Genium X3 Microprocessor-Controlled Prosthetic Knee

Reimbursement Reference Guide
Genium® X3

Reimbursement Reference Guide, revised September 1, 2016

Genium X3

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 multi-modal proprioceptive inputs (including knee angle, knee angular velocity, thigh angle, thigh angular velocity, and ground reaction force components). As a result, the X3 is able to monitor 500 knee motion possibilities at any given time. Additionally, the X3 is water resistant up to 1 meter, corrosion resistant and has running functionality.

Billing Codes

There is currently no Healthcare Common Procedure Coding System (HCPCS) code to describe the Genium X3. Therefore a miscellaneous code must be used to describe it until a new HCPCS code can be secured.

The following HCPCS codes are applicable to Genium X3 and recommended for all payers (excluding Medicare & VA):

- **L5828** – Single Axis, Fluid (hydraulic), Swing and Stance Phase Knee.
- **L5845** – Stance flexion feature, adjustable
- **L5848** – Fluid Stance Extension, Dampening feature
- **L5999** – Adaptive Microprocessor-Controlled Swing and Stance Phase prosthetic knee, with Simulated-Physiologic Rule Sets, predicted by Multi-Modal Proprioceptive Input. Features include: Optimized Physiologic Gait, Loading Flexed Knee to Traverse Obstacles and Stairs, Dynamic Stability Control Feature for all transitional gait (i.e. safe multidirectional movement in confined spaces, stance release on ramps, transition to running, weight compensation for stance release), Inertial Motion Unit Control Feature for intuitive standing and walking backwards; Corrosion Resist with IPX7 Waterproof Rating; Protective Cover, Running Mode and Mute Mode.

**Short Description of L5999 for Claim:** Ottobock 3B5-2 X3 Adaptive Microprocessor Controlled Prosthetic Knee

**X3 Protective Covers**

- L5999 Ottobock 4X900 Assurance Protective Cover
- L5999 Ottobock 4X193-1 Xtreme Protective Cover

**X3 Battery and Charger:**

- L7367 Lithium Ion Battery, Replacement
- L7368 Lithium Ion Battery Charger, Replacement

**2016 Manufacturer Suggested Retail Price**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Price</th>
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<tr>
<td>L5999</td>
<td>X3 Adaptive Microprocessor</td>
<td>$115,000</td>
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<tr>
<td>L5999</td>
<td>X3 Protective Covers</td>
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**Veterans Administration (VA):**

Use a single miscellaneous code (L5999) for the entire knee component. (Example: L5999 Lower extremity prosthesis, not otherwise specified - X3)

**FDA Status**

Under FDA’s regulations, the Genium X3 Microprocessor-Controlled Prosthetic Knee is a Class II device, exempt from the premarket notification [510(k)] requirements. The X3 prosthetic knee has met all the general control requirements which include Establishment Registration (21CFR 807), Medical Device Listing (21 CFR part 807), Quality System Regulation (21CFR part820), Labeling (21CFR part 801), and Medical Device Reporting (21 CFR Part 803). The X3 prosthetic knee is listed under external assembled lower limb prosthesis; Listing Number is E206060.

**X3 Warranty**

Three-year manufacturer warranty (extendable to six years); Repair costs are covered except for those associated with damages resulting from improper use. Includes 12 and 24-month fixed service inspections.

**X3 Provider Qualification**

The providing practitioner must be C-Leg qualified prior to qualification for X3 and is required to take an on-line qualification course for X3 and complete an examination prior to placing orders for the X3.

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1. The product/device “Supplier” (defined as an O&P practitioner, O&P patient care facility, or DME supplier) assumes full responsibility for accurate billing of Ottobock products. It is the Supplier’s responsibility to determine medical necessity; ensure coverage criteria is met; and submit appropriate HCPCS codes, modifiers, and charges for services/products delivered. It is also recommended that Supplier’s contact insurance payer(s) for coding and coverage guidance prior to submitting claims. Ottobock Coding Suggestions and Reimbursement Guides are based on reasonable judgment and are not recommended to replace the Supplier’s judgment. These recommendations may be subject to revision based on additional information or alpha-numeric system changes.

2. It is not recommended to bill Medicare L5999 for microprocessor knees.

3. The manufacturer’s suggested retail pricing (MSRP) is a suggested retail price only. Ottobock has provided the suggested MSRP in the event that third-party and/or federal healthcare payers request it for reimbursement purposes. The practitioner and/or patient care facility is neither obligated nor required to charge the MSRP when submitting billing claims for third-party reimbursement for the product (s).
Genium X3 Features and Benefits

Hydraulic Swing and Stance Phase Knee

- Genium X3 has hydraulic swing and stance phase control.
- Hydraulic swing phase control allows patients to vary cadence. The hydraulic fluid flows through narrow channels, providing a frictional resistance, which increases with the speed of compression; a faster gait speed allows quicker knee extension. The hydraulic also provides swing extension damping to prevent a hard impact at terminal swing that may cause vibrations in the prosthesis and, as a consequence, an unsafe feeling in the patient.
- Hydraulic stance phase control allows for knee flexion during weightbearing. This is necessary for walking with physiologic stance flexion on level ground, and natural step-over-step slope and stair descent and negotiation of uneven terrain. The hydraulic also provides sufficient knee flexion resistance for full weightbearing for “stumble recovery” during tripping.

