Centers for Medicare & Medicaid Services
Health Technology Assessment

Lower Limb Prosthetic Workgroup Consensus Document

September 2017

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Introduction

The Centers for Medicare & Medicaid Services convened a multi-disciplinary Lower Limb Prosthetic Interagency Workgroup (Workgroup) in February of 2016 in response to public comment and concern expressed regarding the Durable Medical Equipment Medicare Administrative Contractors Proposed/Draft Local Coverage Determination (LCD): Lower Limb Prostheses (DL33787), released 7/16/2015. The Workgroup is comprised of federal employees who are subject matter experts in the lower limb prosthetic field including clinicians, policy specialists, and patient advocates from various agencies. It has met to develop a consensus statement to inform Medicare policy regarding best practices for beneficiary access to lower limb prosthetics. The Workgroup has also identified areas where evidence gaps exist related to the prescription of lower extremity prostheses. Workgroup participants include representatives from the Administration for Community Living (ACL), the Department of Defense (DoD), Walter Reed National Military Medical Center (WRNMMC), the National Institutes of Health (NIH), the Veterans Health Administration (VHA) and the Centers for Medicare & Medicaid Services (CMS). See Appendix A for a list of Workgroup Participants.

The Workgroup searched the literature (including that provided by interested stakeholders) to compile and review pertinent clinical evidence relevant to the identification of best practices regarding the care of Medicare beneficiaries with lower limb amputations in need of prostheses. During Workgroup meetings, this literature was extensively discussed in order to inform policy suggestions. The Workgroup concentrated on those topics which appeared to generate the most significant concern of interested stakeholders as noted by comments submitted in response to DL33787.

It is important to note that the Workgroup considered only the evidence base germane to the provision of appropriate prosthetics for Medicare beneficiaries with lower limb amputations. Coding and billing concerns were not within the scope of the Workgroup’s mission.

K Level Characteristics of Individuals Classified as K0-K4

The Workgroup considered the K modifiers as a means to describe the intended use of a lower limb prosthesis. Based on the intended use of the prosthesis and whether or not the patient can achieve these activities, the selection of appropriate components can be made for a patient.

The Workgroup believes that prostheses and components should be provided for individuals who demonstrate a clear need and whose current and/or potential activity level is described by the K level characteristics listed below. The Workgroup also suggests that exceptions be considered if additional documentation is included which justifies a medical need for componentry in an individual who does not necessarily "fit" the K Level descriptions (e.g., bilateral amputees cannot be strictly held to the K level system).

Please note: Not all traits listed for K levels must be realized by the patient in order to receive a K level assignment, but generally, documentation should demonstrate that equivalent activities can be achieved by the prosthetic user.

Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.

a. The individual does not have sufficient cognitive ability to safely use a prosthesis with or without assistance.
b. The individual requires assistance from equipment or caregiver in order to transfer and use of a prosthesis does not improve mobility or independence with transfers.
c. The individual is wheelchair dependent for mobility and use of a prosthesis does not improve transfer abilities.
d. The individual is bedridden and has no need or capacity to ambulate or transfer.

Note: If a beneficiary has need of a lower limb prosthesis (LLP) to maintain sitting balance in an appropriately fitted wheelchair, but cannot ambulate or transfer using the prosthetic, the individual may be a candidate for a prosthesis which correlates with K1 activities.

Example: A beneficiary with a trans-femoral amputation as well as a spinal cord injury (T4 ASIA B paraplegia) which precludes bi-pedal ambulation or weight bearing during transfers, depends on the resistance of the prosthetic socket portion to maintain sitting balance. Though this individual may exhibit the functional abilities consistent with K0, s/he may be a candidate for a prosthesis typically provided to a beneficiary with K1 activity abilities.

Level 1: Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence, typical of the limited and unlimited household ambulator.

a. The individual has sufficient cognitive ability to safely use a prosthesis with or without an assistive device and/or the assistance/supervision of one person.
b. The individual is capable of safe but limited ambulation within the home or on a similar flat surface like a home, with or without an assistive device and/or with or without the assistance/supervision of one person.

c. The individual requires the use of a wheelchair for most activities outside of their residence.
d. The individual is not capable of most of the functional activities designated in Level 2.

