ÖSSUR®

LIFE WITHOUT LIMITATIONS

POWER KNEE™

Reimbursement Guide

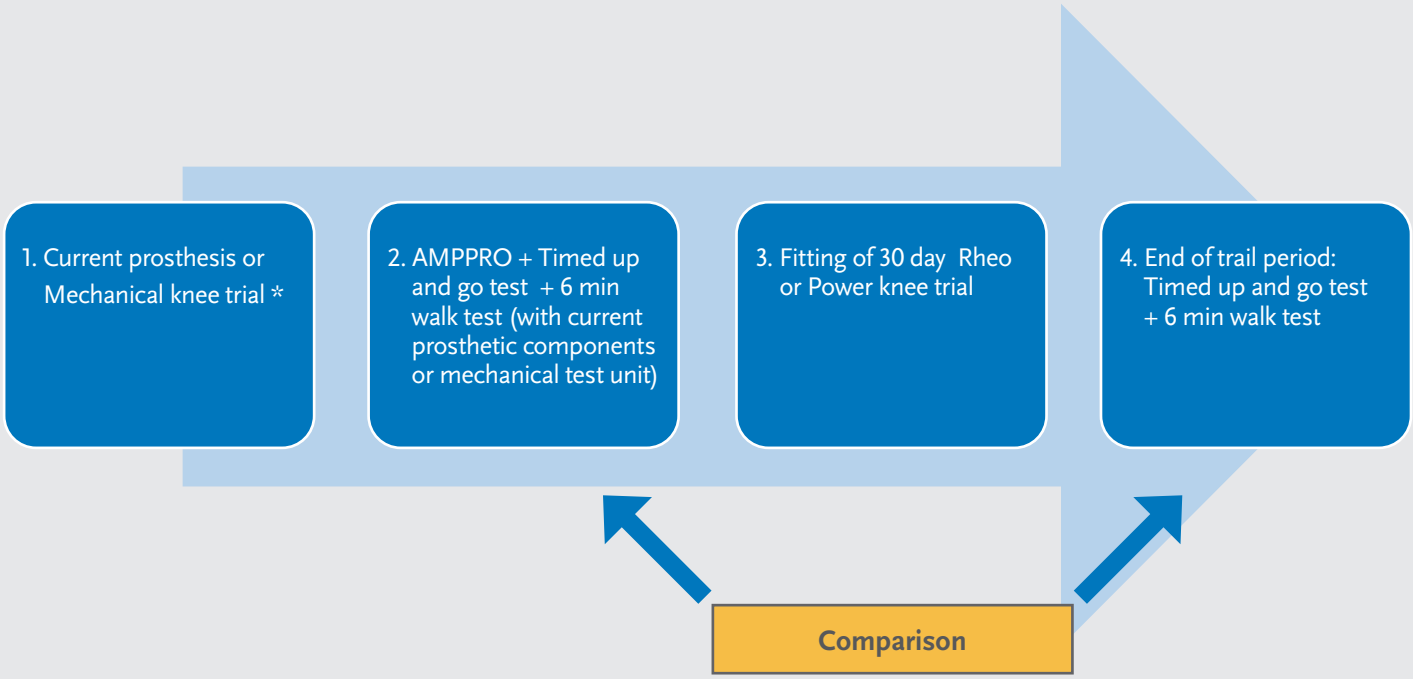
MATCHING THE PATIENT & PRODUCT

Every patient has unique clinical needs and every product offers unique clinical outcomes. Making sure that you map the two to each other is essential if you want (a) a happy and functional patient, and (b) to have a successful outcome for your funding application. The next checklist maps Power Knee's functional benefits to your patient's clinical needs, helping ensure that they're aligned.

