CALIFORNIA TECHNOLOGY ASSESSMENT FORUM®

MICROPROCESSOR-CONTROLLED PROSTHETIC KNEES

A Technology Assessment

INTRODUCTION

The California Technology Assessment Forum is requested to review the scientific evidence for the use of microprocessor-controlled prosthetic knees for individuals with trans-femoral amputations.

BACKGROUND

Artificial limbs date back at least as far as 300 BCE to an iron leg found in a tomb in Italy. Iron limbs continued to be used in the 15th and 16th centuries, progressing to use of wooden limbs in subsequent centuries[1, 2]. Throughout history, injuries from military wars have led to amputation, and in parallel, to increasing development of technology to create lighter weight and more functional prostheses[3]. In developing countries, most amputations result from trauma, while amputation rates in developed countries have traditionally been closely associated with circulatory/vascular dysfunction. For individuals with amputations due to vascular reasons, walking is often limited by co-morbidities, and thus access to a prosthesis with more advanced function is not as urgent a concern[4]. However, recent wars have led to increasing rates of amputation due to trauma, with an amputation rate among combatants with orthopedic injuries in recent US military conflicts (prior to the current Iraq war) from 14% to 19%[5]. Individuals with amputations secondary to trauma tend to be younger and more active than their counterparts with vascular disease; thus, a prosthetic limb with more functional capacity that allows for an active lifestyle is of high priority for these patients[3, 4].

Until the 1980’s, options for patients with a trans-femoral (thigh) amputation were limited to prostheses requiring them to hold their prosthetic knee in full extension throughout most of the stance phase in walking, thus providing little to no shock absorption and limiting mobility[4]. It is through flexion in the early stance phase of the gait cycle that the biological knee provides shock absorption. Since the late 1980’s an increasing number of knee prostheses offer a “stance flexion feature”, which allows the artificial knee to engage a friction brake as the amputee bears weight, stabilizing the knee and allowing a small rubber component enough motion to function as a shock absorber and simulate biologic knee flexion[4]. In the early 1990’s the Intelligent Prosthesis (IP) was introduced. This prosthetic knee utilizes an on-board computer to improve the swing phase of the gait cycle through adjustment to a wide range of walking speeds. Since that time, the same company has introduced the IP+, the Smart IP, and the Adaptive – all of which use microprocessor control in the knee to adjust to swing phases of the gait cycle[6]. The C-Leg knee, introduced in 1999, provides microprocessor control to both swing and stance phases, offering symmetry in the swing phase with more stability in the stance phase via almost continuous input from the microprocessor sensors to adjust resistance to the hydraulic damper[4, 7]. The Rheo Knee is a swing and stance phase system which uses a microprocessor as well as artificial intelligence to 'learn' about the amputee's walking characteristics over time[8]. All of the microprocessor-controlled knees require fitting, programming, and rehabilitative training for the individual user. All of these prostheses are considerably more expensive than more traditional hydraulic knees providing stance flexion only. The potential benefits of microprocessor-controlled knees are increased ability to walk on uneven terrain, up and down stairs and hills, with fewer stumbles and falls, more confidence and more comfort.

TECHNOLOGY ASSESSMENT (TA)

TA Criterion 1: The technology must have final approval from the appropriate government regulatory bodies.

There are several microprocessor-controlled knees available on the market. All of these devices are considered 510(k) exempt by the FDA. If a manufacturer's device falls into a generic category of exempted class I devices, a premarket notification application and FDA clearance is not required before marketing the device in the U.S. The C-Leg (Otto Bock Orthopedic Industry, Inc., Minneapolis, MN), the Rheo Knee (Ossur Americas, Aliso Viejo, CA) and the IP line of prostheses (Endolite North America, Centerville, OH) are all class I 510(k) exempt devices

TA Criterion 1 is met.

TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.