Level 2: Has the ability or potential for ambulation with the ability to transverse low level environmental barriers such as curbs, stairs or uneven surfaces. This level is typical of the limited community ambulator.

a. The individual can, with or without an assistive device (which may include one or two handrails) and/or with or without the assistance/supervision of one person:
    i. Perform the Level 1 tasks designated above
    ii. Ambulate on a flat, smooth surface (e.g., concrete, asphalt) such as might be found outside the home. (e.g., porch, deck, patio garage, driveway)
    iii. Negotiate a curb
    iv. Access public or private transportation
    v. Negotiate 1-2 stairs
    vi. Negotiate a ramp built to ADA specifications.
b. The individual may require a wheelchair for distances that are beyond the perimeters of the yard/driveway, apartment building, etc.
c. The individual is only able to increase his/her generally observed speed of walking for short distances or with great effort.
d. The individual is generally not capable of accomplishing most of the tasks at Level 3 (or does so infrequently with great effort).

Level 3: Has the ability or potential for ambulation with variable cadence, typical of the community ambulator who has the ability to transverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

a. With or without an assistive device (which may include one or two hand rails), the individual is independently capable (i.e. requires no personal assistance or supervision) of performing the Level 2 tasks above and can:
    i. Walk on terrain that varies in texture and level (e.g., grass, gravel, uneven concrete)
    ii. Negotiate 3-7 consecutive stairs
    iii. Walk up/down ramps built to ADA specifications
    iv. Open and close doors
    v. Ambulate through a crowded area (e.g., grocery store, big box store, restaurant)
    vi. Cross a controlled intersection within his/her community within the time limit provided (varies by location)
    vii. Access public or private transportation
    viii. Perform dual ambulation tasks (e.g. carry an item or meaningfully converse while ambulating)
b. The individual does not perform the activities of Level 4.

Note: If the beneficiary can accomplish the physical tasks described by the K3 level, but requires personal assistance or supervision due to cognitive, sensory or communicative disability, then the individual is a candidate for a prosthesis which correlates with K3 usage.

Example: In addition to the lower limb amputation, if the beneficiary has also experienced a TBI and is capable of performing the above K3 activities, but frequently needs supervision and assistance for safety purposes and redirection of attention, then s/he is a candidate for a prosthesis which correlates with K3 usage.

Level 4: Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress or energy levels typical of the prosthetic demands of the child, active adult, or athlete.

With or without an assistive device (which may include one or two hand rails), this individual is independently capable (i.e. requires no personal assistance or supervision) of performing high impact domestic, vocational or recreational activities such as:

a. Running
b. Repetitive stair climbing
c. Climbing of steep hills
d. Being a caregiver for another individual
e. Home maintenance (e.g. repairs, cleaning)

Note: If the beneficiary can accomplish the physical tasks described by the K4 level, but requires personal assistance or supervision due to cognitive, sensory or communicative disability, then the individual is a candidate for a prosthesis which correlates with K4 usage.

Example: The beneficiary exhibits a significant visual impairment in addition to a lower limb amputation. Though s/he demonstrates no other significant co-morbidities, and performs physically at a very high level (e.g., running, climbing stairs), he sometimes requires supervision for safety. S/he is a candidate for a prosthesis which correlates with K4 usage.

The Workgroup has further determined that research to-date has failed to connect a patient's medical condition (e.g. strength, ROM, balance, etc.), functional abilities, or outcome measure results to his/her K level. The Workgroup therefore considered the use of pre-authorization in order to ensure the provision of the most appropriate prosthesis to the Medicare beneficiary. A study of the coverage policies of twelve major third party insurers indicated that virtually all implement their coverage criteria through a prior authorization procedure pursuant to which providers must show medical necessity through provision of detailed documentation of the beneficiary's need and capacity to use the specific prosthetic being prescribed. This knowledge solidified the suggestion of the Workgroup that pre-authorization of lower limb prosthetics should be allowed in the Medicare population.

Pre-authorization should be based on the information in the submitted history and physical exam (H&P).[1] It would be expected that the H&P would report, at a minimum, the following:

History

- Name
- *Age
- *Age at limb loss
- *Level of amputation
- *Etiology of amputation
- *Co-morbidities of the patient and medical readiness related to safe use of a prosthesis
- *Emotional readiness of the patient
- *Cognitive abilities of the patient related to safe use of a prosthesis
- Current or past therapy applicable to amputation (if appropriate)
- Prior level of functioning
- Current level of functioning (including use of prosthesis and assistive devices, if applicable)
- Patient goals
  - Short term
  - Long term
- Patient social situation information
  - Type of residence (e.g., private home, nursing facility or assistive living)
  - Need /availability of caregiver (if required)
- Architecture of home
  - Architecture of home (e.g., required steps to entrance/kitchen/bathroom/bedroom)