Optimized Prosthetic Gait (OPG) with pre-flex function

- Genium X3 uses simulated physiologic rule sets with multi-modal proprioceptive input (six separate sensors) run by a state-of-the-art microprocessor. It significantly improves overall prosthetic function, especially ambulation, utility, social burden and well-being (4) as well as the perceived difficulty and safety of many activities of daily living (5).
- Unlike all other microprocessor controlled knees that have to be (unphysiologically) fully extended at heel strike, these simulated physiologic rule sets allow Genium X3 for optimized prosthetic gait (OPG) with a nearly physiologic pre-flexion of the knee at heel strike (1, 2, 6)
- Pre-flexion allows for easier “riding into the knee” with a reduction of braking forces during walking (reduction of the feeling to have to “climb over the prosthesis”) and easier use of physiologic knee stance flexion for shock absorption (1, 2, 6).
- Pre-flexion facilitates earlier foot-flat and increased prosthetic weight bearing resulting in improved safety and more physiologic step-over-step gait pattern during slope descent (1-6).
- Pre-flexion supports easier and more physiologic step-over-step slope ascent by reducing the need to “climb up over the limb” (1-6).
- The improvements in safety and gait patterns in slope ambulation also facilitate the negotiation of uneven terrain that is basically a permanent switchover between inclines and declines (1-6).
- Pre-flexion facilitates a consistent positioning of the foot for step-over-step stair descent, resulting in more confidence and prosthetic side weight bearing (1-3, 5, 6).

References for OPG with Pre-Flex
Genium X3 Features and Benefits

Obstacles and Stairs Function

- The Genium X3 allows for nearly normal stepping over bigger obstacles (4) 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 (1-3, 5, 6). All other MPK´s 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 (4) with the sound leg first. Using this function of Genium X3, the trailing prosthetic leg can be normally bent and moved over the obstacle (1-3, 5, 6). All other MPK´s 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.

- Genium X3 allows for ascending stairs in the natural step-over-step manner with a prosthetic knee that bends to maximize clearance of the stair with each step (1-6). In the walk upstairs mode, the bent prosthetic knee produces enough flexion resistance that the patient can use the prosthesis as a counter bearing to lift his/her body up to the next step using his/her hip and residual limb muscles (1-3, 5, 6). The conventional method for ascending stairs with a prosthetic knee is to take two steps at a time with the sound-side limb and ascend stairs with a straight knee on the prosthetic side, which results in a significant strain to the sound limb joints and muscles (2, 3, 5, 6).

Dynamic Stability Control

- The Genium X3 allows for safe multi-directional motion and transitional gait by controlling the switch from stance to swing. Thus, it significantly improves overall prosthetic function, especially ambulation and utility (3) as well as the perceived difficulty and safety of many activities of daily living (4).

- It also provides stability in crowds and confined areas, because of its ability to reliably transition from stance into swing phase while taking small and shuffling steps (3-5).

- 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 (1,2,4).

- The optimized swing phase control also results in increased knee flexion and thus toe clearance and safety when ascending and descending slopes (1-5).

References for Obstacles and Stairs feature


Genium X3 Features and Benefits

- **Walk2Run feature:** The 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.

References for the Dynamic Stability Control feature

- **Inertial Motion Unit**
  - The Inertial Motion Unit (IMU) consists of a separate microprocessor that processes the information of a 3D-gyroscope and a 3D-accelerometer to calculate the position and movement directions of the prosthesis to feed it into the main microprocessor board of Genium X3.
  - This patented technology allows the patient to intuitively stand on a flexed and stable knee on level, uneven, or inclined surfaces (ramps or hills) (1-3). The user does not need to activate or deactivate the stance function; both occur intuitively. Stance function is ended with a simple step (prosthesis side or sound side) (3). With traditional prosthetic knees it is imperative that the user cognitively ensure at all times that the center of mass stays ahead of the knee axis in order to prevent unexpected flexing of the prosthetic knee, which can cause the knee to collapse. In this situation, the user will uncomfortably stand with the hip extended in order to attempt to stabilize the knee.
  - This IMU also provides stability when taking steps backwards. Traditional microprocessor knees do not accommodate backward walking, because the knee is programmed to go into swing when the toe is loaded, causing the knee to collapse when stepping backward.

