Washington State Health Care Authority, HTA Program
FInal Key Questions
Microprocessor-controlled lower limb prosthetics

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.