Physical Exam

- *General description of cardiopulmonary status
- *General description of bilateral lower limbs (e.g., scars, neuromas, wounds, edema, skin quality)
- *Specific description of limb to receive prosthesis (e.g., length, shape, incision site, overall readiness for prosthesis
- Range of motion and strength (bilateral as appropriate):
  - Hip

[1] The Program Integrity Manual, Chapter 5, Section 5.7, states: “For any DMEPOS item to be covered by Medicare, the patient’s medical record must contain sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient’s diagnosis and other pertinent information including, but not limited to, duration of the patient’s condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc.” The Program Integrity Manual, Chapter 5, Section 5.8, states: “The supplier should also obtain as much documentation from the patient's medical record as they determine necessary to assure themselves that coverage criteria for an item have been met. If the information in the patient's medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved unless a properly executed ABN of possible denial has been obtained.”

  - Knee
  - Ankle
- Sensation (bilateral)
- Proprioception (bilateral)
- General description of upper limb range of motion and strength
- Description of sitting and (if appropriate) standing balance
- Description (if appropriate) of transfer and ambulation abilities (include description of balance and mobility aids uses)

The H&P may also report any other information believed pertinent, including general health considerations and the results of specific measures used to evaluate the function of beneficiaries with amputations.

Based on the above and any other information obtained from consultants (see below), the referring physician will determine the patient's current or potential use for a prosthesis. That usage will then be described by a K level designation. If at the time of the initial pre-authorization, the referring physician determines that a patient has the potential to reach a higher K-level designation in the future, the physician must provide a comprehensive treatment plan with compensatory techniques like surgery, therapy, or counseling, that will achieve this increase in functional level. The plan should specify a reasonable and predetermined period of time in which to address the factors currently limiting the patient's physical performance or safety. It will be at the discretion of the pre-authorization team to allow (or not) the prescribed prosthesis based on the totality of the information received.

The Workgroup does not anticipate that the referring physician make a K level determination in isolation (though s/he may do so if comfortable with this decision); however, the physician's medical documentation must support the beneficiary's current and expected functional capabilities within the context of his or her overall medical problems. Therefore, the physician must provide, at a minimum, the information related to all items with an asterisk (*) above. Additionally, the physician may obtain any other information (including a plan to address physical or safety limitations) from a consultation performed by a physical/occupational therapist or prosthetist. Each of these specialists shall examine and evaluate the patient for the appropriate information for which s/he is educated and skilled, per state regulations and society guidance as applicable. Neither the physician nor the physical therapist may have any compensatory arrangement with the prosthetist. Furthermore, as a general principle for DMEPOS, entities with a financial stake in the outcome of the claim decision are not granted sole authority to document medical necessity (e.g., the prosthetist record may not be used as sole justification for medical necessity). Therefore, it would be expected that for the pre-authorization process to begin, all pertinent physician, therapist and prosthetist notes must be submitted together.

Submission of the above information can be accomplished either by the physician or the prosthetist. This entity is known as the 'submitter". After receipt of all relevant documentation from the submitter, the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) will have 10 business days to approve or reject the first submission. If the first submission (or subsequent submissions) is non-affirmed by the DME MAC, the submitter may revise and resubmit the prior authorization request. The Durable Medical Equipment Medicare

Administrative Contractor (DME MAC) will have 10 business days to approve or reject any subsequent submissions.

In emergency situations, there should also be a mechanism in place to request an expedited 2 business day review. When doing so, a submitter should clearly indicate and provide the supporting rationale that explains how the 10-business day time period could jeopardize the beneficiary's health or safety.

As previously noted, the K level classification should not be considered a functional classification; instead it is a description of the intended use of the prosthesis. Based on the intended use of the prosthesis and whether or not the patient can achieve these activities, the selection of appropriate components can be made for a patient.

See Appendix B for the algorithm for the determination of K Level modifiers for an individual who requires an initial lower limb prosthetic.

Repairs and Replacements of Prosthetic Componentry

Repairs and replacements to a prosthesis are governed by 1834 of the Social Security Act.

> *(G) Replacement of prosthetic devices and parts.—*
> *(i) In general.—Payment shall be made for the replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the provision of a replacement device, or a replacement part of such a device, is necessary because of any of the following:*
> *(I) A change in the physiological condition of the patient.*
> *(II) An irreparable change in the condition of the device, or in a part of the device.*
> *(III) The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.*
> *(ii) Confirmation may be required if device or part being replaced is less than 3 years old.—If a physician determines that a replacement device, or a replacement part, is necessary pursuant to clause (i)—*
> *(I) such determination shall be controlling; and*
> *(II) such replacement device or part shall be deemed to be reasonable and necessary for purposes of section 1862(a)(1)(A);*
> *except that if the device, or part, being replaced is less than 3 years old (calculated from the date on which the beneficiary began to use the device or part), the Secretary may also require confirmation of necessity of the replacement device or replacement part, as the case may be.*

The Workgroup advises that the pre-authorization process described previously should be used if a replacement of a prosthetic part less than 3 years of age is deemed necessary due to a change in the physiologic condition of the patient. If changes to the prosthesis are required due to a downgrade in the patient's functional status, an expedited review can be used.

