

OFFICIAL STATEMENT Final Local Coverage Determination ("LCD") L33787 Lower Limb Prostheses

The American Academy of Orthotists and Prosthetists worked together with its O&P Alliance partners to submit extensive comments to the proposed LCD in March of this year, stressing the importance of this new coverage policy for Medicare beneficiaries with limb loss. This final LCD concludes that microprocessor-controlled prosthetic knees may be a viable therapeutic option for some limited community ambulating Medicare beneficiaries with lower limb amputations. The final LCD states, "Therefore, the criteria in the Lower Limb Prostheses Local Coverage Determination will be expanded to allow coverage of fluid, pneumatic, or electronic/microprocessor control additions for prosthetic knees in MFCL-2 beneficiaries when supporting documentation in the medical record outlines the rationale for selection of the higher-level knee."

This documentation must include how the selected knee will improve the beneficiary's functional health outcomes and help the beneficiary accomplish their daily living activities. In addition, alternative lower-level knee options must be determined to have been considered and ruled out based on the beneficiary's individual functional and medical needs. Billing code modifiers (i.e., KX, GA, GY, and GZ) are also required to facilitate claims processing and assist in the prevention of improper claims payments.

The LCD also addresses complementary prosthetic foot options for Medicare beneficiaries who qualify under the new coverage policy. The policy states, "Criteria of higher-level foot systems will also be expanded to include MFCL-2 beneficiaries who meet the new coverage criteria for a fluid, pneumatic, or electronic/microprocessor control addition for a prosthetic knee and who will require a compatible foot."

The final LCD closely mirrors the proposed coverage policy but makes two important modifications: (1) The final LCD removes the word "all" from the requirement to consider and rule out lower-level knee systems (e.g., knee systems that exclude the use of fluid, pneumatic, or microprocessors). This is a much more reasonable standard for coverage of MPK knee systems and will help practitioners serve beneficiaries in need without undue burdens to prove that all alternative lower limb knee systems would not meet patients' needs. This is consistent with our comments on the proposed LCD. (2) The final LCD also clarifies that HCPCS code L5841 (Addition, endoskeletal knee-shin system, polycentric, pneumatic swing, and stance phase control) is covered under the category of fluid and pneumatic knees for MFCL-2 beneficiaries.

This finalized coverage policy is a major improvement in lower limb prosthetic coverage for Medicare beneficiaries with limb loss and limb difference. It comes after 20 years of clinical research, eight years after CMS stated that the Medicare program should consider coverage of MPKs for MFCL-2 amputees, and significant efforts by Otto Bock and others to improve Medicare coverage in this manner. This LCD represents a significant advance forward in the treatment of lower limb amputees to improve function and safety, specifically with respect to fall prevention.

The revised Local Coverage Analysis that accompanies this new LCD contains several key revisions. Most of the changes provide greater detail on operationalizing this new coverage expansion, but the LCA also contains a significant rewrite of the Functional Levels. There are examples offered that should help prescribers and practitioners to more accurately identify which beneficiaries should be assigned a particular functional level. Notably, the LCA also explicitly includes reference to the statute that the Academy and the O&P Alliance supported several years ago, as follows: "Based on Social Security Act §1834(h)(5), for purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the individual's medical record to support documentation created by the treating practitioner."