Response to Denial Based on "Experimental/Investigational"

DENIAL: Microprocessor-Controlled Prosthetic Ankles are investigational or experimental.

RESPONSE:

There is ample research evidence which demonstrates the functional benefits of microprocessor-controlled prosthetic ankles for lower limb amputees and therefore it is not investigational or experimental.

Sloped and uneven surfaces pose a debilitating environmental barrier to persons with lower limb amputation due to the lack of accommodation from fixed ankle prosthetic feet. What patients experience when using fixed ankle prosthetic feet and attempting to walk on sloped and uneven terrain is excessive pressure and torque on the residual limb which causes pain and drastic compensatory strategies of proximal joints. Without addressing the lack of accommodation to sloped and uneven terrain, persons with lower limb loss are restricted in the environments where they can ambulate and are at risk of residual limb skin breakdown and damaging loading of the proximal joints.

Research evidence has demonstrated that microprocessor-controlled prosthetic ankles address the problems summarized above. Using a microprocessor ankle was shown to reduce the socket pressures on slopes and ramps to be more comparable to pressure experienced during level ground walking[1], which greatly reduces the pain and risk of skin breakdown associated with walking on sloped or uneven terrain with a fixed ankle.

Microprocessor prosthetic ankles are shown to do more negative work while descending a ramp and allows less negative work done by the residual knee[2]. This benefit will reduce stress and overuse injuries in proximal joints and the contralateral limb. The same study showed that a microprocessor prosthetic ankle arrives at foot flat more quickly and slows the rotational velocity of the tibia over the prosthesis in stance phase when compared to a fixed ankle. This benefit is vital for persons with lower limb amputation to improve stability and balance when walking on sloped or uneven terrain.

In summary of the research evidence reviewed above, there are several benefits of microprocessor-controlled prosthetic ankles which are supported with objective data.

Additionally, the CMS HCPCS decision tree notes that "when an item operates in a significantly different manner, or provides a significant therapeutic distinction compared to existing coded treatments or products, a new or revised code shall be created"[3]. In fact, throughout the history of establishing L codes for prosthetics, additional codes have been generated to describe and acknowledge new technology and enhanced functionality.

CMS established the L5973 code and added it to the Medicare fee schedule. **CMS, a conservative payer, does not assign HCPCS codes for investigational components or services.** *L5973: Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source.* The technology is not labeled investigational, as required by law for investigational devices[4], because the technology is not investigational and not limited to investigational use. The technology is established, proven, effective, desired, reimbursable, and being used by thousands of lower limb amputees around the world.

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[1] Wolf, Sebastian I., et al. "Pressure characteristics at the stump/socket interface in transtibial amputees using an adaptive prosthetic foot." Clinical Biomechanics 24.10 (2009): 860-865.

[2] Struchkov, Vasily, and John G. Buckley. "Biomechanics of ramp descent in unilateral trans-tibial amputees: Comparison of a microprocessor controlled foot with conventional ankle–foot mechanisms." Clinical Biomechanics 32 (2016): 164-170.

[3] HCPCS Decision Tree for External Requests to Add or Revise Codes, CMS.gov

[4] US Food & Drug Administration, Facts about IDE, Labeling