

Genium[®]

Medical Necessity Template

To use when documenting in your patient's contemporaneous medical record.

1. PATIENT'S BACKGROUND

Describe date of amputation, cause of amputation and course of treatment and goals

Describe rehabilitation process - example: _____ is working hard to reach full rehabilitation potential. _____ is diligent about attending physical therapy appointments but is also mindful to not overextend and injure ___self so ___limits strenuous activities and allows for recovery time. _____ is prescribed _____ to manage pain in low back, knees, hip, ankle, foot and residual limb and also takes _____ for phantom pain. _____ has gained _____ pounds since the accident due to the decrease in ___ physical activity. (list any pertinent health issues reported by patient)

2. DAILY ACTIVITIES BEFORE AND AFTER AMPUTATION

Discuss functional level and daily activities prior to amputation and prior to the condition causing the amputation. These should include as many community ambulation type activities as possible. Describe how patient's lifestyle has changed since the amputation/cause of the amputation. Describe which reasonable activities he/she would like to get back to. Sometimes patients have a difficult time remembering what they used to do. Try using our activity chart. State the patient's desire and motivation to get back to these activities and what it would take (Physical Therapy, etc.) to assure success.

3. CURRENT PROSTHETIC PRESCRIPTION

If applicable, describe the current prosthesis and problems he/she is having with it. How is this affecting home life, work, exercise, and therapeutic activities? How is this affecting sound side joints and spine?

4. PROSTHETIC REQUIREMENTS

___ must return to work (describe work) and is also anxious to participate in family functions with family. In other words, _____ would like to safely perform desired daily activities. Genium significantly improves overall performance in activities of daily living and when compared to able-bodied subjects the difference was not statistically significant.

5. RISK OF FALLING AND NEED FOR STABILITY

Describe patient's history of falls, stumbles and instability.

_____ 's physicians have recommended the Genium microprocessor-controlled prosthetic knee because there are multiple published peer-reviewed studies that demonstrates a significant reduction in falls and stumbles when a microprocessor knee is compared to a standard prosthesis.

The Genium provides resistance if the toe catches during midswing. As soon as the knee stops flexing and maximum heel rise is achieved, this feature is immediately activated; thus, if at any point the toe catches a supporting resistance is available. This allows patients enough time to bring their

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contralateral side through to catch themselves, thus preventing a fall and keeping it at a controlled “stumble.” This resistance is angle dependent, meaning it will provide additional resistance compared to normal stance phase resistance. The further the knee bends (or the further the patient is into the fall) the higher the resistance that will be provided.

6. LONG DISTANCE WALKING AND VARIABLE CADENCE FOR COMMUNITY AMBULATION

It is the qualified opinion of this practitioner that _____ has the ability to ambulate with varied cadence when using the Genium. This assessment of performance and ability makes it clear that _____ will dramatically benefit from using these prosthetic components.

The Genium utilizes a complex sensory system (including a gyroscope and accelerometer) along with sophisticated rule sets to mimic natural gait more closely. The appropriate resistances are calculated using multimodal proprioceptive inputs (including knee angle, knee angular velocity, thigh angle, thigh angular velocity, and ground reaction force components). As a result, the Genium is able to monitor 500 knee motion possibilities at any given time.

The Genium's pre-flex function reduces the perception of having to “climb over the prosthesis” at loading response, reduces braking forces during level walking making it easier to “ride into the knee” and use stance flexion for shock absorption. Improved swing control provides more consistent knee swing flexion (=toe clearance) across all walking speeds.

Genium provides stability in crowds because of its ability to reliably transition from stance into swing phase while taking small and shuffling steps. The Genium also offers an optimized swing phase control with a nearly physiologic swing knee flexion angle of 64° independent of walking speed. This provides improved toe clearance in slower walking speeds as well as timely shank swing in higher walking speeds – that patient doesn't have to wait for a lagging shank to swing forward

7. SLOPE AMBULATION / UNEVEN TERRAIN

Describe difficulties encountered when negotiating slopes / uneven terrain and/or considerable compensatory movements when walking on slopes / uneven terrain (uneven terrain = permanent switch between inclines and declines)

Genium improves self-selected walking speed and quality of slope descent (decreased reliance on handrail use), and provides increased knee flexion at initial contact and in swing phase (=toe clearance) during slope ascent and descent. Its pre-flex function also supports more physiologic and symmetric slope descent with higher prosthetic side weight bearing and step length.

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8. STAIR NEGOTIATION

Describe difficulties to negotiate stairs and/or considerable compensatory movements when walking on stairs

Descending Stairs: Genium mean knee flexion moment was significantly increased compared to C-Leg when descending stairs, with resulting decrease in sound-side ground reaction forces.

Ascending Stairs: The conventional method for ascending stairs with a prosthetic knee is to take 2 steps at a time with the sound-side limb and lift the prosthetic side to the level of the same step. With the Genium, the subjects ascended stairs step-over-step. When step-over-step (Genium) was compared to the conventional method (C-Leg), gait parameters that more closely approximate those seen in unaffected users (including more physiologic movement of both the sound side and affected side, reduced loading on the sound side knee joint, and more physiologic usage of the residual limb) were significant in favor of Genium .

Genium allows more consistent positioning of the foot on the stair and increased prosthetic side weight-bearing during stair descent. Genium allows the ability to walk upstairs step over step with unloading of the sound knee and more natural appearance. Greater self-reported ease of stair ascent and descent are also proven.

