**Introduction**

HTA has selected microprocessor-controlled lower limb prosthetics to undergo a health technology assessment where an independent vendor will systematically review the evidence available on the safety, efficacy, and cost-effectiveness. HTA posted the topic and gathered public input on all available evidence. HTA published the Draft Key Questions to gather public input about the key questions and any additional evidence to be considered in the evidence review. Key questions guide the development of the evidence report. HTA seeks to identify the appropriate topics (e.g. population, indications, comparators, outcomes, policy considerations) to address the statutory elements of evidence on safety, efficacy, and cost effectiveness relevant to coverage determinations.

Several types of lower limb prostheses are available to replace the function of a lower extremity. Microprocessor-controlled/computer-controlled prostheses have been proposed as an alternative to standard prostheses. Information is needed about what the potential and demonstrated benefits are, what are the risks and what are the cost implications.

**Final Key Questions**

When used in patients living with lower limb loss:

1. What are the expected treatment outcomes of use of microprocessor-controlled lower limb prosthetics? Are there validated instruments related to measurement of outcomes of this technology? Has clinically meaningful improvement in outcomes been defined for use of this technology?

2. What is the evidence of efficacy and effectiveness of microprocessor-controlled lower limb prosthetics? Including consideration of validated tools to measure both short term and long term outcomes.
   a. Energy and cognitive requirements of ambulation
   b. Impact on ambulation: daily step frequency; estimated step distance; performance on level or varied surfaces; stopping and standing safely, adaptation to different walking speeds, with estimation of number of falls
   c. Patient perception; QOL; impact on activities of daily living; work; work performance

3. What is the evidence about the safety microprocessor-controlled lower limb prosthetics? Including consideration of:
   a. Adverse events type and frequency (mortality, other major morbidity)
   b. Equipment failure, equipment longevity, reoperation
   c. Ulcers, infections, falls, etc.
4. What is the evidence that microprocessor-controlled lower limb prosthetics has differential efficacy or safety issues in sub populations? Including consideration of:
   a. Gender
   b. Age
   c. Psychological or psychosocial co-morbidities
   d. Baseline functional status using instruments such as Medicare’s Orthotics and Prosthetics K levels of function.
   e. Other patient characteristics or evidence based patient selection criteria such as stump length and BMI
   f. Provider type, setting or other provider characteristics
   g. Payor/ beneficiary type: including worker’s compensation, Medicaid, state employees

5. What evidence of cost implications and cost-effectiveness of microprocessor-controlled lower limb prosthetics? Including consideration of:
   a. Costs (direct and indirect) and cost effectiveness
   b. Short term and long term
   c. Ongoing maintenance and replacements for the prosthetic

Policy Context:

1.6 million people were living with limb loss in 2005, expected to double by 2050; 65% are lower limb amputees. Prostheses are devices that are used to replace or compensate for the absence of a body part (present at birth, or due to illness or trauma). For prostheses used to replace lower limbs, there is a need for a device to replace the normal function of the knee and/or ankle. There are several devices available that use computer technology to enhance the function of the basic mechanical knee/ankle design. Objective evidence is needed to determine whether significant benefit is obtained.

Technology Description:

The simplest artificial prostheses is a hinged leg that swings on one axis. Next is a polycentric joint that has more than one axis of rotation. Micro processor devices are newer types of prosthetic leg device and include a computer and sensors that detect movement and timing of gait/swing to then adjust the resistance via a fluid control system. At least one device senses and controls the swing phase as well as the stance phase via a microprocessor.

Potential advantages of microprocessor controlled knees include: reduced energy expenditure compared to traditional artificial legs/knee joints, ability to compensate for variable walking speeds; more natural movement.

Issues:
Objective evidence is needed to determine what appropriate clinical measures are; whether significant clinical benefit is obtained from microprocessor-controlled mechanisms; and what the risks and costs are.
Joseph M. Czerniecki, MD is the Associate Director, of the VA Research Center of Excellence in Limb Loss Prevention and Prosthetic Engineering at Seattle and Professor of Rehabilitation at the University of Washington. He is a clinical specialist in Physical Medicine and Rehabilitation, with a clinical focus in the area of amputee rehabilitation. He has an active ongoing research program, studying many facets of amputee rehabilitation including, the biomechanics of amputee gait and prosthetic components, pain after amputation, and most recently the prediction of outcomes in veterans who are about to undergo amputation secondary to diabetes or vascular disease. He has published over 60 scientific papers.
## Disclosure

Any unmarked topic will be considered a "Yes"

<table>
<thead>
<tr>
<th>Potential Conflict Type</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>1. Salary or payments such as consulting fees or honoraria in excess of $10,000</td>
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<tr>
<td>2. Equity interests such as stocks, stock options or other ownership interests</td>
<td>X</td>
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<tr>
<td>3. Status or position as an officer, board member, trustee, owner</td>
<td></td>
<td>X</td>
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<tr>
<td>4. Loan or intellectual property rights</td>
<td>X</td>
<td></td>
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<tr>
<td>5. Research funding</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>6. Any other relationship, including travel arrangements</td>
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If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________

<table>
<thead>
<tr>
<th>Potential Conflict Type</th>
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<th>No</th>
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<tbody>
<tr>
<td>7. Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).</td>
<td></td>
<td>X</td>
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7. If yes, Provide Name and Funding Sources:

____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may attach additional sheets explaining why you believe that you should not be excluded.

---

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

**Signature**  [Signature]

**Date**  07/12/2011

**Print Name**  [Print Name]

---

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742, PO Box 42712, Olympia, WA 98504-2712
CURRICULUM VITAE

Name
Joseph M. Czerniecki, M.D.

Date of Birth
August 19, 1953

Place of Birth
Nelson, British Columbia, Canada

Current Address
4232 Bagley Ave. N.
Seattle, Washington 98103

Telephone
(206) 277-1812 (Work)

Undergraduate Education
1971-1975 Bachelor of Science in Rehabilitation (Physical Therapy and Occupational Therapy) University of British Columbia, Vancouver, B.C.

Medical School
1977-1981 M.D., University of British Columbia, Vancouver, B.C.

Post Graduate Training
1981-1982 Internal Medicine Internship, University of Toronto, Sunnybrook Medical Centre, Toronto

1982-1985 Residency Training in Physical Medicine and Rehabilitation Medicine University of Washington, Seattle, WA

1985 Masters of Science, University of Washington, Seattle, WA
Thesis Entitled: An Electrogoniometric Analysis of Rotational Motion at the Knee in Normal Subjects and those with Anterior Cruciate Ligament Injury

1985-1986 Research Fellowship, Department of Rehabilitation Medicine University of Washington, Seattle, WA

Faculty Appointments
July '86-Feb '89  Acting Assistant Professor, Dept. of Rehabilitation Medicine  
University of Washington, Seattle, WA

Feb '89-July '95  Assistant Professor, Dept. of Rehabilitation Medicine  
University of Washington, Seattle, WA

July '90-Present  Member, Graduate Faculty  
University of Washington, Seattle, WA

July '95-July '03  Associate Professor, Department of Rehabilitation Medicine  
University of Washington, Seattle, WA

July '03-Present  Professor, Department of Rehabilitation Medicine  
University of Washington, Seattle, WA

Hospital Appointments

July '86-July'04  Attending Physician, STAMP/PACT Service, Physical Medicine and  
Rehabilitation Medicine Service, Seattle V.A. Medical Center, Seattle, WA

July '88-July’07  Director, Motion Analysis Laboratory, Seattle VA Medical Center, 
Seattle, WA

July '88-Present  Director, VA Regional Amputee Clinic

July '88-Present  Associate Medical Staff, Harborview Medical Center

July '88-Present  Associate Medical Staff, University of Washington Medical Center

July '88- July'92  Attending Physician, University Hospital Child Myoelectric Clinic

Feb '91- Dec '93  Co-Director, STAMP (Special Team for Amputation, Mobility &  
Prosthetics/Orthotics), Seattle VA Medical Center, Seattle WA

Dec '93-July’04  Co-Director PACT Program (Preservation Amputation Care Team), 
Seattle VA Medical Center, Seattle WA

