status. This corroboration of the prosthetic functional determination with the independent medical record information is essential to assure that the item(s) provided are appropriate for the beneficiary and eligible for reimbursement.

As we have discussed previously, Medicare looks to the documentation in the *treating physician's records* as the primary source of information to support that the item or service is reasonable and necessary. The prosthetic record provides key supplemental information as described by the policy provision noted above and consistent with the provisions set out in CMS' Program Integrity Manual Chapter 5, Section 5.7.

You agree with this position in your letter. You acknowledge that the physician must make a prognosis "based on science and principles of medicine" and that it amount to "that physician's prognosis of the likelihood of the patient's ability to become a community ambulator, able to discharge the activities of daily living most fully, with the mobility assistance provided by a specific advanced technology incorporated into a prosthetic limb." CMS agrees.

Your letter then contends that the contractor should not be taking overall health status into consideration as they evaluate medical record information. While you previously agreed that the physician must use all of his or her diagnostic skill and medical training that would, by necessity, include the beneficiary's past medical history and illnesses, you then criticize Jurisdiction B medical review staff for attempting to conduct claim review in a similar manner. Your letter states:

"Specifically, we are aware of claims in which Jurisdiction B claims reviewers have been using details of the patient's health that are unrelated to their amputation or limb loss. These factors include the use of hypertensive medications to treat blood pressure, history of cancer treatment, history of peripheral vascular disease, body weight conclusions derived from scrutiny of every factor in the patient's medical record."

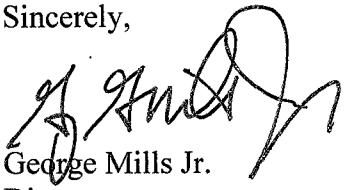
As you know, there are many factors other than the physical loss of a limb that impact a beneficiary's ability to function. It is entirely appropriate for medical claim reviewers to evaluate documentation concerning-morbid conditions when such conditions could reasonably be expected to impact a beneficiary's overall functional ability when making reasonable and necessary determinations. For example, a beneficiary with Class IV heart failure as a result of their hypertension is not likely to improve with a limb amputation such that they are now a K-3 level ambulator. The ordering physician's medical documentation must support the K-level determination they themselves make. Reviewers are neither altering these determinations nor affecting the standard of care in any way. Reviewers only confirm whether or not submitted documentation is sufficiently supportive.

To provide an example of the relevance of this approach, CMS staff conducted data analyses on claims paid for K-3 and K-4 level prosthetic feet. Using Medicare paid claims data, CMS discovered illogical claim groupings. For example, CMS found that over ten percent of beneficiaries receiving K-3 and K-4 feet received a Power Mobility Device to assist them in activities of daily living within the home (close in time to their receipt of a prosthesis) or had an

illness so severe that they required oxygen in the home. Therefore, these claim payments appear to be potentially contradictory to a high functional level assessment. While an individual claim determination cannot be made based upon data suggesting that these claims for prosthetics were all incorrect, these findings would suggest further review is required. Similar claim reviews performed by the contractors have identified an unexpectedly high level of disconnect between the prosthetic functional assessment and the information contained in the medical record.

To summarize, the material published by Jurisdiction B simply restates existing requirements in order to encourage suppliers to adhere to Medicare's existing payment rules. This article does not create new policy. I hope you find this information useful. In addition, CMS looks forward to working with your organization to develop an electronic clinical template. If you have any additional questions, please do not hesitate to contact me at George.Mills@cms.hhs.gov.

Sincerely,



George Mills Jr.
Director
Provider Compliance Group