ottobock.

Genium X4.

Reimbursement Guide.

Product Information.

The 3B5-4 *Genium X4* utilizes a complex sensory system including inertial motion unit (IMU) control with gyroscope and accelerometer, paired with optimized physiologic gait technology. The appropriate resistances are calculated using multi-modal proprioceptive inputs (including knee angle, knee angular velocity, ankle angular velocity, and ground reaction force components). As a result, the *Genium X4* is able to monitor the user's motion possibilities at any given time. Additionally, the *Genium X4* is rated for both IP68 (waterproof and completely submersible) and IP66 (protected from powerful water jets), is corrosion resistant and has running functionality.

FDA Status.

Under FDA's regulations, the *Genium X4* Microprocessor-Controlled Prosthetic Knee is a Class I device, exempt from the premarket notification [510(k)] requirements. The *Genium X4* prosthetic knee has met all applicable 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 *Genium X4* prosthetic knee is listed under JOINT, KNEE, EXTERNAL LIMB COMPONENT. Listing Number is E253231, and Manufacturer Registration Number is 3005190268.

Health Canada Compliance.

This device meets the requirements of the Medical Device Regulations (SOR/98-282). It has been classified as a class I medical device according to the classification criteria outlined in schedule 1 of the Medical Device Regulations.

Warranty.

Genium X4 comes with a three-year manufacturer warranty (extendable to six years) which includes:

- Repair costs*
- Service maintenance in month(s) 24 (3- year warranty) and 48 (6-year extended warranty)**
- Service loaner unit during the repair and service maintenance.

*Superficial damage and damage resulting from improper use, intent, negligence, or force majeure are not covered. See *Genium X4* Warranty for details.

**Maintenance service(s) are necessary to ensure the continuity of the warranty.

Who Can Provide a *Genium X4*?

The *Genium X4* is prescribed by a physician and may only be provided by a qualified Prosthetist that has received specific product training. Ottobock employs a team of orthotists and prosthetists to educate practitioners on fabricating and fitting our products. This includes in-person and online training, webinars, and technical bulletins. We also provide Cooperative Care Services for the more challenging fittings, which includes on-site assistance with the fitting in conjunction with product qualification training for the practitioner.

Billing for the *Genium X4* (U.S.only).

Coding[1]

Currently, there is not an existing Healthcare Common Procedure Coding System (HCPCS) code to fully describe the *Genium X4* and miscellaneous code L5999 is available to use. We do not recommend billing *Genium X4* to Medicare until specific coding is secured.

L5999[1] Addition to lower extremity endoskeletal system, Ottobock 3B5-4 Genium X4 adaptive microprocessor-controlled swing and stance phase knee, with stance flexion; stance extension damping; simulated physiologic rule sets, predicted by multi-modal proprioceptive input. Dynamic stability control **(DSC)** for all transitional gait which includes loading a flexed knee using Stairs and Obstacles, Early Stance Phase Support, Late Stance Phase Support, Maximum Stance Flexion, Supported Sitting, Optimized Slope Ascent, Walk to Run, Running Mode, and additional My Modes; inertial motion control unit **(IMU)** feature for Dynamic Backward Movement, Start to Walk, Sitting Function, Intuitive Cycling, Stance Function and Locked Stance Phase, IP 68 submersible (Saltwater, Fresh water & Chlorinated), IP 66 protection against sprays and jets. Includes battery and charger.

Short narrative description of L5999 for *Genium X4* for use on a claim[1]

L5999[1] Addition to LL prosthesis Ottobock 3B5-4 *Genium X4* prosthetic knee, MSRP $_____

Manufacturer Suggested Retail Price (MSRP)[2]

$148,000

[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 do not replace the Supplier's judgment. These recommendations may be subject to revision based on additional information or alpha- numeric system changes.

[2]The manufacturer 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).

Justification for L5999.

Hydraulic Swing and Stance Phase Knee.

Hydraulic swing phase control allows patients to vary cadence. The hydraulic fluid flows through narrow channels, providing frictional resistance, which increases with the speed of compression; a faster gait speed allows quicker knee extension. The hydraulic also provides swing extension dampening 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.

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.

Optimized Physiologic Gait (OPG) with Pre-Flex.

Physiologic Rule Sets: The 3B5-4 *Genium X4* 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 as well as the perceived difficulty and safety of many activities of daily living.

Unlike all other microprocessor-controlled knees that have to be (unphysiologically) fully extended at heel strike, the 3B5-4 *Genium X4*'s simulated physiologic rule sets allow optimized prosthetic gait (OPG) with a nearly physiologic pre-flexion of the knee at heel strike on level ground and slope ascent.