The Workgroup also believes that a "physiologic" change in the patient' condition does not necessarily solely relate back to an alteration in the condition of a patient's amputated limb. Instead, the physiologic change may also describe other aspects of a patient's health that affect

his/her mobility status. Therefore “physiologic change” should encompass the patient’s global status as it affects his/her mobility.

For adjustments or repairs of a prosthetic component that has rendered the prosthesis inoperable or unsafe, the Workgroup suggests no preauthorization be required. However before the repair is accomplished, a physician’s prescription for the repair of the component and the prosthetist’s description of the necessity of the repair must be entered into the patient’s record. This information must be available if requested by an auditing entity. All payment rules denoted in Social Security Act §1834 must be followed.

Componentry

In its deliberations of the pertinent scientific literature, the Workgroup addressed the componentry topics which appeared to generate the most significant concern among interested stakeholders as noted by public comments submitted in response to DL33787. Please see the bibliography for a list of the materials considered.

Preparatory vs Definitive Prosthesis for New Amputee

There is no evidence found by the Workgroup to define best practices regarding the prescription of a preparatory versus a definitive prosthesis to an individual with a new amputation. Therefore, it is expected that based on patient characteristics, the team of professionals evaluating the patient will make an appropriate decision regarding these needs. The rationale regarding whether the patient is first prescribed a preparatory or definitive prosthesis, and the manner in which this decision fits into the patient’s overall prosthetic and personal goals and projected timeline to highest level of functioning, must be submitted with the preauthorization materials. However it is to be noted that the Workgroup does not recommend the use of non-alignable preparatory prosthetics [L5500 – L5600]. (See Appendix C for code descriptions).

Microprocessor Knees

The Workgroup was divided on the quality and strength of the literature pertaining to microprocessor knees (MPKs) for beneficiaries who ambulate at the K2 level. Some argued that the individual articles noted in the literature which discuss this topic, do adequately demonstrate that those who utilize their prosthesis at the K2 level might improve their functional abilities (e.g., walking speed on level and unlevel ground; ramp descent speed, falls, etc.) with MPK technology. Others argued that the studies comprising this literature were significantly flawed (e.g., small sample sizes, attrition, confounders such as training differences, sole use of laboratory studies, significant conflict of interests, etc.). Those arguing the limitations of these studies are aware that these findings may not agree with the conclusions of other federal agencies.

Therefore, the Workgroup acknowledges an amputee functioning at the K2 level may benefit from MPK technology. However, as a population, these individuals cannot be categorically defined for policy purposes.

Consequently, the Workgroup recommends that if consideration is to be given to the provision of a microprocessor knee for an individual who currently utilizes his/her prosthesis at the K2 level,

the rationale for that component must be justified in a pre-authorization request. To make that request stronger, a trial of usage should be considered by the prosthetist (prior to payment for the component) with pertinent results of that trial (i.e. pre/post data) as they relate to functional health outcomes including, but not limited to, falls/injuries and the accomplishment of activities of daily living / instrumental activities of daily living (ADLs/IADLs), being highlighted in the pre-authorization information. It will be the decision of the pre-authorization team to approve (or not) the request.

Power Assist Ankles

The Workgroup believes that at the present time, the literature does not support coverage of the power assist ankle for Medicare beneficiaries. However, the Workgroup is hopeful that advances in research will eventually describe the benefit of this component to a defined subgroup of the Medicare population.

Shock Absorbing Pylons

The Workgroup believes that at the present time, the literature does not support coverage of shock absorbing pylons for Medicare beneficiaries who utilize their prosthesis at the K2 level. However, the Workgroup is hopeful that advances in research will eventually describe the benefit of these components to a defined subgroup of the Medicare population.

