Clinical Review Criteria
Lower Limb Prosthesis

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc., provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. Member contracts differ in their benefits. Always consult the patient's Medical Coverage Agreement or call Kaiser Permanente Customer Service to determine coverage for a specific medical service.

Criteria
For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
</tr>
<tr>
<td>National Coverage Determinations (NCD)</td>
<td>None</td>
</tr>
<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>Lower Limb Prosthesis (L33787)</td>
</tr>
<tr>
<td>Local Coverage Article</td>
<td>Lower Limb Prostheses - Policy Article - Effective October 2015 (A52496)</td>
</tr>
</tbody>
</table>

For Non-Medicare Members
Kaiser Permanente has elected to use the Lower Limb Prosthesis (KP-0487) MCG* for medical necessity determinations.

*MCG manuals are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
A large number of lower limb prosthetic designs are now available. The choice of the most appropriate prosthetic depends on factors such as amputation level, height, weight, and activity level of the amputee. Prosthetics fall mainly under two broad functional groups: non-microprocessor controlled prosthetics and microprocessor controlled prosthetics. The normal gait cycle is comprised of the stance phase, the period when the leg is on the ground, and the swing phase, the period when the leg is off the ground. Non-microprocessor controlled prosthetics incorporate friction, pneumatic, or hydraulics in the joint to control the swing and stance phases of gait. While they have helped amputees gain mobility these prosthetics have limitations. Prosthetics that utilize friction to control the swing phase can only be adjusted for one walking speed. Pneumatic and hydraulics prosthetics allow amputees to change their walking speed; however, these prosthetics do not incorporate adaptive stance phase control. The lack of adaptive stance phase control requires the amputee to lock the knee mechanism in full extension during stance to avoid buckling. The limitations of the non-microprocessor controlled prosthetics result in gait asymmetries which may contribute to problems such as increased energy expenditure and secondary disabilities.

Microprocessor-controlled prosthetics incorporate sensors that measure angles and movement every 20 millisecond and alter the damping of the hydraulic unit for each phase of gait. This technology is intended to normalize the swing and stance phase of gait over a wide range of walking speeds. Potential benefits of this technology include: decreased effort in walking, improved gait symmetry, reduced need for muscular compensation on the contralateral limb, fewer falls, and more stable gait on uneven terrain, ramps, inclines, and stairs (Berry 2009, Segal 2006).
C-leg® is a microprocessor-controlled knee joint system with hydraulic stance and swing phase control. In 1999, C-Leg® (Otto Block Healthcare, Duderstadt, Germany) received FDA approval.

Medical Technology Assessment Committee (MTAC)
Lower Limb Prosthesis
08/11/2004: MTAC REVIEW
**Evidence Conclusion:** The few studies published in peer-reviewed journals, included a small number of selected active participants, and do not provide sufficient evidence on effectiveness of the microprocessor-controlled lower limb prosthesis.

**Articles:** The search yielded 32 articles. The majority dealt with the technical aspects and mechanisms of action of the prostheses. The search did not reveal any randomized controlled trials. There was a pilot study (N=10) that compared the cognitive demand of walking using the intelligent prosthesis with the conventional damped knees. Another open crossover study of six amputees that compared the gait symmetry, energy expenditure, and patient impressions of the intelligent prosthesis to the standard pneumatic swing-phase control knee was also identified. The other reports/studies revealed by the search were small descriptive case series with less than 25 participants. None of the articles was selected for critical appraisal.

The use of microprocessor-controlled lower limb prostheses in the treatment of lower limb amputation does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

08/07/2006: MTAC REVIEW
Lower Limb Prosthesis
**Evidence Conclusion:** The few studies published in peer-reviewed journals, included small numbers of participants, and do not provide sufficient evidence to determine the effectiveness and benefit of the microprocessor-controlled lower limb prosthesis.

**Articles:** The search yielded 43 articles. The majority dealt with the technical aspects and mechanisms of action of the prostheses. The search identified one recent (Klute 2006)* small randomized controlled that compared the functional mobility and daily activity level of microprocessor-controlled hydraulic knee vs. the nonmicroprocessor hydraulic knee. Eighteen transfemoral amputees agreed to enroll in the study, but the majority withdrew before randomization. Eight amputees were randomized, and only five completed the trial. The other reports/studies revealed by the search were small comparative non-randomized studies or case series with less than 10 participants each. None of the articles were selected for critical appraisal.

The use of microprocessor-controlled lower limb prostheses in the treatment of lower limb amputation does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

10/18/2010: MTAC REVIEW
Lower Limb Prostheses
**Evidence Conclusion:** *Energy expenditure* - Two studies investigated the use of microprocessor-controlled prosthetics and non-microprocessor controlled prosthetics with respect to energy expenditure. Both studies used a non-randomized, non-blinded cross-over design. The first study found no significant difference in energy efficiency; however, there was an increase in physical activity related energy expenditure when subjects used the microprocessor-controlled prosthetic (Kaufman 2008). The second study compared energy expenditure at self-selected typical and fast walking paces on a motorized treadmill. There was no significant difference in heart rate at either pace; however, when subjects used the microprocessor-controlled prosthetic there was a small, but statistically significant decrease in energy expenditure (Seymour 2007). *Walking speed and dynamics* - Seymour and colleagues also found that on a standardized walking obstacle course when subjects wore the microprocessor-controlled prosthetic they were significantly faster, took less steps, and had less step-offs than when they used the non-microprocessor controlled prosthetic (Seymour 2007). Another study found that when subjects wore the microprocessor-controlled prosthetic walking speeds on a variety of surfaces improved and self-reported falls and stumbles decreased (Kahle 2008). Significant improvements in stair decent, hill decent time, hill affected side step length, and falls/stumbles were also found when subjects used a microprocessor-controlled prosthetic compared to when they used a mechanical prosthetic (Hafner 2007). Additionally, after receiving the microprocessor-controlled limb, subjects demonstrated significant improvements in gait and balance (Kaufman 2007). *Preference* - In a survey of 368 amputees, the majority of participants reported improvements with the microprocessor-controlled prosthetic compared to the non-microprocessor controlled prosthetic with regard to comfort, security, maneuverability, cosmetic attributes, adverse events, and safety (Berry 2009). The prosthesis evaluation questionnaire (PEQ) measures subjective prosthesis function and prosthesis-related quality of life.
Three studies found improvement in PEQ scores when subjects used the microprocessor-controlled prosthetic (Hafner 2007, Kahle 2008, Kaufman 2008).

Conclusion: As the majority of the published studies to date are small and non-randomized it is hard to draw firm conclusions regarding the superiority of microprocessor-controlled prosthetics compared to non-microprocessor controlled prosthetics; however, results from the above studies suggest that the microprocessor-controlled prosthetics decreased energy expenditure, improved walking speed and dynamics, and improved PEQ scores.


The use of microprocessor-controlled lower limb prostheses in the treatment of lower limb amputation does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*


The use of microprocessor-controlled lower limb prostheses in the treatment of lower limb amputation does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*