The Medline database, Cochrane clinical trials database, Cochrane reviews database and the Database of Abstracts of Reviews of Effects (DARE) were searched using the key words 'microprocessor prosthetic knee', cross-referenced with the keyword 'amput*'. The search was performed for the period from 1966 to September 2007, and was limited to the English language. The bibliographies of systematic reviews and key articles were manually searched for additional references. The abstracts of citations were reviewed for relevance and all potentially relevant articles were reviewed in full. Only publications which compared a microprocessor-controlled knee to another prosthetic knee, and reported on more than a single subject were included in this review. We found 13 such studies published from 1997-2007 [9-21]. Four of these evaluated the IP, one evaluated the Rheo Knee, and the remainder studied the C-Leg. (Table 1) All of these studies are crossover designs in which the participant's performance using the microprocessor-controlled knee is compared to his/her performance using a non-microprocessor-controlled knee (NMC). A few studies randomized the order in which the participant wore the prostheses, but most followed a pre-determined order, usually with the NMC being worn first. Very few studies blinded the researchers measuring performance to the type of prosthesis being worn. The earlier studies did not provide much time for the participants to acclimate to the new microprocessor-controlled knee, while the more recent studies generally had a period of acclimation. All of the studies except three [12,15,21] included otherwise healthy, unlimited community ambulators adults (primarily men) with unilateral trans-femoral amputations for non-vascular reasons, who were already accustomed to wearing and using an NMC prosthetic knee. The studies with medically compromised participants included subjects that were limited community ambulators (K-Level 2)[12], older dysvascular Veterans[15], and a K3-K4 ambulating group of trauma, cancer, vascular disease and congenital defect subjects[21].

Level of Evidence: 2, 3

TA Criterion 2 is met.

Inclusion criteria – peer reviewed publication, more than a single case, comparison to a mechanical prosthesis or to another microprocessor controlled prosthesis.

Table 1. Studies published in English-language peer-reviewed journals comparing a microprocessor-controlled prosthetic knee to another prosthetic knee.

Study (author year)	Participants	Study Design	Microprocessor Controlled Prosthesis / Comparison Group	Outcome
Kaufman 2007	K3-K4 unlimited community ambulating adults with unilateral trans-femoral amputation due to trauma, cancer, vascular disease and congenital defects, 2-year post amputation with current use of NMC* prosthesis N=15 N=15 analyzed	Non-randomized, non-blinded crossover design	C-Leg / NMC (Mauch SNS)	Gait analysis Balance
Seymour 2007	K3-K4 unlimited community ambulating adults with unilateral trans-femoral amputation due to non-vascular cause, already using the C-leg, and with past use of NMC* prosthesis N=13 3 incomplete data N=10 analyzed	Non-randomized, non-blinded crossover design	C-Leg / Any NMC prosthesis (patient's own prosthesis)	Energy expenditure Obstacle course performance
Hafner 2007	K2-K3 community ambulating adults with unilateral trans-femoral amputation, 2-year minimum use of NMC prosthesis prior to enrollment N=21 recruited 4 dropped out N=17 analyzed	Non-randomized, non-blinded controlled reversal design A-B-A-B (condition A = NMC, condition B = C-Leg)	C-Leg / Any NMC prosthesis (patient's own prosthesis)	Daily step frequency / daily distance Stair ascent and descent function Hill descent time Level and hill affected & sound-side step length Cognitive demand while walking Self-reported frequency of stumbles and falls Frustration with falling Self-reported difficulty multi-tasking Satisfaction with prosthesis

Chin 2006	Healthy, active young adults with unilateral trans-femoral amputation for trauma N=4	Non-randomized, non-blinded crossover design comparing two microprocessor-controlled prosthetic knees	Intelligent Knee Prosthesis (IP) compared to the C-Leg	Walking speed Energy consumption at variable walking speeds
Williams 2006	Active US Veteran adults with unilateral trans-femoral amputation, long-term users of NMC N=18 recruited 10 dropped out N=8 analyzed	Randomized crossover design (non-blinded)	C-Leg / NMC (Mauch SNS)	Cognitive performance --verbal fluency --Attention and working memory --Walking speed during cognitive tasks Perceived cognitive burden
Klute 2006	Older dysvascular US Veteran adults with unilateral trans-femoral amputation, long-term users of NMC N=5 (5 of the 8 participants in the Williams study above; 3 excluded for not wearing study prosthesis for duration of protocol)	Randomized crossover design (non-blinded)	C-Leg / NMC (Mauch SNS)	Level of activity (steps/day) Duration of activity (minutes/day)
Segal 2006	Active US Veteran adults with unilateral trans-femoral amputation, long-term successful use of NMC N= 12 recruited 4 dropped out N=8 analyzed	Randomized crossover design (non-blinded)	C-Leg / NMC (Mauch SNS)	Step length and Walking speed at Controlled Walking Speed (CWS) and Self-Selected Walking Speed (SSWS)
Orendurff 2006	Active US Veteran adults with unilateral trans-femoral amputation, long-term successful use of NMC N= 18 recruited 10 dropped out N=8 analyzed (apparently same 8 as in Segal 2006 study)	Randomized crossover design (non-blinded)	C-Leg / NMC (Mauch SNS)	Energy expenditure at various controlled walking speeds, and at self-selected walking speed.