Prosthetic Liners/Socket Inserts

The Workgroup has found no evidence to direct the choice of interface material between prosthesis and skin. Instead the Workgroup believes this is a decision which is individualized based on various characteristics of the beneficiary, including: the physical condition of the residual limb and the patient's hand/upper extremity function, as well as the activity level, suspension, comfort and limb/skin protection provided by the material and needed by the user. Therefore, based on these and any other relevant factors presented in the medical record, the Workgroup recommends that the team of professionals evaluating the patient make an appropriate decision regarding the required interface. The rationale regarding the particular interface the patient is prescribed, and the manner in which this decision fits into the patient's overall prosthetic and personal goals and projected timeline to highest level of functioning, is to be submitted with the preauthorization materials.

The Workgroup further believes that in certain cases where documentation is adequate, "mixed" inserts (those with different HCPCS codes) may improve the function and comfort of a prosthesis (e.g., silicone insert plus spacer)

Furthermore, the Workgroup believes that the items identified by HCPCS codes L5654-L5665 are typically custom made over a positive model. Therefore the Workgroup does not believe it is appropriate to distinguish "custom" inserts" (L5673, L5679, L5681, L5683) from "non-custom inserts" (L5654 – L5665) in policy documents. (See Appendix C for code descriptions).

Prosthetic Suspension

There is no evidence found by the Workgroup on the use of 'multiple suspension systems' in the prosthetic leg of a single individual. The Workgroup believes that multiple suspension systems (e.g., supracondylar suspension plus pin suspension; belt suspension plus pin suspension) may be complimentary in order to maintain adequate suspension and alignment of a prosthetic leg. Based on any relevant factors presented in the medical record, the Workgroup recommends that the

team of professionals evaluating the patient will make an appropriate decision regarding the required prosthetic suspension. The rationale regarding the particular suspension system the patient is prescribed, and the manner in which this decision fits into the patient's overall prosthetic and personal goals and projected timeline to highest level of functioning, is to be submitted with the preauthorization materials. It will be the decision of the pre-authorization team to approve (or not) the request, based on the information provided.

Elevated Vacuum Suspension Systems

The Workgroup believes that though some physiologic benefits are exhibited by the use of elevated vacuum suspension systems (for example, stabilization of limb volume and decreased pistoning), the current literature does not support improved functional health outcomes with the use of this component. Therefore, at the present time, it is unknown how these physiologic results translate into beneficial health outcomes for individual users.

Therefore, the Workgroup deems that if consideration is to be given to the provision of an elevated vacuum suspension system for an individual with a lower limb amputation, the rationale for that componentry choice must be justified in a pre-authorization request. To make that request stronger, a trial of usage should be considered by the prosthetist (prior to payment for the component) with pertinent results of that trial (i.e. pre/post data) as it relates to functional health outcomes including, but not limited to, falls and their associated injuries, skin breakdown and wound healing, donning, doffing and quantitative usage of the prosthesis and the ability to perform ADLs/IADLs, being highlighted in the pre-authorization information. It will be the decision of the pre-authorization team to approve (or not) the request.

Research Gaps in Lower Limb Prosthetic Investigations as They Pertain to the Medicare Population

The Workgroup has reviewed the body of literature noted in the bibliography. It has also studied the findings of a draft of the document entitled: Lower Limb Prostheses Systematic Review written by Brown University Evidence Based Practice Center, under a contract to the Agency for Healthcare Research and Quality. The Workgroup has concluded that in general, this information does not adequately provide the evidence necessary to inform Medicare policy in the provision of the most appropriate prostheses to its beneficiaries. Therefore, the Workgroup recommends that the appropriate federal agencies (e.g. NIH, VA, DoD, AHRQ, CMS, ACL) convene an Interagency Panel to develop and publicize consensus criteria that will begin to provide the basis for the development of the best evidence possible to demonstrate the potential functional and safety benefits of new and evolving prosthetic technology. In this way, both publicly and privately funded researchers will be aware of the general requirements that would determine whether or not the evidence presented is of sufficient quality to support a finding that any given item provides significant clinical and/or health related quality of life (HRQoL) benefits to its user.

The Workgroup endorses (at a minimum) the following characteristics of evidence in future prosthetics research:

a. Determination of outcome generalizability to the Medicare population or other appropriate subpopulations (e.g., evidence that supports use in those 65 and older, with a dysvascular etiology to their amputation);
b. Consideration of outcomes by race, gender and co-morbidities;
c. Stratification of outcomes that are specific or equivalent to K level activities, demographic categories, level of amputation, previous prosthetic experience, and/or etiology of amputation;
d. Determination of reasons for poor adherence or abandonment of the prosthetic, preferably by subgroups as noted in item c above;
e. Similar co-interventions for all patients and trials (e.g., appropriate rehabilitation therapy provided for both the “new” as well as the comparative technology);
f. Standardization of acclimation periods as well as length of study and tasks/activities performed;
g. Determination of *a priori* expectations of outcome differentials in terms of function and HRQoL that would determine the success of the research (e.g. “long term” counts of falls/stumbles; amputee specific questionnaires; measures of ability to ambulate on various terrain; measures of comfort; change in usage of assistive devices; accomplishment of new ADL /IADL/recreational tasks; step monitors; etc.);
h. Use of research techniques that strengthen the overall quality of the investigation (e.g. blinding of evaluators; use of appropriate sample sizes calculated upon effectiveness data);

