C-Leg® Microprocessor Knee Patient Evaluation Protocol

Introduction

On May 21st and 22nd, 2003, Walter Reed Army Medical Center hosted a forum to establish clinical protocols and procedures for microprocessor prosthetic knees in the treatment of individuals with a transfemoral amputation. Microprocessor knees were defined as those knees that provide microprocessor function in all aspects of gait, both stance and swing. This program was sponsored and funded by the American Academy of Orthotists and Prosthetists.

Forum participants were selected based upon their personal clinical experience in fitting, prescribing, evaluating and/or clinical research with the microprocessor knee component. Forum members were assigned a topic related to their specific experience and knowledge and prepared a 30-minute presentation for the forum. Each presentation concluded with specific recommendations with regard to the topic.

It was determined by the panel that an evaluation process and form is recommended to ensure clear, concise and uniform documentation for a microprocessor controlled knee component. The following form captures the essential information to ensure relative data is captured during the evaluation process and thus providing a consistent and uniform standard for determining the appropriate application of microprocessor controlled technology.

Page 2, Practitioner and Patient Information
- The top portion of the page is completed by the practitioner with general professional contact information.
- The lower 2/3 of the page in completed by the patient to provide personal, medical history and activates of daily living information.

Page 3, Prosthetics Activity & Comfort Assessment
- This page is completed by the patient to assess the function, comfort and stability of the present prosthesis.
- If the patient is a new amputee and does not presently have prosthesis, the page should be marked NA for Not Applicable.

Page 4, Functional and Gait Evaluation
- To be completed by the practitioner to identify the patients functional level and gait deviations.
- If the patient is a new amputee and does not presently have prosthesis, the gait deviation portion should be marked NA for Not Applicable.

Page 5, Prosthetic Component and Residual Limb Evaluation
- To be completed by the practitioner to assess the condition and status of select prosthetic components on the existing prosthesis, specifically, why does the present component require replacement.
- If the patient is a new amputee and does not presently have prosthesis, the prosthetic component evaluation portion should be marked NA for Not Applicable.

Page 6, Prosthetic Recommendations
- To be completed by the practitioner to identify the specific components required for the patient with specific rational as to how and why the recommended components will benefit the patient.

Page 7, Activities of Daily Living (ADL) Justification
- To be completed by the practitioner to identify how the recommended components will benefit and/or assist the patient in completing specific activities of daily living.

Page 8, Functional Requirements Verification
- To be completed by the practitioner to validate and verify that the patient meets criteria as determined by the US Veterans Administration.

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Practitioner Information

Primary Practitioner: _____ ☐CP ☐CPO ☐CO ☐BOCOP ☐_____

Administrators Name: _____

Address: _____

City, St Zip: _____

Phone #: _____

Fax #:

Patient Information

General Information

Name: _____ Social Security #: _____

Date of Birth: _____ Age: _____ Amputation side: ☐ Left ☐ Right ☐ Bilateral

Ht_____ Wt_____ Sex: ☐Male ☐Female Amputation length:

☐ Short ☐ Mid-thigh ☐ Long

Home Address: _____ ☐ Knee disarticulation ☐ Hip disarticulation

City, State, Zip: _____ Date of amputation: _____

Home Phone: _____ Cause of amputation: _____

Work Phone: _____ Age of current prosthesis:_____

Health Related Information

		Comments
Diabetes	☐No ☐ Yes	_____
Heart Condition	☐No ☐ Yes	_____
Lung Condition	☐No ☐ Yes	_____
High Blood Pressure	☐No ☐ Yes	_____
Joint Pain	☐No ☐ Yes	_____
Muscle Pain	☐No ☐ Yes	_____
Back Pain	☐No ☐ Yes	_____
Medication(s)	☐No ☐ Yes	_____

Other Injuries_____

Has your weight remained consistent for the past year? ☐Yes ☐ No _ Gained / Lost _____ *(please circle)*

Activities of Daily Living Information

Living Status ☐ Live Alone ☐ Live with Assistance

Living Conditions
- ☐ Level Surfaces
- ☐ Stairs
- ☐ Uneven Surfaces
  - ☐ Carpet
  - ☐ Gravel
  - ☐ Grass
- ☐ Ramps/Inclines

Profession _____

Normal Daily Activity % Seated _____% % Standing/Walking _____%

Activities of Daily Living Recreation Activities
- ☐ Bicycling
- ☐ Jogging/Running
- ☐ Sports
- ☐ Aerobics
- ☐ Other _____
- ☐ Other _____

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This page to be completed by Patient, for new amputees, please check box and proceed to page 4 ☐

