BrainRobotics

K2 Justification and Reimbursement Support

LCD Update to include K2 MPK Coverage: Revision Effective date 09/01/2024

A fluid or pneumatic knee unit (L5610, L5613, L5614, L5615, L5722, L5724, L5726, L5728, L5780, L5814, L5822, L5824, L5826, L5828, L5830, L5840, and L5841), or control addition, fluid (L5848), or electronic/microprocessor (L5856, L5857, L5858) is also covered under limited circumstances for beneficiaries whose functional level is 2, when all of the following criteria (1-3) are met (see the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section in the LCD related Policy Article):

1. The beneficiary has had a clinical evaluation to determine their functional level (see FUNCTIONAL LEVELS section above); and, Documented K level after a face-to-face with Physician or Prosthetist, supportive of K2 status.

   Ensure the supporting documentation from your clinician includes a statement of the patient's K2 activity level.

2. Supporting documentation in the medical record outlines, in the context of the beneficiary's overall medical health, the rationale for selection of a fluid, pneumatic, or electronic/microprocessor controlled knee, including (at minimum) how the selected knee will:

   a. Improve the beneficiary's functional health outcomes (e.g., fall reduction, injury prevention, lower energy expenditure)

   A MPK will improve stability to reduce falls or near falls, make sure to document patient-reported falls or near falls. Kneuro includes stumble recovery feature.

   A MPK can reduce fatigue for patients who lack muscular strength and coordination.

   Falls can be influenced by fatigue, lack of muscular strength or coordination, and poor sensation, all of which have been shown to be improved with a MPK compared to a mechanical knee.

   Consider cardiac or pulmonary comorbidities that will benefit from lowered energy expenditure i.e. CHF, pulmonary edema, shortness of breath etc.

   b. Help the beneficiary accomplish their activities of daily living (ADLs); and improve functional health outcomes:

   List patient-specific ADLs and the benefit of a MPK for those activities. Activities to consider: Walking in a crowded store, crossing parking lots, carrying groceries, playing with or caring for children or grandchildren, transfers in and out of cars, stairs or steps.

   i.e. improved safety during ambulatory tasks such as walking on uneven terrain or stairs, carpet, rugs, backyard or curbs due to enhanced stumble recovery capabilities. Increased efficiency of gait to allow the patient to accomplish ADLs more efficiently and with less fatigue

3. Lower-level knee systems (e.g., knee systems which exclude use of fluid, pneumatic, or microprocessor) have been considered and ruled out based on the beneficiary's specific functional and medical needs.

   Consideration of lower-level knees does not dictate they be delivered. List which patient activities or ADLs will be contraindicated or limited by the delivery of a lower activity knee. Lower-level knee systems may not have the safety features needed by a K2 ambulator, such as stumble recovery, default stance, and extension assist.

   Stumble recovery will reduce falls and allow the patient to safely recover from an adverse ambulatory event, and reduce risk associated with walking on uneven terrain such as parks and yards. Default stance improves stability, allows for comfortability while stationary, allows the patient to safely stand at ease for activities like washing dishes or cooking.

   Extension assist is necessary for patients with muscular weaknesses or comorbidities of the cardiac system.

In addition, for coverage of an electronic/microprocessor-controlled knee system (L5856, L5857, or L5858 plus associated components) for beneficiaries whose functional level is 2, all of the following criteria (1-4) must also be met (see the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section in the LCD related Policy Article):

1. The electronic/microprocessor knee is indicated for functional level 2

   Kneuro is PDAC approved for K2, K3 and K4 level patients. PDAC verification letter available at Brainrobotics.com

2. The electronic / microprocessor knee has integrated technology that allows the knee to detect when the user trips or stumbles and can automatically adjust to stabilize the knee unit (e.g., stumble recovery)

   Kneuro includes a stumble recovery feature, as listed in the product IFU.

3. The beneficiary is able to make use of a product that requires daily charging

   Consider the patient's phone or other medical devices that may require daily charging. If they are able to keep a cell phone charged, they are able to keep the Kneuro charged.

4. The beneficiary is able to understand and respond to error alerts and alarms indicating problems with the function of the unit

   Consider the patient's phone or other medical devices that may alert the patient, i.e phone ringer, blood glucose monitor, personal devices, etc.

Best Practices for Clinical Documentation

Patient-Specific ADLs:
Include detailed examples of how the MPK will enhance safety and performance during specific ADLs (e.g., navigating stairs, walking outdoors, carrying groceries).

Fall History:
Document the patient's history of falls or near falls and how the MPK's stability features will mitigate these risks. Consider improved physiological gait and microprocessor control for features like stumble recovery.

Comorbidities:
Provide a rationale for reduced energy expenditure benefits, particularly for patients with cardiac or pulmonary issues. Also consider the importance of fall reduction for patients with reduced sensation and proprioception due to diabetic neuropathy.

Lower-Level Knee Systems:
Clearly explain why a lower-level system is not suitable for the patient, citing specific contraindications or risks. Remember that lower-level knee systems may not include features like manual lock or extension assist, and will definitely not include microprocessor control and stumble recovery.

References

LCD - Lower Limb Prostheses (L33787). (n.d.). Www.cms.gov.
https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33787