i. Use of 'real world' as well as laboratory outcome measures to include the impact of the intervention versus the control on measures of cognitive burden, energy consumption and ability to accomplish physical tasks, hill/ramp/stair walking, minutes/hours of prosthesis wear and/or ambulation per day), changes in use of mobility aides, etc.;
j. Consideration of adverse effects (e.g. incidence of falls and stumbles, skin wounds, skin conditions; development of pain in proximal joints; frequency and duration of equipment failure);
k. Measurements of durability to study outcomes (e.g., long term usage/ satisfaction);
l. Provision of the highest level of comparator.

The Workgroup further suggests that federal agencies provide one or more policy avenues that might offer assistance for well-conducted research defined by these criteria. It would be expected that such research could expedite earlier patient access to innovative prosthetic technology while ensuring that systematic patient safeguards, including assurance that the technology is provided to clinically appropriate patients, are in place to reduce the risks inherent to new technologies, or to new applications of older technologies. Such a paradigm might be accomplished for example, through the currently established Medicare Clinical Trials Policy (https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&fromdb=true) or the Medicare National Coverage Determination Coverage with Evidence Development (https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27).

Specific Topics of Research Interest

1. The Workgroup suggests that federal agencies provide research opportunities as well as research parameters to interested stakeholders in order to advance the knowledge regarding microprocessor technology. Specifically, the Workgroup would like to advocate that high quality investigations be funded that have as their purpose to define the functional and safety related benefits that such componentry may provide the patient who utilizes his/her prosthesis at the K2 level.

   The Workgroup also acknowledges that there is a wide range of prosthetic knees that fit into the broad MPK classification and that not all of these can be considered to have the same characteristics and functional benefits. Most of the research literature found and reviewed by the Workgroup involving MPK use in the individual utilizing a prosthesis at the K2 level, has focused on a select few components. The Workgroup believes that future research should compare the differences that occur in patient function when using varying types and manufacturer brands of MPKs, as well as non-MPKs.

2. The Workgroup also suggests that federal agencies provide research opportunities as well as research parameters, to interested stakeholders in order to advance the knowledge regarding elevated vacuum suspension systems. Specifically, the Workgroup would like to recommend that high quality investigations be funded which have as their purpose to define that patient population who may functionally benefit from receiving such a system.

3. The Workgroup believes that the information available to advise the medical community is not adequate to inform the best practices involving the frequency, duration, type or setting of rehabilitation for either the new amputee or the individual who changes prosthetic components. This research gap should be addressed in a coordinated manner to meet the needs of specific subpopulations among those individuals with lower limb amputations (e.g. individuals with amputations caused by diabetes, trauma, peripheral vascular disease; pediatric or younger individuals covered by Medicare who require changes in prosthesis due to development; etc.).

Final Considerations

While this document contains the Workgroup's suggestions on numerous topics relating to lower limb prostheses, the Workgroup recognizes that, if accepted, many of these may take a prolonged length of time to implement. However, the Workgroup believes that the following four suggestions can be implemented by CMS in the short term:

1. The Proposed/Draft Local Coverage Determination (LCD): Lower Limb Prostheses (DL33787), currently 'on hold', be retired.
2. The current Local Coverage Determination (LCD): Lower Limb Prostheses (L33787) remain in force for the immediate future.
3. CMS supports the establishment of an interagency federal research group in order to create a guidance document to promote industry research standards in the field of lower limb prostheses.
4. CMS strongly consider opening a National Coverage Determination to consider the use of microprocessor knees in those individuals utilizing their prostheses at the K2 level.