PATIENT TO PRODUCT CHECKLIST

Patient Clinical Issue	Power Knee Function & Researched Based Evidence
Comorbidity of spine or sound limb with: • Impaired hip extension, or • Impaired quadriceps function • Impaired knee function/causes pain • Impaired ankle function/causes pain • Impaired foot function/causes pain • Impaired Spinal pain/ROM	Motor-powered flexion and extension: • allow users with impaired hip or sound side quad/knee ankle or foot function to walk more symmetrically. • decrease need to aggressively walk over toe of prosthetic foot to initiate knee flexion.
Comorbidity of upper body that impairs: • Arm function/causes pain • Shoulder function/causes pain	Motor-powered flexion and extension: • allow users with upper-body impairments to exit chairs without having to rely on their arms and shoulders as much as passive devices.
Documented fall history	Motor-powered stance phase stability actively supports user's body weight. Motor-powered swing phase pushes prosthetic foot through obstacles (e.g. rugs, grass, sand) and prevents prosthetic toe from "catching" on underlying terrain, something that passive MPKs and mechanical knees can't.
Inability to walk far enough without stopping	Motor-powered flexion and extension reduce the amount of force and energy required by passive MPK's and mechanical knees to activate appropriate knee function.
Difficulty walking up and down inclines	Motor-powered extension permits users to ascend ramps more easily, as the user does not have to physically generate extension momentum in order for the knee to swing through to full extension, something that passive MPKs and mechanical knees can't do. Motor-powered flexion permits users to descend ramps in a controlled, safe manner.
Gait deviations: • Circumduction/little-no prosthetic knee bend • Vaulting • Exaggerated hip movement during knee extension (i.e. kicking prosthetic foot forward)	The Power knee`s motor initiates knee flexion and extension, preventing "stiff leg" walking, to obtain adequate foot-ground clearance. Motor-powered knee extension decreases need for user to kick prosthesis forward to obtain full extension, promoting more symmetrical gait.
Inability to get out of chair independently	Motor generates force that can actively lift users with arm and/or shoulder deficits out of chair.

CLINICAL TESTS AND TRIALS



*Mechanical knee component received as trial unit or current prosthesis (private funding, public sector or medical scheme)

ÖSSUR ACADEMY

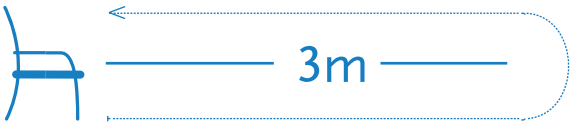
PROTOCOL TIMED UP AND GO TEST

DESCRIPTION

The Timed Up & Go test measures (in seconds) the time that the user takes to get up from a chair, walk 3 meters comfortably, turn around and walk back to sit down on the chair. The user may use his own walking aid and / or orthotic device, but there should be no physical assistance given. The test is simple to use and practical.

EQUIPMENT NEEDED/ REQUIRED

- Quiet space with flat terrain
- Chair with arm-rests and a height between 45-47 cm
- Stopwatch
- 1 Cone
- Users aid
- Measuring tape to measure 3 meters



EXECUTION

- Inform the user prior to the test that the first time is for practice. Only the second run is timed.
- The user sits on a chair with his back resting against the backrest. At the time that the test taker gives the go-ahead, the user can stand up (choosing whether or not to use the armrests).
- The time starts when the user takes off his back from the backrest.
- The user then walks at a self-selected speed without running to the turning point (cone).
- The user turns around at the cone (to the left or to the right) and walks back to the chair and sits down.
- Time stops when the user's buttocks reach the seat surface.
- The therapist is required to walk with the user but must avoid encouraging of the user.

ÖSSUR ACADEMY

PROTOCOL FOR 6 MINUTE WALK TEST

DESCRIPTION

The 6 Minute Walk Test assesses a subject's gait and is a way of measuring walking speed and endurance of a prosthetic user. The user will walk for the duration of 6 minutes at a self-selected, as fast as possible but comfortable speed. The outcome of the test is the total covered distance (in meters) during these 6 minutes. The subject is allowed to use walking aids during the test.