May '95-Jan'97  Director Outpatient Clinics, Physical Medicine and Rehabilitation Service, 
Seattle VA Medical Center, Seattle WA

Jan '97- Jan’99  Director Electrodiagnostic Services, Physical Medicine and Rehabilitation Service, 
Seattle VA Medical Center, Seattle WA
Aug’05–May’10 Director of Rehabilitation Care Service Line, VA Puget Sound Health Care System, Seattle WA

Academic Honors Scholarships

1971 Norman A. MacKenzie Scholarship
1978 Dr. and Mrs. S. Schaffer Memorial Scholarship
1979 Cornelius Leonard Mitchell Scholarship
1980 Samuel Diamond Scholarship
1981 Peter Bain Scholarship Dr. and Mrs. J. Nemetz Memorial Scholarship
1989 Teacher of the Year, Dept of Rehabilitation Medicine
University of Washington, Seattle, WA
1992 Physical Medicine and Rehabilitation, Education and Research Foundation Award
Best publication by a Physiatrist in 1992 (role: co-author)


1994 Teacher of the Year, Dept. of Rehabilitation Medicine
University of Washington, Seattle, WA
1996 Physical Medicine and Rehabilitation, Education and Research Foundation Award
Best publication by a Physiatrist in 1996 (role: co-author)


2003 Visiting Professor, University of Geneva, Geneva, Switzerland
2004 Visiting Professor, Dalhousie University, Halifax Canada.
Presented the Arthur H. Shears Lectureship “Critical Issues in the Rehabilitation of People with Amputations”.

2006 Professional Achievement of the Year Award, awarded by the Amputee Coalition of America.

2009 Visiting Professor, University of Colorado, Denver Colorado, Gersten Lectureship “Innovations in Lower Extremity Amputee Rehabilitation and Prosthetic Technology: The near term and more distant horizon”.

2011 2010 Ernest W. Johnson / AAP Excellence in Research Writing Award honorable mention winner. (role: senior author)


**Specialty Board Status**

1986 Fellow of the Royal College of Physicians (Canada) Physical Medicine and Rehabilitation

1987 American Board of Physical Medicine and Rehabilitation

1988 American Board of Electrodiagnostic Medicine

**Medical Licensure**

1982 - Present Washington State Medical License

**Professional Membership**

American Academy of Physical Medicine & Rehabilitation

Royal College of Physicians (Canada)

**Teaching Responsibilities**

*Courses*

1986 – Present Rehab 685/687 Chronic Disease and Disability
Four times/year two week clinical rotation for medical students
1986-1994  Rehab 529 Prosthetic Orthotic Conference  
Bi-monthly clinical/didactic case centered conference on amputation related issues.

1986-1988  Ortho 585 Sports Medicine for Medical Students  
2-3 lectures on biomechanics in sports medicine

1987-1994  Rehab 654 Medical Student Introduction to Rehabilitation Medicine  
2 hour lecture in this course to introduce medical students to issues related to amputation prevention and amputation rehabilitation

1988-1991  ICM II Introduction to Clinical Medicine II  
I provided a single 2 hour lecture in this course

1986-1991  Hubio 553 Medical Student Anatomy  
One quarter per year of Anatomy Lab supervision. This involved approximately 28 hours of involvement in a quarter.

1987-1992  Rehab 445 Therapy Students Anatomy  
One quarter per year three lectures and 3 hrs of anatomy lab participation

1987-1992  Rehab 545 Rehabilitation Medicine Resident Anatomy Course  
One quarter per year three lectures and anatomy lab participation.

1993-1997  Rehab 442 Advanced Clinical Kinesiology and Biomechanics  
Co-course chair complete redesign of course and administrative responsibility for the course as well as 3-4 lectures in the quarter.

1995-2008  Rehab 593 Principles of Prosthetic Use in Rehabilitation  
Designed a new course for 3rd year Rehab Residents consisting of 11 lectures in a quarter. Full administrative responsibility and ½ of the lectures. Development of the course to include Web based materials.

1998  Chair Educational Symposium. Biomechanics of Prosthetic Components.  
American Academy of PM&R Meeting, Seattle.


2001  Co-chair. Department of Rehabilitation Medicine, University of Washington Review Course. Coordinated all aspects of this 10 day review course.
Local CME Lectures


National CME Lectures


28. Amputee Rehabilitation: Current treatment and new research directions. War Illness and Injuries Study Center, New Jersey, May, 2006


31. The effect of Microprocessor Controlled Knees on the metabolic costs and biomechanics of Transfemoral Amputee Gait, AAOPA meeting, Atlanta, March, 2009.


34. VA National Amputation System of Care, VISN 20 Regional Amputation Conference, Seattle WA, July 2010.


Graduate Students Supervised


2. Ib Odderson, MD, Masters of Rehabilitation Medicine June 1988, Thesis entitled: "RSD in an Amputee: Case Study" Role: Chairman of Committee


4. Margaret Forgette, MD, Masters of Rehabilitation Medicine, June, 1989. Thesis entitled: "Reflex Sympathetic Dystrophy in a Child, A single subject study design of the Role of Calcium Channel Blockers". Role: Member of Committee.


10. Mary Zdrojewski, MD, Masters of Rehabilitation Medicine, July 1994, Thesis entitled: Is the self-selected walking speed of AK amputee ambulation their most efficient. Role Chairman of Committee.


20. Andrew Sawyers, PhD Candidate, Rehabilitation Sciences, University of Washington, August 2008 to present, Member of Dissertation Committee.


Editorial Responsibilities

May '91-Present    Ad Hoc manuscript reviewer
                    Journal of Biomechanics

May '89-Present    Ad Hoc manuscript reviewer
Archives of Physical Medicine and Rehabilitation

June '97-July '00  Ad Hoc manuscript Reviewer
                  Clinical Orthopedics and Related Research

July '99-Present  Ad Hoc manuscript reviewer
                  VA Journal of Rehabilitation Research and Development

Aug '00-Mar ‘04  Editorial Board member
                  Archives of Physical Medicine and Rehabilitation

Special National Responsibilities

Apr ‘89-Apr ‘96  Oral Board Examiner
                  American Board of Electrodiagnostic Medicine

Jan '89-Sept '92  Member, Self-Assessment Examination Subcommittee
                  American Academy of PM&R

May '92-May ‘02  Guest Oral Board Examiner, American Board of PM&R

June '92  Grant Review Panel Member, Biomedical Engineering to Aid the
          Disabled, National Science Foundation

March'94-June'95 Study Guide Committee (Prosthetics/Orthotics Section)
                  American Academy of PM&R

May '94  Grant Review Panel Member, Biomechanics and Rehabilitation,
          National Science Foundation

Jun '97 - Present  Associate Director, VA Rehabilitation Research and Development Center
                  (Limb Loss Prevention and Prosthetic Engineering). A specialized
                  research center of excellence in the Veterans Administration Health Care
                  System.

Mar’99-Jul ‘02  Grant Review Panel Member, NIH Small Business Innovation Research
                  Grant, Rehabilitation Special Emphasis Panel.

Oct’99-Jul ‘01  Question Writer for American Board of PM&R Re-certification
                  Examination

June '01  Invited Participant in a National Conference (Veterans Administration and
          NIH ) to establish future directions and research priorities for Prosthetic
          Research.
Apr ’02-Apr’03 Member of Executive Committee of the US- ISPO. This is the US division of the International Society of Prosthetics and Orthotics.

Oct ’03 Invited Member National VA committee to evaluate and enhance amputee care in the VA Health Care System.

June ’05 Invited Member Consensus Conference on the Biomechanics of Prosthetic Feet, sponsored by the American Academy of Orthotists and Prosthetists, Dallas.

Sept ’04- Jan’08 VA National Advisory Board for Physical Medicine and Rehabilitation

Dec ’06 Invited to participate in a conference to develop international accreditation standards for Amputee Specialty Programs, CARF International, Washington, DC

Dec ’06 Participated in a committee to develop clinical practice guidelines for amputation care within the VA health care system, Denver, CO.

July ’07-present Member VA National Research Advisory Committee, review and advise on VHA’s research portfolio regarding OIF/OEF combat injured.