Appendix A. Lower Limb Prostheses Interagency Workgroup Participants

Alison Cernich, PhD, ABPP-Cn
Director, National Center for Medical Rehabilitation Research
National Institutes of Health

Andrea E. Crunkhorn, DPT
Clinical Affairs Program Coordinator
Extremity Trauma and Amputation Center of Excellence (EACE)

Vicki Gottlich, JD, LLM,
Director, Center for Policy and Evaluation
Administration for Community Living

Michael Handrigan, MD, MSHA, FACEP
CAPT, USPHS
Centers for Medicare & Medicaid Services
Center for Program Integrity (CPI)

David Laufer
Service Chief, Orthotic and Prosthetic Service
Department of Rehabilitation
Walter Reed National Military Medical Center

Martin McDowell, L/CPO, FAAOP
VHA Orthotic and Prosthetic Clinical Services
Department of Veterans Affairs

Susan M. Miller, MD
Centers for Medicare & Medicaid Services
Coverage and Analysis Group (CAG)

Louis Quatrano, PhD
Director , Behavioral Sciences and Rehabilitation Technology Research Program.
National Center for Medical Rehabilitation Research
National Institutes of Health

Billie J. Randolph, PT, PhD
Deputy Director, Extremity Trauma
and Amputation Center of Excellence
Rehabilitation and Prosthetic Service
Department of Veterans Affairs

Marcel Salive, MD, MPH
Division of Geriatrics and Clinical Gerontology (DGCG)
National Institute on Aging
National Institutes of Health

Joseph B. Webster, MD
Staff Physician, Hunter Holmes McGuire VA Medical Center, Richmond, VA
National Medical Director, VA Amputation System of Care

Appendix B. Algorithm for Determination of K Modifiers for Initial Lower Limb Prosthetic