Datta 2005	Healthy, active adults with unilateral trans-femoral amputation due to non-vascular cause, long-term successful use of NMC N=10 (same participants as in Heller 2000 study)	Non-randomized crossover design; single-blind gait analysis	Intelligent Prosthesis / Any NMC prosthesis (patient's own prosthesis)	Energy consumption Gait evaluation
Johansson 2005	Healthy, active adults with unilateral trans-femoral amputation due to non-vascular cause, long-term successful use of any prosthesis N=8	Non-randomized, non-blinded crossover design	C-Leg , Ossur Rheo / NMC (Mauch SNS)	Energy expenditure Affected-side walking dynamics --Walking speed --Step time --Step length Sound-side walking dynamics --Walking speed --Step time --Step length
Schmalz 2002	Healthy, active adults with unilateral trans-femoral amputation due to non-vascular cause, long-term successful use of NMC N=12 N=6 analyzed (unclear why half not-analyzed)	Non-randomized crossover design	C-Leg / NMC (3C1)	Energy expenditure
Heller 2000	Healthy, active adults with unilateral trans-femoral amputation due to non-vascular cause, long-term successful use of NMC N= 10	Non-randomized crossover design	Intelligent Prosthesis / Any NMC prosthesis (patient's own prosthesis)	Gait quality measured by sway Ratio of sway for complex distracting task over simple distracting task = automation index
Buckley 1997	Healthy, active adults with unilateral trans-femoral amputation due to non-vascular cause, long-term successful use of NMC N= 3	Non-randomized crossover design	Intelligent Prosthesis / NMC	Energy expenditure

*NMC = non-microprocessor control prosthesis

TA Criterion 3: The technology must improve net health outcomes.

Energy Expenditure

A number of studies focus on energy expenditure, usually measured as oxygen consumption. The majority of these demonstrate a small, but statistically significant decrease in energy expenditure using the microprocessor-controlled prosthesis as compared to an NMC[9, 11, 14, 17, 19]. There was, however, some variation in which walking speeds showed a significant difference. (Table 2) One study which showed no difference in energy expenditure noted that self-selected walking speeds were higher when using the C-Leg microprocessor-controlled prosthesis, and the fact that participants used the same amount of energy to achieve these speeds implies that there was an increase in energy efficiency with the C-Leg[16]. Two studies comparing two different microprocessor-controlled prostheses (IP versus C-Leg and Rheo versus C-Leg) found no differences in energy expenditure [10, 14]. However, it is unclear how energy expenditure, which is at best an intermediate marker, actually impacts on either functional outcomes or net health outcomes. None of the studies assessed energy expenditure as a predictor of a functional health outcome, perhaps because all of the included studies had a very small number of participants.

Table 2. Results of peer-reviewed, English-language published comparison studies of microprocessor-controlled knees.

Study (author year)	Outcomes Examined	Results
Kaufman 2007	Knee flexion and moment during initial part of stance phase Balance and equilibrium measured by dynamic posturography sensory organization tasks (SOT)	C-Leg with internal knee extension moment (more normal loading response) compared to NMC internal flexion moment (p<.01) Higher scores on all SOT indicating improved equilibrium with C-Leg (P<.01)
Seymour 2007	Oxygen Consumption Obstacle course performance Quality of Life (SF-36v2) – compared to national norms	Oxygen Consumption (ml/kg/min) C-Leg / NMC Prosthesis / p-value Typical Pace: 12.6 ± 1 / 13.5 ± 2 / .04 Fast Pace: 16.0 ± 2 / 17.2 ± 2 / .03 Standardized Walking Obstacle Course C-Leg / NMC Prosthesis / p-value Hands Free # of steps: 15.6 ± 2.9 / 17.0 ± 3.1 / .0004 Time (sec): 11.5 ± 2.4 / 12.7 ± 2.4 / .0004 Step-offs: 0.2 ± 0.3 / 0.5 ± 0.4 / .03 Carrying 10lb basket # of steps: 15.6 ± 2.9 / 18.2 ± 4.6 / .08 Time (sec): 11.5 ± 2.4 / 15.6 ± 3.7 / .007 Step-offs: 0.3 ± 0.4 / 0.4 ± 0.5 / .67
Hafner 2007	Daily step frequency / daily distance Stair ascent and descent function Hill descent time Level and hill affected & sound-side step length Cognitive demand while walking Self-reported frequency of stumbles and falls Frustration with falling Self-reported difficulty multi-tasking Satisfaction with prosthesis	No difference in daily step frequency or distance No difference in step length on level ground (affected and sound-side) No difference in stair ascent function Improved stair descent function with C-Leg (p<.001) Increased affected side step length on hill with C-Leg (p<.001) so that it approximated sound side step length. Decrease hill descent time with C-Leg (p<.01) No difference in walking speed or test accuracy for cognitive demand test Fewer reported stumbles and falls with C-Leg (p<.05) Lower frustration with falling and less difficulty multi-tasking while walking with C-Leg (p<.05) Higher satisfaction with C-Leg (p<.001)
Chin 2006	Walking speed Energy consumption at variable walking speeds	No difference between IP and C-Leg for either walking speed or oxygen consumption while walking.