References for the Internal Motion Unit feature

Stumble Recovery Feature
- 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 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.
Genium X3 Features and Benefits

Stance Flexion Yielding
- When the prosthesis initially contacts the ground, this feature allows the patient to mimic the natural gait pattern by loading the knee in a flexed position. Benefits include shock absorption, reducing the modulation of the center of gravity throughout the gait cycle, energy efficiency (less energy spent on “pulling back” on hamstrings to lock a fully extended knee), and an overall more natural gait pattern. Hip and lower back stress will also be minimized.
- This feature also allows patients to “ride” the knee (the knee supports patients’ weight on flexed knee without buckling and lowers them into desired position) when sitting into a chair, kneeling, and when descending stairs and slopes.

Stance Extension Damping
- After the knee is flexed during stance phase (stance flexion), it needs to extend again to advance the body forward through mid- and terminal stance. This feature provides increased resistance to this extension. Without this dampening the patient will feel a pronounced “snap back” or “jerk” at the knee that may cause a feeling of insecurity, and will also present with an unnatural looking gait pattern. Energy is conserved by having this feature, as the patient will not have to attempt to use hamstrings to control this motion.

Water and Corrosion Resistant
- The X3 has undergone stringent waterproof testing and is completely submersible up to a depth of 1 meter.
- 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 is constructed with corrosion resistant materials (titanium, hard anodized aluminum, stainless steel, coatings).
- The 4X193 Rubber Protector on the X3 was designed in cooperation with users at Walter Reed and Brook Army Medical Centers and protects the joint against impacts and scratches. The X3 protector can be replaced by the user if worn out.

Running Mode
- 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.

Additional Features
- **Deliberate Stance Function:** When enhanced stability is needed (e.g. bilateral, hip disarticulation, etc.), the Genium X3 has a deliberate stance function feature that can be programmed by the prosthetist. Deliberate stance function is initiated by simply holding the prosthesis still for just 125 milliseconds. This stance function is ended when the user takes the weight off the prosthesis or extends it slightly.
- **Activity Report:** The provider can track and document the user’s progress towards rehabilitation goals. The tracking system can also be used to satisfy reimbursement requirements or optimize service of the device.
- **Patient App:** In addition to the remote control, Genium X3 has a Cockpit app designed for Android smartphones. With this app the user can switch between the five MyModes. The Cockpit app also allows the user to check battery life and view step counts.
Research Article Summary

Immediate Effects of a New Microprocessor-Controlled Prosthetic Knee Joint: A Comparative Biomechanical Evaluation

Reference

Summary
This was an intervention, cross-over study with repeated measures investigating the immediate biomechanical effects after transitioning from a C-Leg to a Genium prosthetic knee joint. The study enrolled 11 subjects (mean age: 36.7 ± 10.2 yrs SD). All study subjects were transfemoral amputees, experienced C-Leg users, and had functional classification levels of K3-K4. Subjects were initially tested with their C-Leg on day 1 and then switched to the Genium. Only the prosthetic knee was changed. Subjects then trained for a half-day with the Genium and were allowed an additional half-day of accommodation after which identical testing was conducted on day 2 using the Genium. Immediate biomechanical improvements were experienced with the Genium as compared to the C-Leg.

Results

Level Ground Walking

**Improved Step-Length Symmetry:** Active above-knee amputees typically take longer steps with the affected side when walking on level ground. This often results in compensatory movements on the sound side. The Genium knee provides 4° of pre-flexion at initial contact, resulting in increased step-length symmetry. Compared with C-Leg, the Genium reduced the mean asymmetry of the step length in all walking velocity tests, and was statistically significant (p<0.05) at both slow and mid walking speeds.

**Swing Phase Control (Knee Flexion Symmetry):** Insufficient flexion (bent knee) during the swing phase can result in inability to clear the foot, which may result in a stumble or fall. Physiologically, independent of velocity, the knee should be flexed between 60° and 65° during swing phase. During testing, the mean knee flexion for the C-Leg increased by 14.6° as velocity increased by 1m/s, while Genium stayed constant at 63.8°, indicative of a more natural gait pattern.

**Taking Small Steps:** Transfemoral amputees often find themselves in unsafe situations when transitioning from stance into swing phase while taking small steps. With the C-Leg, switching was not initiated in 24.7% of all tests, and with the Genium, it was not initiated in only 4.9%. Thus, Genium enabled safer small step walking as compared to C-Leg.

Inclines and Declines

**Standing on a 10° Decline:** The Genium accepted a higher load than the C-Leg (p<0.05), thus giving relief to the same side hip joint and reduction of postural sway (P<0.01)

**Improved Walking on Ramps:** Genium mean knee flexion angles were significantly increased (p<0.01), compared to C-Leg, both when ascending and descending ramps.

**Descending Stairs:** Genium mean knee flexion moment was significantly increased (p<0.05) 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 (p<0.01).
Genium X3 Clinical Studies


Schmalz T, Bellmann M, Proebsting E, Blumentritt S. Effects of adaptation to a functionally new prosthetic lower-limb component: Results of biomechanical tests immediately after fitting and after 3 months of use. JPO. 2014;26(3):134. [http://journals.lww.com/jpojournal/pages/currenttoc.aspx]