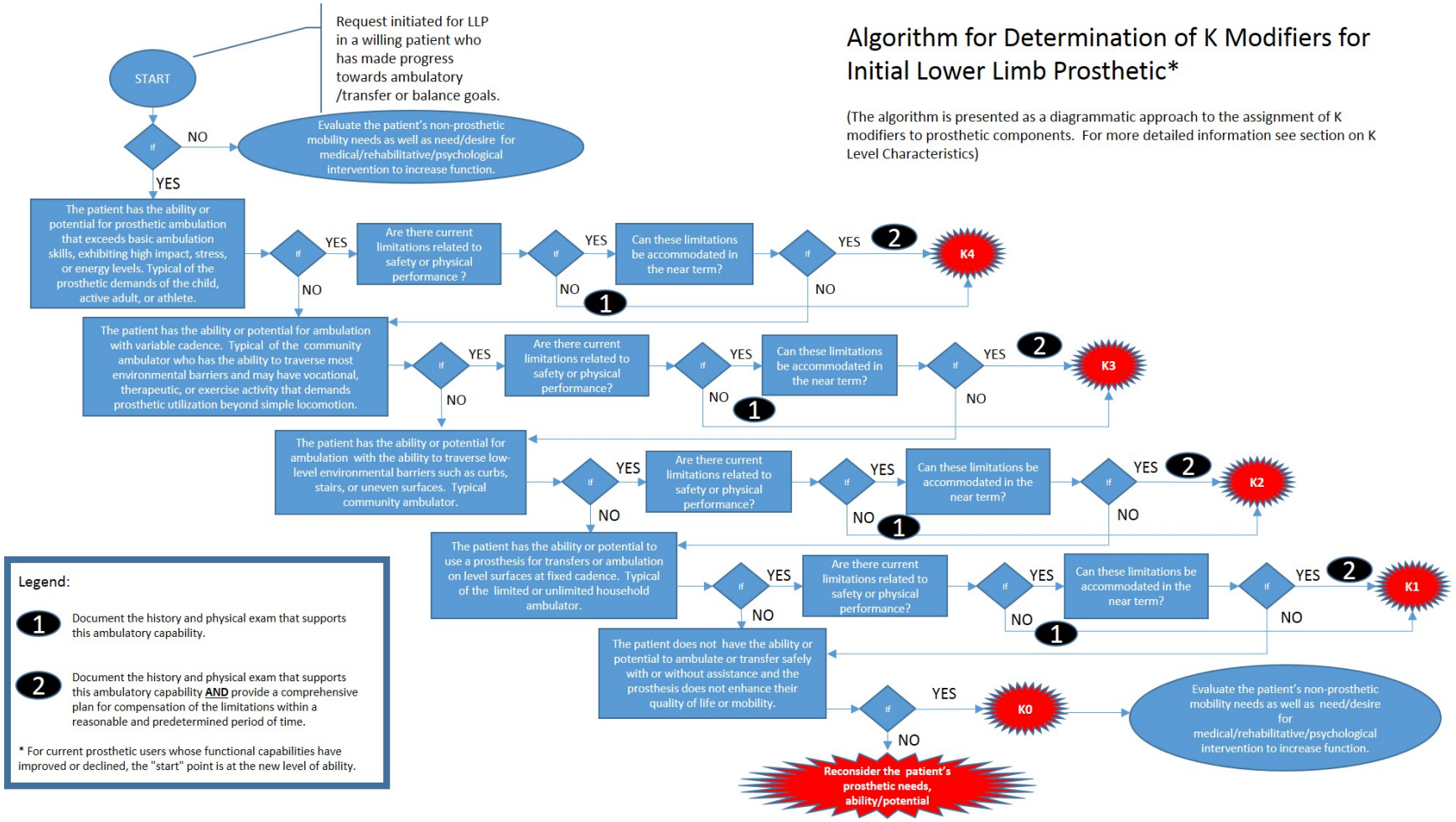

Figure 1. Algorithm for Determination of K Modifiers for Initial Lower Limb Prosthetic

Appendix C. HCPCS Codes

Table 1. HCPCS Codes

HCPCS Code	HCPCS Code Description
L5500	Initial, below knee 'ptb' type socket, non-alignable system, pylon, no cover, sach foot, plaster socket, direct formed
L5505	Initial, above knee - knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, sach foot, plaster socket, direct formed
L5510	Preparatory, below knee 'ptb' type socket, non-alignable system, pylon, no cover, sach foot, plaster socket, molded to model
L5520	Preparatory, below knee 'ptb' type socket, non-alignable system, pylon, no cover, sach foot, thermoplastic or equal, direct formed
L5530	Preparatory, below knee 'ptb' type socket, non-alignable system, pylon, no cover, sach foot, thermoplastic or equal, molded to model
L5535	Preparatory, below knee 'ptb' type socket, non-alignable system, no cover, sach foot, prefabricated, adjustable open end socket
L5540	Preparatory, below knee 'ptb' type socket, non-alignable system, pylon, no cover, sach foot, laminated socket, molded to model
L5560	Preparatory, above knee- knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, sach foot, plaster socket, molded to model
L5570	Preparatory, above knee - knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, sach foot, thermoplastic or equal, direct formed
L5580	Preparatory, above knee - knee disarticulation ischial level socket, non-alignable system, pylon, no cover, sach foot, thermoplastic or equal, molded to model
L5585	Preparatory, above knee - knee disarticulation, ischial level socket, non-alignable system, pylon, no cover, sach foot, prefabricated adjustable open end socket
L5590	Preparatory, above knee - knee disarticulation ischial level socket, non-alignable system, pylon no cover, sach foot, laminated socket, molded to model
L5595	Preparatory, hip disarticulation-hemipelvectomy, pylon, no cover, sach foot, thermoplastic or equal, molded to patient model
L5600	Preparatory, hip disarticulation-hemipelvectomy, pylon, no cover, sach foot, laminated socket, molded to patient model
L5654	Addition to lower extremity, socket insert, symes, (kemblo, pelite, aliplast, plastazote or equal)
L5655	Addition to lower extremity, socket insert, below knee (kemblo, pelite, aliplast, plastazote or equal)
L5656	Addition to lower extremity, socket insert, knee disarticulation (kemblo, pelite, aliplast, plastazote or equal)
L5658	Addition to lower extremity, socket insert, above knee (kemblo, pelite, aliplast, plastazote or equal)
L5661	Addition to lower extremity, socket insert, multi-durometer symes
L5665	Addition to lower extremity, socket insert, multi-durometer, below knee
L5666	Addition to lower extremity, below knee, cuff suspension

HCPCS Code	HCPCS Code Description
L5668	Addition to lower extremity, below knee, molded distal cushion
L5670	Addition to lower extremity, below knee, molded supracondylar suspension ('pts' or similar)
L5671	Addition to lower extremity, below knee / above knee suspension locking mechanism (shuttle, lanyard or equal), excludes socket insert
L5672	Addition to lower extremity, below knee, removable medial brim suspension
L5673	Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism
L5676	Additions to lower extremity, below knee, knee joints, single axis, pair
L5677	Additions to lower extremity, below knee, knee joints, polycentric, pair
L5678	Additions to lower extremity, below knee, joint covers, pair
L5679	Addition to lower extremity, below knee/above knee, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism
L5680	Addition to lower extremity, below knee, thigh lacer, non-molded
L5681	Addition to lower extremity, below knee/above knee, custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code l5673 or l5679)
L5682	Addition to lower extremity, below knee, thigh lacer, gluteal/ischial, molded
L5683	Addition to lower extremity, below knee/above knee, custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code l5673 or l5679)

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