July ’07 NIH grant review panel member, Musculoskeletal Rehabilitation Study Section. Bethesda, MD.

Feb’08 – Sept‘08 National Technical Advisory Team, develop and implement a plan for Post Deployment Health Care for returning combat exposed patients.

Sept’09 – May’10 Interim National Director VA Amputation System of Care,

**Special Local Responsibilities**

July ’87-July ’90 Member, Advisory and Evaluation Committee for Physical Therapy, University of Washington, Dept of Rehab Medicine

Aug ’87-July ‘99 Departmental Career Advisor
University of Washington, School of Medicine

July ’88-April ’89 Chairman, Committee to Evaluate Residency Training in Musculoskeletal Medicine

July ’88-July’92 Member, Standing Committee on Prosthetics and Orthotics
Undergraduate Education, University of Washington, Dept of Rehab Medicine
July '89-July '90  Member, Departmental Physician Search Committee

Sept '90-May '93  Member, Rehabilitation Medicine Quality Improvement Committee, Seattle VA Medical Center

July '91-July '92  Member, Departmental Residency Training Advisory Committee, University of Washington, Dept of Rehab Medicine

July '91-July '02  Member, Advisory Committee Medical Rehabilitation Research Training Program, University of Washington, Dept. of Rehab Medicine

Dec '91-May '04  Chair, Credentialing & Privileging Committee, Rehab Medicine Service, Seattle VA Medical Center

July '92-May '93  Chair, Committee to Reformulate Kinesiology 442 Course, University of Washington, Dept of Rehab Medicine

May '93- July '98  Chair, Rehabilitation Medicine QI Committee, Seattle VA Medical Center

Mar '95-July '96  Member, Search Committee, Head of the Division of Prosthetics/Orthotics, Dept of Rehab Medicine, University of Washington

Mar '95-Mar'97  Member, Search Committee, Head of the Division of Physical Therapy, Dept of Rehab Medicine, University of Washington

Jan '97- July '03  Member, Departmental Physician Search Committee

July '97-Oct '03  Member, Standing Committee on Prosthetics and Orthotics, Undergraduate Education, University of Washington, Dept of Rehab Medicine

Oct '97-Oct '01  Member, Washington State Department of Health, Advisory Committee on Prosthetics and Orthotics

Apr ‘99-Oct ‘99  Member, Search Committee, Associate Chief of Staff for Research, VA Puget Sound Health Care System, Seattle Washington

Nov ‘99-July '02  Member, Veterans Affairs Medical Center, Research and Development Committee

Sept '00-Mar'01  Chair, Department of Rehabilitation Medicine, Physical Medicine and Rehabilitation Review Course
Aug '03-Aug ‘04 Member Departmental Graduate School Council, evaluation of need for doctoral program in Physical Therapy

May ‘06-July ‘07 Member Search Committee, for the Chair, Department of Rehabilitation Medicine, University of Washington

May ’09-May’10 Member VAPSHCS Credentialing and Privileging Committee

July ’07-Present Member VAPSHCS Physician Compensation Panel

Nov ’10-Present Member VAPSHCS IRB Committee

Grant Support

1. Use of Tri-Axial Electrogoniometer in the Study of the Anterior Cruciate Deficient Knee, Associate Grantee
   Co-Grantees: Sigvard Hansen, MD, Frederick Lippert, MD, John Olerud, MD.
   Date: January 1, 1984 - January 1985, Extended to June 1986
   Agency: Orthopedic Research Education Foundation
   Amount: $8,950

   Role: Principal Investigator
   Funding Period: Sept.1, 1988 - Sept.1, 1989
   Agency: Whitaker Foundation
   Amount: $58,005

3. Biomechanical Power Output Analysis of Prosthetic Feet
   Role: Co-Investigator
   Funding Period: September 1988 - September 1989
   Amount: $26,000
   Agency: VA Regional Advisory Group Proposal

4. A Metabolic and Biomechanical Analysis of Above Knee Amputee Gait
   Role: Co-Principal Investigator
   Date: October 1990 - October 1992
   Amount: $145,000
   Agency: VA Merit Review

5. Management of Chronic Pain in Rehabilitation, Principal Investigator, Mark Jensen PhD
   Project Title: Management of Chronic Pain in Persons with Amputations
   Role: Co-investigator
   Amount: $2,857,349 Direct Costs
   Funding Period: August 1996 - August 2001
6. RR&D Center for Amputation Prosthetics and Limb Loss Prevention.
   Role: Co-Principal Investigator
   Amount: $3,719,000
   Funding Period: October 1997 - October 2002
   Agency: Veterans Administration, Rehabilitation Research and Development

7. Effect of Motor imbalance on bony deformity and plantar pressure in the foot.
   Role: Co-investigator
   Amount: $231,400
   Date: October 1999 – October 2001
   Agency: Veterans Administration, Merit Review

8. Management of Chronic Pain in Rehabilitation
   Role: Co-investigator 5%, Principal Investigator, Mark Jensen PhD
   Amount: $3,640,609
   Date: Resubmission June 2001
   Agency: NIH

9. Performance of Shock Absorbing Pylons: Laboratory and Clinical Evaluation
   Role: Co-Principal Investigator
   Amount: $287,400
   Date: October, 2000 submission. Funding period Apr 2001- Apr 2004
   Agency: Veterans Administration, Merit Review

10. RR&D Center for Amputation Prosthetics and Limb Loss Prevention.
    Role: Co-Principal Investigator
    Amount: $3,429,000
    Agency: Veterans Administration, Rehabilitation Research and Development

11. A Longitudinal Study of Social Support Following Limb Loss
    Role: Co- Investigator 5%, Principal Investigator Dawn Ehde PhD
    Amount: $325,502
    Date: June, 2000
    Agency: CDC

12. The Effects of Novel Prosthetic Knees on the Function of Veterans with Transfemoral Amputation
    Role: Principal Investigator
    Amount: $100,000
    Agency: VA Merit Review;
    Funding Period Apr 2002- Apr 2004

13. Transtibial Amputation Management Strategies
    Role: Co-Investigator 5%
Amount: $96,000
Agency: VA Merit Review;
Funding Period Oct 2003 – Oct 2005

14. Controlled Plantar Pressure Re-Distribution
   Role: Co: Investigator 5%
   Principal Investigator: Glenn Klute, PhD
   Agency: VA Merit Review;
   Funding Period Aug 2004 – July 2005

15. Turning Corners: prosthetic components and stability in amputee gait(A3611I)
   Role: Co-investigator 5%
   Amount: $487,162
   Agency: VA Rehabilitation Research and Development Merit Review
   Funding Period: July 2005 – July 2008

16. Controlled plantar pressure re-distribution (A3217P)
   Role: Co-investigator 5%
   Amount: $45,097
   Agency: VA Rehabilitation Research and Development, Pilot Project
   Funding Period July 2004-July 2005

17. Vacuum suspension: effect on tissue oxygenation, activity, and fit (A3666I)
   Role: Co-investigator 5%
   Amount: $719,261
   Agency: VA Rehabilitation Research and Development, Merit Review
   Funding Period: July 2005-July 2008

18. Ankle equinus and plantar pressure in individuals with diabetes
   Role: Principal Investigator
   Agency: VA Rehabilitation Research and Development, Merit Review
   Amount: $403,440
   Funding Period: July 2005-July 2008

19. Functional Outcome Prediction in the Dysvascular/Diabetic Amputee during the
    Preamputation Period.
    Role: Principal Investigator
    Agency: VA Rehabilitation Research and Development, Merit Review
    Amount: $738,607
    Funding Period: April 2006- April 2010

20. RR&D Center for Amputation Prosthetics and Limb Loss Prevention.
    Role: Co-Principal Investigator(A4843C)
    Amount: $4,750,000
21. Metabolic Cost Savings for Transtibial Amputees Wearing the CESR Foot.
   Role: Principal Investigator
   Agency: VA Rehabilitation Research and Development, Merit Review
   Amount: 749,632
   Funding Period: June 2006 – June 2010

