

## Genium® X3

# 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: (Patient name) is working hard to reach (his/her) full rehabilitation potential. (He/She) is diligent about attending physical therapy appointments, but is also mindful to not overextend and injure (his/her)self so (he/she) limits strenuous activities and allows for recovery time. (Patient name) is prescribed \_\_\_\_\_ to manage pain in low back, knees, hip, ankle, foot and residual limb. (He/She) also takes \_\_\_\_\_ for phantom pain. (He/She) has gained \_\_\_\_\_ pounds since the accident due to the decrease in his 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 (his/her) 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

(Patient name) must return to work (describe work) and (he/she) is also anxious to participate in family functions with (his/her) family. In other words (he/she) would like to safely perform (his/her) desired daily activities. Genium X3 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.

(Patient Name)'s physicians have recommended the Genium X3 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 X3 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 (Patient Name) has the ability to ambulate with varied cadence when using the Genium X3. This assessment of performance and his ability makes it clear that (he/she) will dramatically benefit from using these prosthetic components.

The Genium X3 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 X3 is able to monitor 500 knee motion possibilities at any given time.

The Genium X3'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 X3 provides stability in crowds because of its ability to reliably transition from stance into swing phase while taking small and shuffling steps. The Genium X3 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 X3 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 X3 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 X3) 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 X3.

Genium X3 allows more consistent positioning of the foot on the stair and increased prosthetic side weight-bearing during stair descent. Genium X3 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 X3 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 X3 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 X3 also enables nearly normal stepping over bigger obstacles with the sound leg first. Using this function of Genium X3, 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 X3'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 X3 provides more reliable swing release and swing knee flexion (=toe clearance) in small steps. Genium X3 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 X3'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 X3 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 X3 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 X3 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. If providing an X3, describe patient's routine running activities.

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Walk2Run feature: The Genium X3's 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 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.

The X3 has a Running Mode in addition to the Walk-to-Run function provided by the Dynamic Stability Control feature. The Running Mode is selected via remote control and will stay in running mode until deselected, which is preferred for longer distances. In this case appropriate running feet (e.g. 1E90 Sprinter) or feet with axial compression (e.g. 1C61 Triton Vertical Shock) are required.

#### 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 or showering. If the insurance has restrictions, focus on work, exercise, home maintenance and therapeutic activities.

The X3 is ideal for patients working in or near water and allows unprecedented contact with water including showering, swimming, boating, fishing and more. The X3 has undergone stringent testing and is water and corrosion resistant (IP 68), which allows the prosthesis to be submerged. The X3 also has an IP66 rating and can be exposed to stronger jets of water as well. As a result, the X3 can be thoroughly rinsed after spending time in chlorinated or saltwater. The X3 is constructed with corrosion resistant materials (titanium, hard anodized aluminum, stainless steel, coatings).

#### 17. DIFFICULTY STANDING AND SITTING

Describe difficulty sitting and standing

**Stand more easily:** The Genium X3 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 X3 reduces resistance to take a more natural position—and switches to an energy saving mode.

#### 10. PATIENT'S TEST RESULTS

After briefly trialing the Genium X3, (Patient Name) experienced significant improvements in the following:

- Natural mobility
- Increased self-selected walking speeds

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- 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.

18. WHY THE GENIUM X3 IS SUITABLE FOR THIS PATIENT (summarize patient's need for the X3)  
The Genium X3 provides a level of function, safety and security for (amputation level) amputees that other microprocessor knees cannot provide. The safety provided by Genium X3 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. In addition, (Patient Name) will be able to take advantage of the Genium X3's running mode and participate in water activities, functions which other microprocessor knees do not have.
11. RECOMMENDATION  
In summary, the Genium X3 Microprocessor Knee has been selected for (Patient Name) as the best device that meets (his/her) needs as a (amputation level) amputee. The Genium X3's stability will reduce pain, fatigue and enable him to improve his activities of daily living, and fully participate in his life and most importantly, return to work.