9. OBSTACLE NEGOTIATION

The Genium allows for nearly normal stepping over bigger obstacles with the prosthetic leg first – the knee can be normally flexed, and the prosthesis be moved over the obstacle like taking a long step. Genium is safe while loaded bent past the obstacle. All other microprocessor knees require that the patient has to move the extended/stiff prosthetic leg around obstacle using circumduction, which is associated with a high risk of catching the toes, stumbling and falling. The Genium also enables nearly normal stepping over bigger obstacles with the sound leg first. Using this function of Genium, the trailing prosthetic leg can be normally bent and moved over the obstacle. All other microprocessor knees require that the patient moves the trailing extended/stiff prosthetic leg around the obstacle using circumduction or to hop forward on the sound leg and drag the stiff prosthetic leg over the obstacle. Both ways are associated with a substantial risk of catching toes, stumbling, and falling.

10. DIFFICULTY WALKING WITH HEAVY FOOTWEAR

Describe difficulty patient has walking with heavy footwear (e.g. hard-toed shoes or boots) on a regular basis (if pertinent).

Genium's swing control is able to compensate for additional distal weight and provide sufficient knee swing flexion (=toe clearance).

11. AMBULATE IN CONFINED AREAS OR TAKE SMALL STEPS

Describe activities that require walking in confined areas and/or taking small steps and difficulties.

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Genium provides more reliable swing release and swing knee flexion (=toe clearance) in small steps. Genium had greater self-reported ease of walking with small steps and executing ADLs with multi-directional movements.

12. BACKWARD WALKING

Describe difficulties, compensatory movements, and falls experienced by patient when taking steps backward.

Genium's patented Inertial Motion Unit (IMU) provides safety and stability when the amputee is forced to step backwards (such as when opening a door). Traditional microprocessor knees do not accommodate backward stepping, because the knee is programmed to go into swing when the toe is loaded. This may cause the knee to collapse if a backward step is taken.

13. INTUITIVE STANDING

Describe patient's need to stand for extended periods of time on a regular basis and the difficulties encountered.

Genium allows the user to intuitively stand on a flexed and stable knee when on level, uneven, or inclined surfaces (e.g. ramps and hills). Maintaining safety and balance while standing is critical for amputees. Contrast this to traditional prosthetic knees designed for limited community ambulators, which require the user to extend the hip to stabilize the knee or cognitively ensure that their center of mass stays ahead of their knee axis to prevent unexpected buckling of the prosthetic knee. Unlike mechanical knees, Genium offers clinicians a range of programmable stance stability options that can be customized to support each patient's individual capabilities.

14. GAIT SYMMETRY AND UNLOADING OF THE SOUND LIMB AND SPINE

Describe pain in the joints of the sound limb and/or low back pain.

Genium allows for a more natural gait, greater gait symmetry, and makes it easier to ride into the knee and use knee stance flexion for shock absorption. Increased symmetry of gait is an indicator of more even load distribution and may thus reduce short- and long-term comorbidities of the sound limb and spine.

15. RUNNING FEATURES

Describe situations where patient has to pick up speed significantly and the difficulties encountered. Walk2Run feature: The Genium knee joint is able to detect transition from walking to running automatically while in basic mode and reacts accordingly, by switching into a larger swing phase angle suited for running (higher swing flexion angle, decreased swing extension resistance, with no Preflex

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behavior). This innovative Walk2Run mode is ideal for running short distances and start and- stop running such as across a street, down the hall or to catch a bus.

16. WATER ACTIVITIES

Describe water activities patient will partake in, keeping in mind that some payers do not cover microprocessor knees for leisure and sporting activities. If the insurance has restrictions, focus on work, exercise, home maintenance and therapeutic activities.

Genium carries an IP rating of 67 which means it can be exposed to brief rain showers and come into short-term contact with splashed water.

17. DIFFICULTY STANDING AND SITTING

Describe difficulty sitting and standing

Stand more easily: The Genium can tell when the user is standing and automatically resists further flexing. This translates into being more relaxed while standing, saving energy and taking stress away from the sound side – even on inclines and uneven surfaces.

Sit more naturally: If the user sits for more than 2 seconds (with thigh parallel to the ground and minimal weight on the leg) the Genium reduces resistance to take a more natural position and switches to an energy saving mode.

18. PATIENT'S TEST RESULTS

After briefly trialing the Genium, _____ experienced significant improvements in the following:

- Natural mobility
- Increased self-selected walking speeds
- Fatigue reduction
- Overall decrease in pain of the residual limb and sound side
- Confidence and increased stability when navigating hills and ramps
- Confidence and increased stability when walking on uneven surfaces

Though the patient reports experiencing reduced effort and immediate improvements in balance and walking patterns, we must also consider the potential long-term benefits the patient may experience. By providing the user with a device that decreases the metabolic cost and restores normal walking mechanics, we can expect that this will result in a long-term decrease in degenerative joint disease, low back pain, instability, and risk of fall.

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19. WHY THE GENIUM IS SUITABLE FOR THIS PATIENT (summarize patient's need for the and why other MPKs will not be sufficient -see "MPK Compare")

The Genium provides a level of function, safety and security for _____ amputees that other microprocessor knees cannot provide. The safety provided by Genium includes stability while walking on level ground; walking in confined spaces; navigating obstacles, backward walking; intuitive standing; sit-to-stand and stand-to-sit activities; sufficient toe clearance for safe navigation on uneven terrain, slopes and stairs; and includes the highly studied stumble recovery technology.

20. RECOMMENDATION

In summary, the Genium Microprocessor Knee has been selected for _____ as the best device that meets _____ needs as a (amputation level) amputee. The Genium's stability will reduce pain, fatigue and enable _____ to improve activities of daily living, and fully participate in _____ life and most importantly, return to work.