22. Distributed sensing in prosthetic sockets
   Agency: NIH R21
   Role: Consultant
   Amount: $193,454
   Funding Period: February 2008- February 2010

23. Prosthetic Knee-Ankle-Foot System with Biomechatronic Sensing, Control,
    and Power Generation - (DR081177)
   Agency: DoD – DRMRP
   Role: Co-investigator
   Amount: $8,712,373
   Funding Period: July 2009 – July 2014

24. Ampredict;  A prognostic System for Selecting Appropriate Level of Amputation(O7119R)
   Agency: VA Merit Review
   Role: Principal Investigator
   Amount: $995,000
   Funding Period: July 2010 – July 2014

25. Optimizing Stiffness in a Multi-Component Prosthetic Foot
   Agency: VA Merit Review
   Role: Investigator (Mike Hahn, PhD Principal Investigator)
   Amount: $822,142
   Funding Period: Oct 2010 – Sept 2013

26. Prosthetic foot characteristics and Knee osteoarthritis in Amputees
   Agency: VA Career Development
   Role: Mentor (David Morgenroth, MD Career Development Awardee)
   Amount $1,156,250
   Funding Period: Oct 2010 – Sept 2015

For complete CV (includes bibliography) – please request from HTA program at: shtap@hca.wa.gov
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<th>COI</th>
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NO SCHEDULED PUBLIC COMMENTS ON PROSTHETICS
Microprocessor-controlled Lower Limb Prosthetics (MPC)

Dr. Gary Franklin
Medical Director
L&I
11/18/2011

Microprocessor-controlled Lower Limb Prosthetics

Background

Background: Better computerized control of prosthetic functions could theoretically improve balance, gait speed, efficiency

• Does MPC prosthetic improve function and work capacity in a meaningful way?

• What constitutes a meaningfully better use of energy?
Microprocessor-controlled Lower Limb Prosthetics

Background

AMDG Perspective
Concerns
• Safety = Low
• Efficacy = High
• Cost = High

Is the hugely increased cost of MPC worth the added gain?
• In whom?
• For what purpose?
• Under what conditions?

Prosthetic Functional Level Assessment

K-0  Inability or potential to ambulate or transfer safely with or without assistance, and a prosthesis does not enhance their quality of life or mobility.

K-1  Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at a fixed cadence. Typical household ambulator.

K-2  Has the ability or potential for ambulation with the ability to transverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.

K-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.

K-4  Has the ability or potential for ambulation that exceeds basic ambulation skills, exhibiting high impact, stress or energy levels. Typical of prosthetic demands of the child, active adult or athlete.
Microprocessor-controlled Lower Limb Prosthetics
Current State Agency Policy

Labor and Industries Coverage
CMS functional level 3 or 4 AND (all of)
1. Transfemoral unilateral amputation
2. Client’s work requires ability to ambulate
   • long distances (>400 yds) at varying speeds OR
   • over uneven ground OR
   • frequent use of stairs required at work
3. Client has mastered the use of a prosthetic
   knee with stance and hydraulic swing control
4. Weight <220 lbs with cardiovascular capacity to ambulate at
   faster than normal walking speed

Medicaid, UMP/PEB Coverage
Covered

Foot/ankle system is not covered by any agency

---

Microprocessor-controlled Lower Limb Prosthetics
Billing Codes

<table>
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<tr>
<th>CPT Codes</th>
<th>Short Description</th>
<th>Add'l Info</th>
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<tr>
<td>L5856</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type</td>
<td>MCP Component</td>
</tr>
<tr>
<td>L5857</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type</td>
<td>&quot;</td>
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<tr>
<td>L5858</td>
<td>Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, Stance phase only, includes electronic sensor(s), any type</td>
<td>&quot;</td>
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<tr>
<td>L5975</td>
<td>Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and /or planar (flexion) control, includes power source (added 1/2010)</td>
<td>&quot;</td>
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<tr>
<td>L5000-L5999</td>
<td>Lower Limb Prostheses and parts</td>
<td>All</td>
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<td>L7510-L7520</td>
<td>Parts and labor for repair of prosthetic</td>
<td>Repair</td>
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### Microprocessor-controlled Lower Limb Prosthetics
#### State Agency Combined Utilization

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<th>Agency Experience</th>
<th>PEB</th>
<th>L&amp;I</th>
<th>Medicaid</th>
<th>All Agencies</th>
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<tbody>
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<td>$482,271</td>
<td>$812,966</td>
<td>$166,234</td>
<td>$1,461,471</td>
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<tr>
<td>Member Count</td>
<td>14</td>
<td>8</td>
<td>15</td>
<td>37</td>
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<tr>
<td>Average Payment/Member*</td>
<td>$43,569</td>
<td>$101,621</td>
<td>$11,082</td>
<td>$39,499</td>
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<tr>
<td>Annual Average</td>
<td>$10,892</td>
<td>$25,405</td>
<td>$2,771</td>
<td>$9,874</td>
</tr>
<tr>
<td>Non-MCP Payments</td>
<td>$1,273,586</td>
<td>$7,838,247</td>
<td>$10,067,406</td>
<td>$19,179,239</td>
</tr>
<tr>
<td>Member Count</td>
<td>186</td>
<td>350</td>
<td>1844</td>
<td>2380</td>
</tr>
<tr>
<td>Average Payment/Member*</td>
<td>$9,735</td>
<td>$22,395</td>
<td>$5,460</td>
<td>$8,059</td>
</tr>
<tr>
<td>Annual Average</td>
<td>$2,434</td>
<td>$5,599</td>
<td>$1,365</td>
<td>$2,014</td>
</tr>
</tbody>
</table>

*PEB averages do not include claims where PEB was secondary payer, as primary payer claims are more representative for comparison between agencies.

### MCP LL Prosthetics, State Agency Utilization, 2007-2010

- **PEB MCP**: $482K serving 14 mbrs
  - 6% Add-ons
  - 45% Services
  - 5% Modifications

- **L&I MCP**: $812K serving 8 clmnts
  - 0% Add-ons
  - 46% Services
  - 1% Modifications

- **Medicaid MCP**: $166K serving 15 clmnts
  - 1% Add-ons
  - 59% Services
  - 1% Modifications

- **PEB Non-MCP**: $1.3 M serving 186 mbrs
  - 58% Add-ons
  - 40% Services
  - 2% Modifications

- **L&I Non-MCP**: $8.1 M serving 350 clmnts
  - 73% Add-ons
  - 13% Services
  - 2% Modifications

- **Medicaid Non-MCP**: $10.7 M serving 1860 clmnts
  - 64% Add-ons
  - 12% Services
  - 4% Modifications

[Health Care Authority]
MCP LL Prosthetic Replacements, State Agencies, 2007-2010

**PEB MCP Prosthetic & Replacement Claims**
- 15 mbrs
- 20 total clms
- $9937 avg/claim
- 20%

**L&I MCP Prosthetic and Replacement Claims**
- 7 mbrs
- 17 total clms
- $4683 avg/claim
- 29%

**PEB Non-MCP Prosthetic & Replacement Claims**
- 111 mbrs
- 194 total clms
- $1566 avg/claim
- 24%

**L&I Non-MCP Prosthetic &Replacement Claims**
- 298 mbrs
- 615 total clms
- $3338 avg/claim
- 28%

Microprocessor-controlled Lower Limb Prosthetics
Other Centers, Agencies and HTAs

Most insurers lean toward coverage with conditions for MPC knees,

N/C for MPC ankles/feet
Microprocessor-controlled Lower Limb Prosthetics

State Agencies Summary View

Cost/benefit of MPC knee prostheses unproven for clinically meaningful outcomes

High cost necessitates functional assessment/classification and careful performance based assessment as part of medical necessity determination

No evidence to support coverage of MPC ankle/foot prosthesis

Microprocessor-controlled Lower Limb Prosthetics

State Agencies Recommendation

MPC knee prostheses - coverage with conditions

- Functional level 3 or 4
- Weight, cardio limitations
- Demonstrated need for higher performance (e.g., to work)
- Performance-based assessment of functional capacity with classic knee prosthesis with stance and hydraulic knee control

MPC ankle/foot prosthesis - non-coverage
Questions?