EQUIPMENT NEEDED/ REQUIRED

- Flat walking surface with a course of at least 30 meter
- Measuring tape
- Stopwatch
- Cones

EXECUTION

- The test is executed at a flat, continuous course of at least 30 meters.
- If necessary, the test can be executed outdoor, as long as it is flat. For the sake of comparability, the same course setup has to be used for all subjects. ● ⟷ ● 30 meter
- Mark the course with cones at a minimal distance of 30 meters.
- The subject receives the instruction that he is going to walk for 6 minutes and that his speed should be high enough to cover as much distance as possible, without running.
- Time starts when the subject is at the beginning of the course and the therapist/CPO gives the start signal.
- The therapist/CPO walks behind the user in order not to influence the walking speed.
- After one minute, the therapist/CPOP gives the instruction: 'You have walked one minute, five minutes left'.
- This is repeated every minute.
- 15 seconds before the end of the test, the subject receives the instruction: '15 seconds to go, please come to an immediate and full stop when I say so'. Directly after the stop signal, the therapist/CPO measures and notes down the covered distance in meters.
- During the test, the subject is allowed to change walking speeds or even come to a full stop; time will, however, continue.
- During each measurement, the subject should wear the same shoes and should receive the same encouragement

SAMPLE PROSTHETIST MOTIVATION

Patient: _____

ID number: _____

Funder: _____

Funder reference: _____

General:

- ✓ Patient gender and age
- ✓ Date of amputation
- ✓ Weight
- ✓ Date of evaluation
- ✓ Is the amputee currently wearing a prosthesis?
- ✓ Patient referred by

Comorbidities:

Elaborate on any comorbidities and patient-stated symptoms that could affect ambulation or rehabilitation potential:

- Other acquired conditions (Diabetes, Cardiac conditions, Vascular conditions etc.)

Surgeries:

Surgeries and patient-stated symptoms that could affect ambulation or rehabilitation potential

Living Arrangements:

- o Geographical area description where the patient lives
- o Are there stairs and inclines at the residence?
- o Electricity supply
- o With whom does the patient reside?

Current Functions:

Is the patient currently a prosthetic user?
For what activities are the prosthesis currently used?

Employment:

- o Description of duties
- o Vocational demand (Stakeholder visits, site inspection, long distance ambulation through different terrains etc.)
- o Physical activity demand (hills, stairs, ladder climbing, lifting objects, navigation in narrow spaces etc.)
- o Exposure to fluids & liquids
- o Previous falling incidences recorded at work

Recreational:

- o Household activities and family responsibilities
- o Aids of daily living (cooking, cleaning, general maintenance etc.)
- o Community involvement
- o Sporting activities

Medical/Physical:

Describe the following:

- Patient`s physical condition description
- Motivation to walk
- Sensation on upper and lower limbs including amputation site
- Balance with and without prosthesis
- Cognition unimpaired or impaired. If impaired provide a detailed description.

Amputation and Prosthetic History:

- Amputation type presented by patient
- Cause of amputation
- Date of amputation

Current Prosthesis:

Patient has the following prosthesis:

- Endo or Exo-skeletal prosthesis
- Socket design
- Suspension method
- Components: prosthetic knee and foot.
- Warrantee status of major components (knee and foot)

The following problems, concerns, and significant adjustments were reported:

- Socket fitting troubleshoot (weight gain/loss, stump revision, muscle atrophy etc.)
- Suspension loss
- Skin breakdown
- Failure of current prosthetic knee and foot
- Erroneous / inadequate previous prosthetic prescription

Residual Limb Evaluation:

- Position and condition of scars
- Abrasions/Blisters
- Soft tissue condition
- Current contractures
- Skin graft or muscle flap
- Additional surgery: stump revision, neuroma removal

Contralateral Limb And Upper Limb Evaluation:

- Reported chronic pain
- Position and condition of scars
- Abrasions/Blisters
- Soft tissue condition
- Current contractures
- Skin graft or muscle flap
- Deformities reported

Gait Evaluation:

- Assistive devices used (if any)
- How was assessed observed? Any instrumentation used or only visually
- Circumduction gait (include possible reason)
- Vaulting (include possible reason)
- Exaggerated hip movement i.e., kicking prosthetic foot forward (include possible reason)
- Trendelenburg gait

Activity level:

The AMPPRO, TUG and 6MWT was performed on Mr. xxxx on YY/YY/YYYY and again after the 30 day trial period ended ZZ/ZZ/ZZZZ. The results are indicated below:

Date of test	Knee and foot component used	AMPPRO or AMPnoPRO score	K-level (1-4)	Timed up and go test (TUG)	6 minute walk test (6MWT)	Test conductor	Signature

Record the 3 outcome tests to get a baseline score as indicated in the "clinical tests and trials" section. Thereafter fit the proposed prescription's trial unit and record the score after 30 day trial period ends.