Prosthesis Assessment

	Poor	*Fair*	*Good*	*Very Good*	*Excellent*	*Comments*
Ability of the knee to keep up with my walking speed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
Ease of standing up out of a chair	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
Ease of sitting down into a chair	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
My overall balance with the prosthesis	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
My confidence walking in large crowds	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
My confidence walking in unfamiliar places	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
My overall confidence using the prosthesis	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
My ability to walk at a slow speed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
My ability to walk at a fast pace	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
My ability to jog/run	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
My ability to change speeds while walking	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
My stability on uneven surfaces (rocks, gravel etc)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
My ability to walk down stairs step over step	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
Ability to walk down ramps, hills & slopes with confidence	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	

Activity & Comfort Assessment

	Always	**Often**	**Sometime**	**Seldom**	**Never**	**Comments**
I get tired at the end of the day	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
I have low back pain or discomfort	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
I have pain/discomfort in my hips	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
While standing, I am afraid the knee might buckle	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
My prosthesis holds me back from doing normal day-to-day activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
My prosthesis holds me back from doing special activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
My knee buckles while I am standing	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
My knee does not keep up with me when I walk fast	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
I fall while wearing my prosthesis	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
I avoid going up or down stairs	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
I avoid going up or down ramps	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
I use a hand rail when going down stairs and/or ramps	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
I have to stop for a rest when out in public	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
I use disabled/handicap parking spaces	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	
Walking in crowds makes me feel unstable	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	

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Functional Level Evaluation

Patient Name _____

Evaluation Performed By _____ **Date:** _____

ASSISTIVE DEVICES ☐ Walker ☐ Cane ☐ Crutches ☐ None

FUNCTIONAL ABILITIES

Patient able to transfer by self	☐ Yes	☐ No
Patient able to walk up and down stairs	☐ Yes	☐ No
Patient able to walk at variable cadence	☐ Yes	☐ No
Patient able to run and play recreational activities	☐ Yes	☐ No

FUNCTIONAL LEVEL

- ☐ 0 No ability or potential to ambulate or transfer
- ☐ 1 Ability or potential to transfer or ambulate on level surfaces at fixed cadence
- ☐ 2 Ability or potential to traverse low level environmental barriers
- ☐ 3 Ability or potential to ambulate with variable cadence
- ☐ 4 Ability or potential to ambulate which exceeds basic ambulating skills

Present Prosthesis ☐ Definitive ☐ Preparatory ☐ IPOP ☐ None, New Amputee*

For new Amputee Proceed to residual limb evaluation on page 4

Gait Evaluation

Gait Evaluation was performed by: ☐ Observational Assessment ☐ Instrumented Gait Lab Analysis

Prosthetic Length	☐ Short	☐ Long	☐ Correct
Comments			
ML Stability	☐ Lateral Shift	☐ Medial Shift	☐ Correct
Comments			
Step Length	☐ Short Pros. Step	☐ Long Pros. Step	☐ Correct
Comments			
Whip	☐ Lateral Whip	☐ Medial Whip	☐ Correct
Comments			

Gait Deviations				*Cause*
	Abducted Gait	☐ Yes	☐ No	_____
	Circumducted Gait	☐ Yes	☐ No	_____
	Vaulting	☐ Yes	☐ No	_____
	Lateral Trunk Bending	☐ Yes	☐ No	_____
	Knee Instability	☐ Yes	☐ No	_____

Other Injuries, Observations & Comments

_____

_____

_____

_____

_____

_____

_____

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Patient Name: _____

Prosthetic Component Evaluation

☐ **New Amputee**

For new Amputee Proceed to residual limb evaluation on page 4

Foot
Status of present foot
Present Foot is a _____
_____
_____

Knee
Status of present knee
Present Knee is a _____
_____
_____

Suspension
Status of present suspension
Present Suspension is _____
_____
_____

Socket Design
Status of present socket design
Present Socket is a_____
_____
_____

Liner/Insert
Status of present liner/insert
Present Liner/Insert is a_____
_____
_____

General Prosthetic Observations & Comments

_____
_____
_____
_____

Residual Limb Evaluation

Skin Condition *Location*	☐ Normal	☐ Discoloration	☐ Open Wounds
Limb Shape *Details*	☐ Normal	☐ Bulbous	☐ Conical
Hip Contracture *Details*	☐ Flexion	☐ Abduction	☐ None Present
Other *Location*	☐ Scars	☐ Bony Prominence	☐ Neuroma

General Residual Limb Observations & Comments

_____
_____
_____
_____

C-Leg® Microprocessor Knee Patient Evaluation Protocol

Patient Name: _____

Prosthetic Recommendation

☐ **New Prosthesis** ☐ **Replace Components**

Due To

☐ Change in Residual Limb ☐ Weight Gain ☐ Weight Loss ☐ Functional Level Change ☐ Irreparable Damage ☐ Normal Wear & Tear ☐ New Prosthetic Wearer