More Information:
http://www.hta.hca.wa.gov/limb.html

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Medical Director
Dept of Labor and Industries
Gary.franklin@lni.wa.gov
Tel: 360-555-5555
MICROPROCESSOR-CONTROLLED LOWER LIMB PROSTHESES

Health technology assessment prepared by:

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Erika D. Brodt, BS
Andrea C. Skelly, PhD, MPH

Spectrum Research, Inc., Tacoma, WA

Words/abbreviations

- Transtibial (below the knee)
- Transfemoral (above the knee)
- MCP: Microprocessor-controlled prosthesis
- NMCP: Non-microprocessor-controlled prosthesis
- Swing phase (when leg is in motion)
- Stance phase (when leg is still)
- Swing/stance (switching between the two)
Background

- 1.6 million people living with limb loss
  - 65% lower limb loss
  - Increasing
- Etiology
  - Peripheral vascular disease (80%): hypertension, dyslipidemia, diabetes, atherosclerosis
  - Trauma (17%)
  - Cancer (2%)
  - Congenital (estimated 2%)

Burden of lower limb loss

- Balance
  - Falls, uneven terrain, gait asymmetry
- Cognitive, metabolic demand for walking
  - Walking speed, reduced activity
- Joint pain, back pain, osteoarthritis, osteoporosis, obesity
- Community reintegration, return to work
Lower limb prostheses

- Socket, foot, knee (transfemoral), and adapters to connect them
- More than 50 prosthetic feet (one MCP)
- More than 200 prosthetic knees (~20 MCP)
- Prosthesis choice informed by age, weight, cause of limb loss, functional status, medical history, personal goals, medical coverage

Medicare Functional Classification Levels (MFCL)

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>The patient 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.</td>
</tr>
<tr>
<td>1</td>
<td>The patient 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.</td>
</tr>
<tr>
<td>2</td>
<td>The patient has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.</td>
</tr>
<tr>
<td>3</td>
<td>The patient 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.</td>
</tr>
<tr>
<td>4</td>
<td>The patient 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.</td>
</tr>
</tbody>
</table>

- Used to describe ambulation potential; guides prosthesis selection
- Also called K-level
Technology: Microprocessor-controlled lower limb prostheses

- MCP knees
  - Sensors monitor and adjust movements of prosthesis
  - Swing phase (knee is in motion)
  - Stance phase (leg at rest)
  - Swing/stance (switching between the two)
- MCP feet
  - Modifies ankle angle during gait

Technology: Microprocessor-controlled lower limb prostheses

- Potential benefits
  - Balance, confidence, ambulation, safety
- Potential harms
  - Residual limb effects likely similar to NMCP
  - Device malfunction
- Emerging technologies
  - Powered prostheses; powered knee/foot; volitional control
Microprocessors perform different functions

<table>
<thead>
<tr>
<th>Microprocessor Type</th>
<th>Adjusts Knee Extension During Stance</th>
<th>Adjusts Knee Resistance during Swing</th>
<th>Switch between Stance/Swing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rise (Robo)</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Control (Che Bost)</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>C-Leg (Che Bost)</td>
<td>no</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Compact (Che Bost)</td>
<td>no</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>Oreon (Endolite)</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Smart Adaptive (Endolite)</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
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<tr>
<td>Smart R (Endolite)</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>EP (Endolite)</td>
<td>no</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Single Axis Power / Intelligent Power (Noblesse)</td>
<td>no</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>4 Bar Power Artificial (TruFit)</td>
<td>no</td>
<td>yes</td>
<td>no</td>
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<tr>
<td>Noblesse (Noblesse)</td>
<td>no</td>
<td>yes</td>
<td>no</td>
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<tr>
<td>Concox (Hybrid) (Noblesse)</td>
<td>no</td>
<td>yes</td>
<td>no</td>
</tr>
<tr>
<td>Prosthesis Remodeling</td>
<td>no</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>C-Leg (Noblesse)</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>
**Key questions**

KQ1. Expected treatment outcomes; outcomes measures, clinically meaningful improvement  
KQ2. Efficacy and effectiveness  
KQ3. Safety  
KQ4. Differential efficacy or safety issues in sub populations  
KQ5. Costs (direct and indirect) and cost effectiveness

---

**Aim of report**

- To systematically review, critically appraise and summarize comparative evidence on the clinical efficacy, effectiveness, safety, and cost-effectiveness of MCPs and other alternatives.  
- Focused on outcomes assessed on MCP use in uncontrolled (home or community) settings.  
  - Existing evidence and reviews support efficacy of MCPs in controlled settings  
  - Outcomes assessed in controlled settings (laboratory or obstacle course) are summarized
Inclusion criteria (PICO)

- **Participants**: Age > 18; transfemoral or transtibial limb loss
- **Intervention**: Microprocessor-controlled knee or foot prosthesis
- **Comparators**: any
- **Outcomes**: any assessed in uncontrolled (eg home, work, or community) settings; adverse events; cost-effectiveness
- **Study design**
  - KQ1: All studies included in Questions 2, 3, 4, and 5
  - KQ2, KQ3, KQ4: Comparative clinical studies
  - KQ5: Comparative studies of both costs and outcomes
- **Publication**
  - Published in English in peer-reviewed journals, published HTAs or publicly available FDA reports
Literature search

- Records identified through database searching (n = 95)
- Records identified through other sources (n = 95)
  - Title/abstract review (n = 190)
    - Records excluded (n = 94)
    - Full-text articles reviewed (n = 96)
      - Based on study design
      - Outcomes assessed in controlled settings (laboratory or clinical setting)
        - Excluded (n = 11)
- Studies included in qualitative synthesis (n = 24)
- Studies included in critical appraisal (n = 12)
MCP feet

- No studies on MCP feet met our inclusion criteria
- One MCP foot available
- Still emerging technology

- Insufficient evidence to evaluate the efficacy, effectiveness, safety, or cost of MCP feet.

MCP knees
Methods: quality assessment

- 12 articles included (total of 614 people)
  - Predominantly male, traumatic etiology, mean age 36-54, 10-20 years since limb loss; MFCL 2, 3, 4 or "active"
- All employed crossover design ("within subject")
  - No studies used blinded designs
  - Two studies (same study population) randomized order of knee assessment
- Length of follow-up 7 days to 15 months
- Followup 27% to 100%
- Nine studies: C-Leg (Otto Bock); two studies Intelligent Prosthesis (IP), one study Adaptive Knee.
- All: various NMCP as comparison

Level of evidence

<table>
<thead>
<tr>
<th>Study</th>
<th>MFCL 2 or 3</th>
<th>MFCL 2 or 4</th>
<th>MFCL 3</th>
<th>MFCL 3 or 4</th>
<th>Overall good reason</th>
<th>Wall with upper extremity aid, 3 flights of stairs</th>
<th>Prosthesis use &gt;8 hours/day for 3 years</th>
<th>Able to do study activities</th>
<th>NR</th>
<th>Use of prosthesis &gt;12 hours/day</th>
<th>Generally active</th>
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</thead>
<tbody>
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<td>17</td>
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</tr>
</tbody>
</table>

- Lack of blinding
- Measurement bias (recall, expectation)
- Generalizability
- Heterogeneity of outcome measures
- Length of follow-up (young trauma survivors may have lifetime use)
- Loss to follow-up
  - Eg Klute/Williams 10/18 did not complete study, 6/18 for reasons related to MCP
Results: KQ1

KQ1. a. What are the expected treatment outcomes of use of microprocessor-controlled lower limb prostheses?
b. Are there validated instruments related to measurement of outcomes of this technology?
c. Has clinically meaningful improvement in outcomes been defined for use of this technology?