AMPPRO and AMPnoPRo score [1]:

	AMPPro	AMPnoPro
K0	N/A	0-8
K1	15-26	9-20
K2	27-36	21-28
K3	37-42	29-36
K4	43-47	37-43

1. *Gailey RS, Roach KE, Applegate EB, et al. The amputee mobility predictor: an instrument to assess determinants of the lower-limb amputee's ability to ambulate. Arch Phys Med Rehabil. 2002;83(5):613-627.*

The patient's activity level is reported as K_ . Further describe the patients activity level as described below:

K LEVELS	DESCRIPTION
K0	The patient does not have the ability or potential to move or securely transfer with/without mobility aid. The prosthesis does not affect the quality of life or mobility.
K1	The patient has the ability or the potential use of the prosthesis for transfer and even movement on flat surfaces. Typical for in-house movement.
K2	The patient has the ability or potential to move and climb over lower obstacles such as curbs, stairs or uneven surfaces. Typical of restricted movement in the community. 27-36
K3	The patient is able to overcome most of the obstacles, in therapeutic or sports activity that requires the use of prosthesis. Prosthesis provides a higher level of activity over basic locomotion.-42
K4	The ability or potential to move that goes beyond the basic skills of walking, with a high level of stress, energy, or impact force on the foot. Typically for children, young adults and athletes. 43-47

RECOMMENDATION:

Prosthetic Recommendations:

Include the following description of the recommended prosthesis:

- Endo or Exoskeletal prosthesis
- Socket design (test socket, flexible inner socket, brim design etc.)
- Re-enforcement materials used in the socket design (carbon fiber, nylglass etc.)
- Prosthetic suspension method including liner
- Prescribed components: prosthetic knee and foot.
- Warrantee included for major components

Prosthetic Design:

Why is the patient indicated for new prosthesis?

Rationale for recommendations may include:

- Residual limb changes
- Irreparable damage to socket and components
- Normal wear and tear
- New prosthetic user

A microprocessor knee is medically necessary for Mr. XX due to his ADLs and functional level.

Include clinical reasons for the prescription of the POWER knee:

- ✓ The microprocessor knee will offer varied resistance based on cadence and will continually monitor the gait pattern for appropriate response. The knee will offer enhanced stability and stumble control in the event of tripping or losing balance while ambulating. This significantly decreases the risk of falling and will increase his confidence while ambulating. These features will ensure safety when ambulating in crowded or confined areas.
- ✓ The powered flexion and extension assist control feature of the Össur Power Knee allows users with spine comorbidities or impaired hip or sound side quad/knee/ankle or foot function to walk more symmetrically, reducing additional stress on sound limb resulting from asymmetrical gait. This feature also decreases the need to aggressively walk over the toe of a prosthetic foot to initiate knee flexion, decreasing hyper-lordosis commonly seen in above knee amputees.
- ✓ It allows users with upper-body impairments to exit chairs without having to rely on their arms and shoulders as much as passive devices, reducing cumulative trauma to the upper body.
- ✓ The motor-powered stance phase stability actively supports the user's body weight, and reduces the force and energy required to operate the prosthesis, enabling the patient to walk farther without fatigue.
- ✓ Motor-powered swing phase increases toe clearance and can push through obstacles such as rugs, grass, etc. that would otherwise cause a patient to fall. This knee feature is medically necessary for Mr. XX due to a history of spondylolysis, injured shoulder, limited ROM of the sound hip, fatigue during long distance ambulation, and fall history.
- ✓ Mr. XX has adequate cardiovascular reserve and cognitive learning ability to master this higher level technology and has a history of microprocessor knee use. He has the need for daily long distance ambulation of 400 meters or greater at variably rates when participating in work and recreational activities.

A favourable outcome for the prosthetic application for Mr. XX will be welcomed.

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