Component Recommendations

Foot: _____

Rationale: _____

_____

Knee:_____

Rationale: _____

_____

Suspension:_____

Rationale: _____

_____

Socket Design:_____

Rationale: _____

_____

Liner/Insert:_____

Rationale: _____

_____

Protective Cover: ☐ Yes ☐ No

Rationale: _____

Total Contact: ☐ Yes ☐ No

Rationale: _____

Ultra-Lite Materials: ☐ Yes ☐ No ☐ Reduce Weight ☐ Increase Durability

Rationale: _____

General Observations & Comments

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

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Activities of Daily Living (ADL) Justification	
☐	Patient requires reliable stability in the knee unit when walking and standing in confined areas and in crowded public areas.
	Specific ADL Example:
☐	During normal day-to-day or work activities, patient is required to stand and ambulate while carrying items and performing tasks. These tasks and duties do not allow the patient to focus concentration on controlling the stability of the knee unit.
	Specific ADL Example:
☐	Patient maintains a wide range gait pattern, from slow walking in crowds to a faster gait to move quickly from point A to point B. Patient requires a knee mechanism that will allow for a full range of walking speeds to accommodate a normal life style.
	Specific ADL Example:
☐	Patient routinely walks on uneven terrain, gravel, ramps and stairs and therefore requires the benefit of a knee mechanism that will provide maximum security and stability by being able to adjust to improper knee movement and gait patterns and initiate a stumble recovery feature.
	Specific ADL Example:
☐	Patient gets in and out of a car on a regular basis and requires a knee that will provide maximum stability and security to avoid premature flexion of the knee while initiating a deep bending motion.
	Specific ADL Example:
☐	Patient is an active walker and requires a knee mechanism that will reduce overall energy consumption allowing him/her to walk farther without experiencing fatigue and weariness.
	Specific ADL Example:
☐	Patient routinely walks in public and requires a knee mechanism that will provide maximum security and stability with minimal conscious and muscular control to minimize falls and stumbles.
	Specific ADL Example:

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Patient Name: _____

Functional Requirements Verification

A recent VA Technology Assessment Program Short Report completed by the Management Decision and Research Center suggests two major benefits of computerized control knee prosthesis over standard applications. These include:

1. Possible reduced energy expenditure required for ambulation at non-standard (slower or faster than normal ambulation speed) cadence rates.
2. Potentially improved ability to negotiate uneven terrain or stairs.

The VA has further determined that since these are the only documented benefits of the computer-controlled limb compared with other applications, prescription approval for any computer-controlled lower extremity prosthesis will be limited to patients with documented evidence of all the criteria listed below.

CRITERIA #1: Patients with adequate cardiovascular reserve and cognitive learning ability to master the higher level of technology and to allow for faster than normal walking speed.

Yes	No		*CP Initials*	*Pt Initials*
☐	☐	Patient has adequate cardiovascular reserve to master the ability to utilize a C-Leg to allow for faster than normal walking speed.	_____	_____
		Example _____		
☐	☐	Patient has the cognitive learning ability to master the higher-level technology to allow for faster than normal walking speed.	_____	_____
		Example _____		

CRITERIA #2: The patient must demonstrate the ability to ambulate at a faster than baseline rate using a standard prosthetic application with a swing and stance control knee. *(For new amputees without a prosthesis, the patient has the potential to ambulate at a faster than baseline rate.)*

Yes	No		*CP Initials*	*Pt Initials*
☐	☐	Patient can presently walk at a faster than baseline rate using a standard prosthetic application with a swing and stance control knee. *(For new amputees without a prosthesis, the patient has the potential to ambulate at a faster than baseline rate.)*	_____	_____
		Example _____		

CRITERIA #3: Demonstrated patient need for long distance ambulation at variable rates (greater than 400 yards) on a daily basis. Use of the limb in the home or for basic community ambulation is not sufficient to justify provision of the computerized limb over standard limb applications.

Yes	No		*CP Initials*	*Pt Initials*
☐	☐	Patient needs to walk distances greater than 400 yards on a daily basis for specific activities <u>*other than*</u> for home or basic community ambulating.	_____	_____
		Example _____		

CRITERIA #4: Demonstrated patient need for regular ambulation on uneven terrain or for regular use on stairs. Use of the limb for limited stair climbing in the home or employment environment is not sufficient evidence for prescription of this device over standard prosthetic application.

Yes	No		*CP Initials*	*Pt Initials*
☐	☐	Patient regularly needs to ambulate on <u>*either*</u> uneven terrain <u>*or*</u> stairs for specific or special activities <u>*other than*</u> limited normal use in the home or employment environment.	_____	_____
		Example _____		