KQ1. Expected treatment outcomes

<table>
<thead>
<tr>
<th>Treatment Outcome</th>
<th>Expected Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical parameters</td>
<td>*</td>
</tr>
<tr>
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<td>*</td>
</tr>
</tbody>
</table>

- Also
  - Total energy expenditure (step counts and increased physical activity)
  - Global and/or condition specific quality of life (appearance, comfort, satisfaction, social function)
  - Activities of daily living
  - Improved productivity (eg return to work)
  - Reduced caregiver burden
KQ1. Outcomes assessed in real-world settings

<table>
<thead>
<tr>
<th>Doubly labeled water</th>
<th>Generic measures:</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Total daily energy expenditure (TDEE)</td>
<td>* SF-36/SF-6D</td>
</tr>
<tr>
<td>* Physical-activity related energy expenditure (PAEE)</td>
<td>* EQ-5D</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step activity monitor</th>
<th>Condition-specific measures:</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Steps per day</td>
<td>* Prosthesis evaluation questionnaire (PEQ)</td>
</tr>
<tr>
<td>* Minutes of activity per day</td>
<td>* 50-question survey</td>
</tr>
</tbody>
</table>

- Stumbles, falls, walking speed, distance; stairs, slopes/hills, uneven terrain; energy level; reliability, satisfaction/preference

Bold type: measures that have been assessed for validity or reliability

KQ1: Conclusions

- Two methods used to objectively assess MCP use in real-world settings
- Majority of patient-reported outcomes of real-world use of MCPs are single item
- Generic instruments
  - SF-36
    - Population norms for limb loss
    - SF-60 calculated from a subset of SF-36, validated as utility measure
  - EQ-5D
    - No validity/reliability data found for limb loss “rule of thumb” 5%-10% meaningful improvement
- Condition-specific instruments
  - PEQ (Prosthesis Evaluation Questionnaire):
    - Three subscales demonstrated content, criterion and construct validity
  - Five subscales demonstrated adequate test-retest reliability
  - 50-Question Survey
    - No validity data; reliability testing inadequate
- Minimal clinically important difference (MCID) has not been established for any condition-specific measures
Results: KQ2

KQ2. What is the evidence of efficacy and effectiveness of microprocessor-controlled lower limb prostheses? Including consideration of validated tools to measure both short term and long term outcomes.

KQ2a. Energy and cognitive requirements of ambulation

KQ2b. Impact on ambulation: daily step frequency; estimated step distance; performance on level or varied surfaces

KQ2c. Patient perception; QOL; impact on activities of daily living; work; work performance

KQ2a. Energy use

<table>
<thead>
<tr>
<th></th>
<th>MCP</th>
<th>NMCP</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holker 2009*</td>
<td>76.1</td>
<td>68.9</td>
<td>ns</td>
</tr>
<tr>
<td>Kaufman 2008</td>
<td>71</td>
<td>66</td>
<td>.02</td>
</tr>
<tr>
<td>Williams 2004</td>
<td>21.8</td>
<td>8.4</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Holker 2009*</td>
<td>67.9</td>
<td>53.3</td>
<td>.03</td>
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<td>85.6</td>
<td>77.2</td>
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<td>85.4</td>
<td>69.0</td>
<td>0.002</td>
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</tr>
<tr>
<td>Duna 1998</td>
<td>22</td>
<td>95.5</td>
<td>--</td>
</tr>
<tr>
<td>Kliegel 1096*</td>
<td>1.4</td>
<td>--</td>
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<tr>
<td>58/31/38</td>
<td>47/76/66</td>
<td>&lt;.05/0.01/ns</td>
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<tr>
<td>31</td>
<td>64</td>
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<td>47/55</td>
<td>65/67</td>
<td>&lt;.05/ns</td>
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</tr>
<tr>
<td>47/61</td>
<td>54/68</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Kaufman 2008</td>
<td>14.1</td>
<td>13.0</td>
<td>.02</td>
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<td>5.5</td>
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<tr>
<td>4.4</td>
<td>3.4</td>
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<tr>
<td>7.0</td>
<td>7.0</td>
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</tbody>
</table>

- KQ2a. Evidence from two moderate and three low-quality studies consistently suggests that energy/cognitive requirements associated with MCP are improved compared to NMCP in real-life settings. Strength of evidence: LOW
### KQ2b. Impact on ambulation

<table>
<thead>
<tr>
<th>Study</th>
<th>MCP Mean</th>
<th>NMCP Mean</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hafner 2009*</td>
<td>75.7</td>
<td>64.4</td>
<td>0.008</td>
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<tr>
<td>Kaufman 2008</td>
<td>75</td>
<td>61</td>
<td>0.02</td>
</tr>
<tr>
<td>Berry 2009</td>
<td>28.2 ± 6.6</td>
<td>11.8 ± 3.6</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Gestell 2009</td>
<td>64</td>
<td>44</td>
<td>0.045</td>
</tr>
</tbody>
</table>

**Clinical significance difficult to evaluate**

Evidence from one moderate-quality and six low-quality studies suggests that MCP use is associated with equivalent or improved ability to ambulate compared to NMCP in real-life settings. Strength of evidence: LOW

### KQ2c. Quality of life

<table>
<thead>
<tr>
<th>Study</th>
<th>MCP</th>
<th>NMCP</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senlen 2009*</td>
<td>69 ± 0.08</td>
<td>65 ± 0.09</td>
<td>0.005</td>
</tr>
<tr>
<td>Gestell 2009</td>
<td>75 ± 0.12</td>
<td>65 ± 0.20</td>
<td>0.007</td>
</tr>
<tr>
<td>Brodkorb 2008*</td>
<td>83</td>
<td>53</td>
<td>NR</td>
</tr>
<tr>
<td>Kohle 2008</td>
<td>81.4 ± 18.3</td>
<td>94.2 ± 26.3</td>
<td>0.007</td>
</tr>
<tr>
<td>Hafner 2009*</td>
<td>78.6</td>
<td>76.0</td>
<td>0.016</td>
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<tr>
<td>Kaufman 2008</td>
<td>81</td>
<td>76</td>
<td>0.02</td>
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<tr>
<td>Hafner 2009*</td>
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<tr>
<td>Hafner 2009*</td>
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</tr>
<tr>
<td>Kaufman 2008</td>
<td>89</td>
<td>90</td>
<td>m</td>
</tr>
<tr>
<td>Kaufman 2008</td>
<td>88</td>
<td>78</td>
<td>0.02</td>
</tr>
</tbody>
</table>

**Two moderate-quality studies and four low quality studies consistently suggests that MCP use is associated with improved quality of life compared to NMCP in real-life settings. Strength of evidence: LOW**
KQ2c. Confidence, daily living, comfort

<table>
<thead>
<tr>
<th>Measure of Confidence</th>
<th>Source</th>
<th>MCP</th>
<th>NMCP</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>QOL daily activities</td>
<td>Berry 2009</td>
<td>368</td>
<td>39.8 ± 9.7</td>
<td>27.1 ± 7.9</td>
</tr>
<tr>
<td>Overall health status</td>
<td>Hafner 2009*</td>
<td>17</td>
<td>84.2</td>
<td>70.4</td>
</tr>
<tr>
<td>Self-care and instrumental activities</td>
<td>Ganzell 2009</td>
<td>100</td>
<td>64</td>
<td>44</td>
</tr>
<tr>
<td>Emotional satisfaction</td>
<td>Hafner 2009*</td>
<td>82</td>
<td>66</td>
<td>0.07</td>
</tr>
<tr>
<td>QOL</td>
<td>Hafner 2009*</td>
<td>78</td>
<td>60</td>
<td>0.12</td>
</tr>
<tr>
<td>Barrier to activities</td>
<td>Kaufman 2008</td>
<td>69</td>
<td>60</td>
<td>0.02</td>
</tr>
<tr>
<td>Mobility</td>
<td>Hafner 2009</td>
<td>17</td>
<td>74.8</td>
<td>63.3</td>
</tr>
<tr>
<td>Social integration</td>
<td>Kaufman 2008</td>
<td>15</td>
<td>70</td>
<td>56</td>
</tr>
<tr>
<td>Satisfaction with personal care</td>
<td>Berry 2009</td>
<td>368</td>
<td>21.6 ± 3.2</td>
<td>17.0 ± 3.3</td>
</tr>
</tbody>
</table>

KQ2c. Patient preferences summary

- Evidence from one moderate quality study and two low quality studies consistently suggests that MCP use is associated with improved activities of daily living as measured by the EQ-5D compared to NMCP in real-life settings. Strength of evidence: LOW
- Evidence from one moderate-quality and one low-quality suggests that MCP use is associated with improved balance confidence compared to NMCP in real-life settings. Strength of evidence: VERY LOW
- Evidence from one moderate-quality and two low-quality studies consistently suggests that MCP use is associated with improved comfort and fall compared to NMCP use in real-life settings. Strength of evidence: VERY LOW
- Evidence from two moderate-quality and two low-quality studies consistently suggests that MCPs are preferred by users compared to NMCPs in real-life settings. Strength of evidence: LOW
KQ3. Results

What is the evidence about the safety of microprocessor-controlled lower limb prostheses?