Williams 2006	Cognitive performance --verbal fluency --Attention and working memory --Walking speed with cognitive tasks Perceived cognitive burden	No significant difference in objective cognitive performance measures. C-Leg experienced as less of a cognitive burden (p<.001).
Klute 2006	Level of activity (steps / day) Duration of activity (minutes / day)	No significant difference in either level or duration of activity.
Segal 2006	Step length and speed of Self-Selected Walking Speed (SSWS)	At controlled walking speed, step length was more symmetric for the C-Leg (p<.01). Self-selected walking speed was faster for the C-Leg (p=.003)
Orendurff 2006	Energy expenditure at various controlled walking speeds, and at self-selected walking speed.	No difference in oxygen consumption at any controlled walking speeds. Faster self-selected walking speed with C-Leg (p=.046), but same energy expenditure (p=.19).
Datta 2005	Energy expenditure Gait evaluation	Decreased oxygen consumption with C-Leg at the slowest controlled speeds (p<.05) No difference in video observed gait evaluation.
Johansson 2005	Energy expenditure Walking speed Affected-side walking dynamics --Step time --Step length Sound-side walking dynamics --Step time --Step length	Oxygen consumption 5% lower for Ossur Rheo compared to NMC (p=.009). No difference in walking speed among three prostheses. Affected-side: Faster step time (seconds) for Rheo compared to NMC (p=.04) and C-Leg (p=.007). No differences in step length. Sound-side: No difference in step time or step length.
Schmalz 2002	Energy expenditure	Oxygen consumption 6-7% lower at medium and low self-selected walking speeds (p<.05); no difference at higher self-selected walking speeds.
Heller 2000	Gait quality measured by sway Ratio of sway for complex distracting task over simple distracting task = automation index	Less sway with IP for both simple and complex tasks (p<.05). No difference in sway ratio.
Buckley 1997	Energy expenditure	No difference in oxygen consumption at normal walking pace. At faster / slower pace decreased oxygen consumption with IP for two of three participants.

Walking Speed / Walking Dynamics

Many of the studies assessed self-selected walking speed and all except for one found that participants walked more quickly with the microprocessor-controlled prosthesis compared to the NMC[10, 14, 16, 19]. The two studies comparing different microprocessor-controlled prostheses found no difference in walking speed [10, 14]. Most recently, Seymour et al found that, when wearing a microprocessor-controlled prosthesis, participants walked faster along an obstacle course - with and without carrying a ten pound laundry basket[19]. When wearing a microprocessor-controlled prosthesis, participants also swayed less[13], had more symmetric step-length with their unaffected leg when walking on hills[12], had fewer step-offs when walking on an obstacle course with free hands, and took fewer steps to traverse an obstacle course with free hands and while carrying a ten pound laundry basket[19]. One study comparing types of microprocessor-controlled prostheses found that step-time was faster with the Rheo than with the C-Leg [14]. Again, except perhaps for the obstacle course results, it is difficult to know how these walking dynamics translate into functional outcomes. In fact, one study which blinded a team of experts to type of prosthesis and had them analyze differences in gait found no difference between the IP and NMC[11]. It is inferred by many of the study authors, though, that these results mean that the microprocessor-controlled prosthesis confers a higher level of function with fewer falls and more ability to traverse complex terrain.

