American Orthotic & Prosthetic Association

Impose a Moratorium on Medicare's Draft Lower Limb Prosthetic LCD & All Audits Related to Lower Limb Prostheses

Background

In July 2015 the four Durable Medical Equipment Medicare Administrative Contractors (DME MAC's) issued a draft Local Coverage Determination (LCD) that had the potential to drastically rewrite the coverage rules for prosthetic limb care for Medicare beneficiaries, and the proposed LCD was widely criticized by patients, prosthetists, physicians and numerous beneficiary and clinical organizations. Under the proposed restrictive LCD, beneficiaries would only be eligible for prosthetic limbs that are functionally outdated, less durable and less safe; in essence it sent amputees back to a 1970's level of care. In addition this potential re-write of Medicare's lower limb prosthetic benefit category, appeared to be done without any scientific, clinical basis or credible evidence. For example:

- Beneficiaries with certain conditions such as hypertension, asthma, cerebral vascular conditions or memory loss would be excluded from obtaining coverage for more advanced technologies.
- If beneficiaries have *ever* required Medicare coverage for a walker, a cane, crutches or a wheelchair, they also would be excluded from receiving coverage for technologically advanced prostheses.
- Amputees deemed not to have attained "natural gait," which is an undefined, non-medical term, also would not qualify for these devices.

These changes are inconsistent with current clinical practice and would arbitrarily deny Medicare beneficiaries access to current and possibly future prosthetic limb technologies, stifling innovation; and would have implications beyond the Medicare program since the other insurers tend to follow Medicare requirements. There are already established examples of private insurers already adopting and using some of the misguided information found in the Draft LCD and amputees have been adversely impacted.

After significant public outcry, in November 2015, the Center for Medicare and Medicaid Services (CMS), published a notice that said the DME MACs would not be finalizing the Lower Limb Prosthesis LCD "at this time." CMS, insisting that it has no control over LCDs issued by its Medicare contractors, instead said it would form an interagency workgroup to "develop a consensus statement that informs Medicare policy by reviewing the available clinical evidence that defines best practices in the care of beneficiaries who require lower limb prostheses." The Workgroup's charge is not clear, the identity of the federal agency participants has not been released, the meetings are not open to the public, and there has been virtually no stakeholder input.

In September 2016, the Agency for Healthcare Research and Quality (AHRQ), the "government agency tasked with producing evidence to improve the quality of healthcare while working with partners to ensure that the evidence is understood and used" announced

that it was initiating a systematic review for lower limb prostheses. The stated purpose of the systematic review, performed through the Evidence Based Practice Center Program of the AHRQ, is "to examine the available clinical evidence that defines practices in the care of beneficiaries who require lower limb prostheses (LLP)." While the announcement was not tied to the inter-agency taskforce assigned to review the draft LCD), it is clear that the initiation of the systematic review for lower limb prostheses is directly related to the work of this taskforce. AOPA and several other stakeholders (amputees, clinicians, prosthetists, therapist, etc.) provided written comments on the AHRQ announcement.

As the AHRQ and the "inter agency workgroup" continue to work on establishing a new LCD for lower limb prostheses, and "to better understand the state of the evidence regarding how best to match patients with LLPs that would yield best outcomes for them, and related issues", private insurers continue to hold O&P suppliers to the standards of the draft LCD and CMS through its contractors ,the DME MACs and the Recovery Audit Contractors (RAC), continue to audit suppliers on non-existent or non-published standards of evidence for medical necessity. The DME MAC's and RAC's tend to focus their audits on newer and more advanced technologies, and as a result of these audits O&P suppliers are strongly pushed to provide patients with functionally outdated, less durable and less safe items. Just within the past month, in April, 2017, another example of a new, unwarranted auditing practice adding new impediments via potentially universal pre-payment audits on another of the more advanced K-3 technologies—in this case the microprocessor knee—even before Medicare has completed its policy review of the 2015 proposed LCD is the recent announcement by the Jurisdiction C DME MAC that they will be conducting a widespread prepayment review on microprocessor controlled prosthetic knees described by HCPCS code L5856. Again, Medicare contractors are moving to deny patients access to improved, advanced prosthetics limbs, and this must be reversed.

This practice of auditing to unsubstantiated and undefined parameters places an undue burden on the O&P supplier community, causes unnecessary delays in patient care, and often results in the patient not receiving the level of care they need and deserve.

Recommendations

Given the far reaching impact of the potential policy changes contained in the Draft LCD, as seen by the actions of a select few private payers, an 18-month moratorium, until December 1, 2018 is needed to allow for a thorough review of all material available and a transparent process in which stakeholder feedback is provided and responded to by CMS and its contractors in a public manner, instead of the reliance on the closed door prosthetic LCD-related interagency committee comprised of only government employees and other CMS staff; and to assure no hasty decisions or actions are taken by CMS or its DME MAC contractors.

We also request that this **moratorium encompass and defer all audits and/or reviews for lower limb prosthetic claims be put in place, until December 1, 2018, at which point presumably the composition of the interagency work group has been expanded beyond strictly federal employees, and its work has been completed**, and the AHRQ has published the results of its review. Only at this point can a clear, consistent policy and set of auditing parameters and documentation guidelines be established, and thereafter implemented.

Lastly, we also encourage Congressional oversight to allow for a potential clarification to assure that the HHS statutes and rules clearly allow CMS to properly manage the activities of its contractors on LCD and all other issues.

For more information contact the American Orthotic & Prosthetic Association (AOPA) at (571) 431-0876 or www.AOPAnet.org.