KQ3. Safety

<table>
<thead>
<tr>
<th>Study</th>
<th>Methodology</th>
<th>MCP</th>
<th>HACF</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hoffer 2009</td>
<td></td>
<td>79.3</td>
<td>91.2</td>
<td>ns</td>
</tr>
<tr>
<td>Kaufmane 2008</td>
<td></td>
<td>69</td>
<td>65</td>
<td>.02</td>
</tr>
<tr>
<td>Barry 2009</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>33.0±7.0</td>
<td>25.2±4.8</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td></td>
<td></td>
<td>32.5±7.0</td>
<td>30.8±7.3</td>
<td>&lt;.0001</td>
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<tr>
<td>Gerson 2009</td>
<td></td>
<td>16</td>
<td>14</td>
<td>ns</td>
</tr>
<tr>
<td>Kaufmane 2008</td>
<td></td>
<td>82.3</td>
<td>66.8</td>
<td>0.003</td>
</tr>
<tr>
<td></td>
<td></td>
<td>93.7</td>
<td>84.9</td>
<td>0.03</td>
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<tr>
<td></td>
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<td>0.7</td>
<td>2.3</td>
<td>NR</td>
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<tr>
<td></td>
<td></td>
<td>97.9</td>
<td>93.4</td>
<td>0.806</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.2</td>
<td>0.5</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>94.7</td>
<td>78.3</td>
<td>0.005</td>
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<td></td>
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<td>88.7</td>
<td>84.6</td>
<td>0.23</td>
</tr>
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<td></td>
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<td>3±4</td>
<td>7±6</td>
<td>.004</td>
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<td></td>
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<td>1±2</td>
<td>5±3</td>
<td>.03</td>
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<tr>
<td></td>
<td></td>
<td>28.0</td>
<td>40.0</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td>40.0</td>
<td>6</td>
<td>NR</td>
</tr>
</tbody>
</table>
KQ3. Conclusions

Evidence from two moderate-quality and one low-quality studies suggests that MCP use is associated with equivalent or improved stumbles or falls compared to NMCP use in real-life settings. Strength of evidence: LOW

Evidence from one moderate-quality and one low-quality studies suggests that MCPs are associated with fewer negative effects on residual limbs compared to NMCPs in real-life settings. Strength of evidence: VERY LOW

Evidence from two low-quality studies suggests that there may be fewer incidences of equipment failure or problems with MCPs compared to NMCPs in real-life settings. Strength of evidence: VERY LOW

Morbidity/mortality: INSUFFICIENT evidence to evaluate.

KQ4. Results

KQ4. What is the evidence that microprocessor-controlled lower limb prostheses has differential efficacy or safety issues in sub populations?
KQ4. Subpopulations

- No evidence to evaluate:
  - Gender
  - Age
  - Psychological or psychosocial morbidities
  - Provider type, setting, or other provider characteristics
  - Payor/beneficiary type

KQ4. Subpopulations

- Hafner 2009: Lower-function MFCL 2 group (n=8)
  - MCP knee associated with improved PEQ scores on satisfaction, ambulation, sounds, and well-being (NS)
  - Mental energy expenditure, confidence while walking, multitasking while walking, and difficulty with concentration improved from 10% to 21% in MFCL-2 individuals
  - Improved falls and stumbles, frustration and embarrassment with falls; stumble frequency
  - Higher-function MFCL-3 group showed results of similar direction as the MFCL-2 group but of higher magnitude
- Seelen 2009 (n=26): First time prosthesis users
  - Improved SF-36 in both first time and total group
  - High potential bias
KQ4. Conclusions

- KQ4. Evidence from one moderate-quality study suggests that benefits in energy, ambulation, safety and quality of life are greater in people at higher baseline function (MFCL-3) but people at lower function (MFCL-2) may also experience some benefits. Strength of evidence: VERY LOW

- Evidence from one low-quality study suggests that quality of life benefits of MCPs may extend to people who are first time prosthesis users. Strength of evidence: VERY LOW

KQ5 Economics

KQ5. What is the evidence of cost implications and cost-effectiveness of microprocessor-controlled lower limb prostheses? Including consideration of:

a. Costs (direct and indirect) and cost effectiveness
b. Short term and long term
c. Ongoing maintenance and replacements for the prosthetic
KQ5. Three cost effectiveness studies

- Gerezell 2009 (funded by manufacturer)
  - Population: 100 members with traumatic injury from workers compensation database
  - Health care and societal (health care plus transportation, overnight stays, informal care, productivity)
  - Data sources: survey, administrative data, expert panel, market values, national fee schedules, published literature

- Seelen 2009 (not funded by manufacturer)
  - 26 people receiving amputation care at a rehabilitation center, 16/26 traumatic
  - Societal perspective: health care plus patient/family, productivity costs
  - Data sources: patient survey (recall of NMCP utility), administrative data, Dutch Manual for Economic Evaluations

- Brodkorb 2008 (partial financial support from manufacturer)
  - 20 people from prosthetic clinics who had switched from NMCP to MCP
  - Health care perspective
  - Data sources: interviews with patients of current use of C-leg and hypothetical use of NMCP; interviews with patients’ prosthetists; interviews with manufacturers (cost)

<table>
<thead>
<tr>
<th>KQ5: Economic studies</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Health care costs</td>
</tr>
<tr>
<td>Transportation and overnight stay, prosthetic care and fitting, maintenance and repair</td>
</tr>
<tr>
<td>Prosthetic cost and associated clinical services</td>
</tr>
<tr>
<td>Prosthetic wear</td>
</tr>
<tr>
<td>GP visits, specialist visits, drugs, hospital stay, hospital stay, informal caregivers salary, productivity loss</td>
</tr>
<tr>
<td>Duration of problems for patients, prosthetics time to address problems, production hours for prosthetics</td>
</tr>
<tr>
<td>Baseline</td>
</tr>
<tr>
<td>Use of expert opinion, baseline differences in daily prosthesis use (higher in MCP group), generalizability</td>
</tr>
<tr>
<td>Interviews as source data, MCP group dissociated from NMCP, hypothetical assessment of EQ-5D, retrospective analysis of NMCP</td>
</tr>
<tr>
<td>Economic evaluation</td>
</tr>
<tr>
<td>LoE III, moderate quality economic evaluation methods</td>
</tr>
</tbody>
</table>
Costs

- No studies using US data
  - European studies suggest that MCP purchase and fitting is more expensive than NMCP
  - European studies suggest that cost effectiveness analyses using societal perspective favor MCP
    - Health care: prosthesis and fitting, clinical costs
    - Societal: health care plus indirect, patient, family, and productivity costs
- Insufficient evidence to evaluate long-term costs

Summary and limitations
Summary

- Strength of evidence for all conclusions is LOW or VERY LOW
- Generalizability to larger population of people with lower limb loss (e.g., vascular etiology) unknown
- Evidence on MCP knee use in real-world settings consistently suggests equivalence or small improvements associated with MCP knee use compared to NMCPs
  - Clinical significance difficult to evaluate
- Insufficient evidence to evaluate MCP feet; outcomes beyond one year; costs in US settings

Limitations of current evidence

- Validated, patient-centered measures of MCP use in real-world settings
- Prospective studies of the effect of MCPs on health and function over time
- Study participants of more broadly defined populations (e.g., women, vascular etiology)
- Cost effectiveness of MCP use in US setting
HTCC Coverage and Reimbursement Determination
Analytic Tool

HTA’s goal is to achieve better health care outcomes for enrollees and beneficiaries of state programs by paying for proven health technologies that work.