Gait Analysis

Several studies utilized gait analysis to evaluate differences in the lower limb biomechanics between microprocessor-controlled and NMC prostheses [14, 18, 21]. Two studies demonstrated that patients significantly improved their gait biomechanics when using a microprocessor-controlled knee as compared to a NMC knee [14, 21]. In a newly published study [21], subjects were tested in a NMC knee and had to secure the knee by actively contracting the hip extensors to ‘‘pull back’’ and force the prosthetic knee into extension to prevent the NMC knee from buckling. In contrast, the microprocessor-controlled knee allowed subjects to place more demand on the knee, as measured by an increase in the internal knee extension movement. The microprocessor-controlled knee adjusted the knee flexion resistance in real-time, to provide knee flexion during initial stance for increasing the resistance to prevent the knee from collapsing. These automatic adjustments provided a more natural gait and allowed a smoother trajectory of the body center of mass which should result in improved walking efficiency. These gait changes were statistically significant ($p < 0.01$). In the same study, balance improved significantly when using the microprocessor-controlled knee ($p < 0.01$). All six conditions of a sensory organization test demonstrated improvements in equilibrium score. The composite score also was significantly improved.

The literature has been contradictory regarding the gait characteristics of transfemoral amputees using microprocessor-controlled knee prosthesis. One study demonstrated minimal differences in gait biomechanics between microprocessor-controlled and NMC knees [18].

Functional Outcomes

Few of the studies report on functional outcomes; those that do, while not without limitations, present positive results for improved function with use of a microprocessor-controlled prosthesis. As noted above, Seymour et al conducted observations of participants ability to traverse an obstacle course meant to replicate walking tasks that they would encounter in real-life[19]. Participants were able to complete the obstacle course faster, with few steps and with fewer step-offs from the course while wearing the C-Leg. These results were retained when the participants carried a ten pound laundry basket while walking the course, except the difference in step-offs from the course was no longer significant. This study had some significant limitations. Similar to all of the included studies, there were only a small number of participants, limiting their ability to measure characteristics of participants predicting the most benefit when wearing a microprocessor-controlled prosthesis. The investigators did not randomize the order in which the participants wore the two different prostheses, nor were they blinded to the prosthesis being worn. When they analyzed the data, they did not conduct an analysis that accounted for the fact that each participant traversed the obstacle course multiple times while wearing each prosthesis (repeated-measure analysis). Despite these limitations, the functional results of this study are promising.

Hafner et al also assessed functional outcomes[12]. These investigators found improved function on both stair descent and hill descent with the C-Leg. In addition, the participants reported fewer falls and stumbles as well as less frustration with falls and higher overall satisfaction with the C-Leg compared to their NMC. However, neither this study nor another which examined cognitive function[20], found any difference between the two prostheses in performance on a cognitive test while walking. The Hafner study suffers from some of the same limitations as the Seymour study. While it is the largest study of the group, it is still quite small. The investigators chose not to randomize the order of prosthesis evaluation, explaining that they wanted to replicate clinical practice in which patients usually have used an NMC for many years and then switch to a microprocessor-controlled prosthesis. Like the Seymour study, the investigators were not blinded to the type of prosthesis being worn during a given test, possibly introducing bias to the results. However, their analysis was appropriate for their repeated-measures design.

Kaufman et al assessed functional outcomes and found improved function in gait biomechanics and validated balance measures [21]. Balance was objectively tested using a computerized dynamic posturography moveable dual force platform that can translate or rotate along with a moveable visual surround. The Sensory Organization Test (SOT) was used to assess the three sensory components of balance (visual, somatosensory, and vestibular inputs) under a variety of altered visual and surface support conditions. The Kaufman study is also small and the investigators did not randomize the order of the prosthesis evaluation presumably because all subjects were previously NMC knee users.

Despite the limitations cited above, use of a microprocessor-controlled prosthetic knee does appear to improve both intermediate markers and functional outcomes for the select group of patients which has been studied. Although three microprocessor-controlled knees have been studied (IP, Rheo, C-Leg), the only one to be studied for actual functional outcomes is the C-Leg. The other two appear to be equivalent to the C-Leg in the few intermediate markers studied – energy expenditure and walking dynamics – but their equivalence in gait analysis, balance, obstacle course and cognitive demand functional outcomes has not been published.

TA Criterion 3 is met.

TA Criterion 4: The technology must be as beneficial as any established alternatives.

The primary established alternative to a microprocessor-controlled prosthetic knee is usually a hydraulic NMC. All of the studies included in this review except one[10], which compared two microprocessor-controlled prostheses, had an NMC as their comparison group. Some studies compared to a single NMC (the Mauch SNS), while others compared to whichever NMC the participant was already fitted for and using prior to the study. All participants in the studies had already worn an NMC for an extended period of time, and were accustomed to walking with a prosthetic knee. Thus the positive intermediate and functional outcomes described show benefit over the established alternative of commercially available NMC prosthetic knees.