To find best outcomes and value for the state and the patient, the HTA program focuses on these questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

**Principle One: Determinations are Evidence based**

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective as expressed by the following standards.

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

**Principle Two: Determinations result in health benefit**

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms.

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

---

1 Based on Legislative mandate: See RCW 70.14.100(2).
2 The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm
3 The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm
Using Evidence as the basis for a Coverage Decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. **Availability of Evidence:**
   Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. ** Sufficiency of the Evidence:**
   Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence using characteristics such as:
   - Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
   - the amount of evidence (sparse to many number of evidence or events or individuals studied);
   - consistency of evidence (results vary or largely similar);
   - recency (timeliness of information);
   - directness of evidence (link between technology and outcome);
   - relevance of evidence (applicability to agency program and clients);
   - bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

<table>
<thead>
<tr>
<th>Not Confident</th>
<th>Confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.</td>
<td>Very certain of evidentiary support. Further information is unlikely to change confidence</td>
</tr>
</tbody>
</table>

3. **Factors for Consideration - Importance**
   At the end of discussion at vote is taken on whether sufficient evidence exists regarding the technology’s safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:
   - risk of event occurring;
   - the degree of harm associated with risk;
   - the number of risks; the burden of the condition;
   - burden untreated or treated with alternatives;
   - the importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
   - the degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
   - value variation based on patient preference.

---

4 Based on GRADE recommendation: [http://www.gradeworkinggroup.org/FAQ/index.htm](http://www.gradeworkinggroup.org/FAQ/index.htm)
<table>
<thead>
<tr>
<th>Organization</th>
<th>Date</th>
<th>Outcome</th>
<th>Evidence Base</th>
<th>Grade / Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMS National Policy</td>
<td>2011</td>
<td>The Centers for Medicare and Medicaid Services have no published National coverage determinations (NCD) for MCPs. A relevant local coverage determination (LCD) (LCD 11453) by CMS contractor Noridian Administrative Services has two relevant excerpts that specify coverage of prostheses beyond &quot;basic&quot;, including MCPs, are to be considered for coverage based on participant function of 3 or above: 1. “Basic LOWER extremity PROSTHESES include a single axis, constant friction knee. Other prosthetic knees are considered for coverage based upon functional classification. … A fluid, pneumatic, or electronic knee (L5610, L5613, L5614, L5722-L5780, L5814, L5822-L5840, L5848, L5856, L5857, L5858) is covered for patients whose functional level is 3 or above.” 2. “Basic LOWER extremity PROSTHESES include a SACH [solid ankle cushion heel] foot. Other prosthetic feet are considered for coverage based upon functional classification. … A microprocessor-controlled ankle foot system (L5973), energy storing foot (L5976), dynamic response foot with multiaxial ankle (L5979), flex foot system (L5980), flex-walk system or equal (L5981), or shank foot system with vertical loading pylon (L5987) is covered for patients whose functional level is 3 or above.”</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Centers for Medicare and Medicaid Services</td>
<td></td>
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<tr>
<td>Medicare Prosthetic Benefit, IOM 100-2, Chapter 15, Sections 120 and 130 [CMS, 2011]</td>
<td></td>
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</tr>
<tr>
<td>Guidelines – WA HTA</td>
<td></td>
<td>One guideline addressed rehabilitation of lower limb amputation. In the guideline, a microprocessor knee joint is listed as one of the prescription options for a transfemoral amputation; no specific guidance is given for the use or prescription of the microprocessor-controlled prosthesis. No guidelines were found that specifically addressed microprocessor-controlled prostheses for lower limbs.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>National Guideline Clearinghouse (NGC)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Guidelines – WA HTA</td>
<td></td>
<td>No guidelines specifically addressed microprocessor-controlled prostheses for lower limbs from the National Institute for Health and Clinical Excellence (NICE), which provides guidance on health technologies and clinical practice for the National Health Service in England and Wales.</td>
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<tr>
<td>National Institute for Health and Clinical Excellence</td>
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</tr>
</tbody>
</table>
HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document: What are the key factors and health outcomes and what evidence is there?

<table>
<thead>
<tr>
<th>Microprocessor-controlled Lower Limb Prostheses</th>
<th>Safety Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Outcomes</td>
<td>Safety Evidence</td>
</tr>
<tr>
<td>Mortality</td>
<td></td>
</tr>
<tr>
<td>Morbidity</td>
<td></td>
</tr>
<tr>
<td>Fewer Stumbles or Falls</td>
<td></td>
</tr>
<tr>
<td>Fewer Negative Effects on Residual Limbs</td>
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<tr>
<td>Equipment Failure</td>
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<tr>
<td>Other Adverse Events</td>
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</tr>
<tr>
<td><strong>Efficacy – Effectiveness Outcomes</strong></td>
<td>Efficacy / Effectiveness Evidence</td>
</tr>
<tr>
<td>Energy / Cognitive Improvements</td>
<td></td>
</tr>
<tr>
<td>Improved Ability to Ambulate</td>
<td></td>
</tr>
<tr>
<td>Improved Quality of Life</td>
<td></td>
</tr>
<tr>
<td>Improved Activities of Daily Living</td>
<td></td>
</tr>
<tr>
<td>Improved Balance Confidence</td>
<td></td>
</tr>
<tr>
<td>Improved Comfort and Fit</td>
<td></td>
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<tr>
<td>MCPs vs. NMCPs</td>
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<tr>
<td>Improved Perceived Perceptions by Others</td>
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<tr>
<td>Quality of Life</td>
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<td>Patient Satisfaction</td>
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<tr>
<td>Other Patient Outcomes</td>
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<tr>
<td><strong>Special Population / Considerations Outcomes</strong></td>
<td>Special Population Evidence</td>
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<tr>
<td>Higher Baseline Function</td>
<td></td>
</tr>
<tr>
<td>First Time Prosthesis Users</td>
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<td>-----------------------------</td>
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<tr>
<td><strong>Cost</strong></td>
<td><strong>Cost Evidence</strong></td>
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<tr>
<td>Purchase and Fitting</td>
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<td>Total Health Care Costs</td>
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<td>Societal Costs</td>
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<td>Direct and indirect</td>
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<tr>
<td>- Short terms</td>
<td></td>
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<tr>
<td>- Over expected duration of use</td>
<td></td>
</tr>
<tr>
<td>Repeats or Add-ons</td>
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</tr>
<tr>
<td>Cost Effectiveness</td>
<td></td>
</tr>
</tbody>
</table>
Clinical Committee Evidence Votes

First voting question
The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

**Is there sufficient evidence under some or all situations that the technology is:**

<table>
<thead>
<tr>
<th></th>
<th>Unproven (no)</th>
<th>Equivalent (yes)</th>
<th>Less (yes)</th>
<th>More (yes)</th>
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<tbody>
<tr>
<td>Effective</td>
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</tr>
<tr>
<td>Safe</td>
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<tr>
<td>Cost-effective</td>
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</tbody>
</table>

**Discussion**
Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

**Second vote**
Based on the evidence about the technologies’ safety, efficacy, and cost-effectiveness, it is

- Not Covered
- Covered Unconditionally
- Covered Under Certain Conditions

**Discussion Item**
Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.
Clinical Committee Findings and Decisions

Next Step: Cover or No Cover
If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions
If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   • Refer to evidence identification document and discussion.
   • Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   • Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
   • What are the known conditions/criteria and evidence state
   • What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Efficacy Considerations:
• What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
   o Direct outcome or surrogate measure
   o Short term or long term effect
   o Magnitude of effect
   o Impact on pain, functional restoration, quality of life
   o Disease management
• What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
• What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
• What is the evidence of the magnitude of the benefit or the incremental value
• Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
• For diagnostic tests, what is the evidence of a diagnostic tests’ accuracy
   o Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
• Does the use of the technology result in better sensitivity and better specificity?
• Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
• Does use of the test change treatment choices
**Safety**
- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening.
- Other morbidity concerns
- Short term or direct complication versus long term complications
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

**Cost Impact**
- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

**Overall**
- What is the evidence about alternatives and comparisons to the alternatives
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?