TA Criterion 4 is met.

TA Criterion 5: The improvement must be attainable outside of the investigational setting.

The vast majority of the cited studies took place in clinical settings. In addition, particularly for the more recent studies which required the participants to acclimate to their prosthesis over an extended period of time[12, 15, 20, 21], participants used their prostheses in the course of their everyday lives before having them evaluated by the investigators. Use of a microprocessor-controlled prosthetic knee does, however, require that the prosthetist be trained in fitting and setting that particular knee as well as in training the patient to use the knee, which takes weeks of rehabilitation and teaching. Training for prosthetists is available from the companies selling the microprocessor-controlled knees[6-8].

TA Criterion 5 is met.

CONCLUSION

The majority of published studies to date examined intermediate outcomes, while three studies have focused on actual functional outcomes. The bulk of all of these studies show improvement in outcomes when the microprocessor-controlled knee is used as compared to a more traditional NMC. While it is unclear how some of the intermediate outcomes impact on clinical or functional outcomes, the functional outcomes of improved gait biomechanics, improved balance, few falls, improved performance on an obstacle course and going down stairs and hills, as well as fewer self-reported falls have obvious benefit for the prosthetic users. None of the studies are without flaws; however, the bulk of the evidence is in favor of the studied microprocessor-controlled prosthetic knees for the populations enrolled. Thus, it appears that healthy, active adults with a trans-femoral amputation for a non-vascular cause (usually trauma or tumor) derive functional benefit from wearing a microprocessor-controlled knee. In addition, K2-K4 limited and unlimited community ambulators, appear to derive functional benefit from wearing a microprocessor-controlled knee. However, the only adequately studied knee is the C-Leg.

There are, of course, questions remaining about the C-leg. Many of the studies attempted to enroll more individuals, but some of their enrollees either could not be fit with the prosthesis or could not adapt to it. It is unclear whether there are particular predictors of who these people might be – is it something to do with the interface between stump and socket, or are there other important predictors? All of the studies were of individuals who were long-term users of an NMC previously; is there a population who should be offered a microprocessor-controlled prosthetic knee as their initial prosthesis? Most of the studies enrolled active adults, and only a few enrolled moderately active or older dysvascular adults – is there a group of moderately active adults whose activity level would improve even more with this technology? Perhaps the investigators would have seen even greater differences if they had studied somewhat less active individuals with the potential for enhanced mobility with a more responsive prosthesis.

RECOMMENDATION

It is recommended that use of a C-Leg microprocessor-controlled prosthetic knee in otherwise healthy, active K3-K4 community ambulating adults with a trans-femoral amputation from a non-vascular cause for whom this prosthesis can be fit and programmed by a qualified prosthetist trained to do so, meets CTAF criteria 1-5 for safety, effectiveness and improvement in health outcomes.

The California Technology Assessment Forum voted unanimously in favor of the recommendation.

October 17, 2007

RECOMMENDATIONS OF OTHERS

BLUE CROSS AND BLUE SHIELD ASSOCIATION (BCBSA)

The BCBSA Technology Evaluation Center has not conducted a review of this technology.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The carrier for CMS in the state of California considers the use of microprocessor-controlled prosthetic knees as reasonable and necessary for patients whose functional Level of 3 or better. A functional Level 3 has the ability or potential for ambulation with variable cadence. Typical of the community ambulatory who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.

VA TECHNOLOGY ASSESSMENT PROGRAM

A review of the published literature was conducted by the Management Decision and Research Center and published in March 2000. This report is available at: http://www.va.gov/vatap/pubs/ta_short_3_00.pdf.

CALIFORNIA SOCIETY OF PHYSICAL MEDICINE AND REHABILITATION (CSPMR)

The CSPMR was invited to provide an opinion regarding this technology and to provide representation to the meeting.

CALIFORNIA ORTHOPAEDIC ASSOCIATION (COA)

The COA was invited to provide an opinion regarding this technology and to provide representation to the meeting.

SOUTHWEST REGIONAL CHAPTER AMERICAN ACADEMY OF ORTHOTISTS AND PROSTHETISTS (SWC AAOP)

The SWC AAOP was invited to provide an opinion regarding this technology and to provide representation to the meeting.

ABBREVIATIONS USED IN THIS REVIEW

IP	Intelligent Prosthesis
DARE	Database of Abstracts of Reviews of Effects
NMC	Non-microprocessor-controlled knee
SOT	Sensory Organization Test

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