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 adjustable physiologic knee stance flexion for shock absorption.

Foot-Flat: 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 ascent and descent.

Step-Over-Step: Optimized Slope Ascent allows adjusting the knee flexion angle in loading response to support easier and more physiologic step-over-step slope ascent by reducing the need to "climb up over the limb."

Pre-flexion facilitates a consistent positioning of the foot for step-over-step stair descent, resulting in more confidence and prosthetic side weight bearing.

Incline to Decline: The improvements in safety and gait patterns during slope ambulation also facilitates improved negotiation of uneven terrain.

Stairs and Obstacles.

Obstacles: The 3B5-4 *Genium X4* allows for nearly normal stepping over bigger obstacles with the prosthetic leg first – the knee can be flexed, and the prosthesis moved over the obstacle while taking a long step. *Genium X4* is safe while bent and loaded after clearing the obstacle. All other MPK´s require the patient to move the extended/stiff prosthetic leg around the obstacle using circumduction, which is associated with a high risk of catching the toes, stumbling, and falling.

The 3B5-4 *Genium X4* also enables nearly normal stepping over bigger obstacles with the sound leg first. Using this function of *Genium X4*, the trailing prosthetic leg can be bent and moved over the obstacle. All other MPK´s require the patient to move 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.

Stair Ascension: The 3B5-4 *Genium X4* 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. 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. 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.

Dynamic Stability Control.

Multi-Directional Walking: The *Genium X4* 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 as well as the perceived difficulty and safety of many activities of daily living.

Crowds and Confined Areas: The *Genium X4* 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.

Start to Walk Function allows users to initiate swing consistently on the prosthetic side by starting to walk with either foot, enabling a smooth transition from standing to walking. All other prosthetic knees require the user to start walking by stepping beyond the prosthesis with the unaffected limb first before the knee transitions to swing. For users Start to Walk results in decreased cognitive load while walking, improved toe clearance in swing, and more consistent step lengths.

Walking Speed: The *Genium X4* also offers an optimized swing phase control with a nearly physiologic swing knee flexion angle of 65° independent of walking speed. This provides improved toe clearance in slower walking speeds as well as timely swing extension of the prosthesis at faster walking speeds – users do not have to wait for a lagging prosthesis to swing forward.

Slopes: The optimized swing phase control also results in increased knee flexion and thus toe clearance and safety when ascending and descending slopes.

Walk to Run feature: The *Genium X4*'s knee joint can 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 Walk to Run 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.

Inertial Motion Unit (IMU)

The Inertial Motion Unit (IMU) consists of a separate microprocessor that processes the information of a 3D-gyrosocope and a 3D- accelerometer to calculate the position and movement directions of the prosthesis to feed it into the main microprocessor board of *Genium X4*.

Stance Function: This patented technology allows the patient to stand on a flexed and stable knee on level, uneven, or inclined surfaces (ramps or hills). The user does not need to activate or deactivate the stance function. Stance Functions allows adjustment of the timing for flexion block activation and deactivation. Intuitive Stance activates the block in 1.5 seconds for quick stability demands and releases earlier. When enhanced stability is needed (e.g. bilateral, hip disarticulation, etc.), the 3B5- 4 *Genium X4* 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 ends when the user takes the weight off the prosthesis or extends it slightly.

Stance function disengages with a simple step (prosthesis side or sound side). 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 and attempt to stabilize the knee.

Dynamic Backwards Movement: The Genium X4's 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.

Genium X4 allows stepping backwards on a bent knee with an active predefined flexion block angle active to prevent collapse of the knee when taking a step backwards. In addition to safely walking backwards, the feature allows users to load the prosthetic knee with greater force. For example, when pulling heavy objects or opening a heavy door.

Stumble Recovery Feature.

The *Genium X4* 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 during a stumble,) the higher the resistance that will be provided.

Maximum Stance Flexion

More Natural Gait Pattern: 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. Genium X4 allows for adjustability to the maximum stance flexion achieved on any one step to provide additional stability to users with weak or flaccid hip extensors, above knee amputees with shorter residual limbs, and hip disarticulation users.

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 Knee extension. Without stance extension 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.

Running Mode.

The *Genium X4* 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 the Cockpit App and will stay in running mode until deselected, which is preferred for longer distances. In this case, appropriate running feet (e.g. 1E90 Sprinter, 1E95 Challenger) or feet with axial compression (e.g. 1C61 Triton Vertical Shock) are required.

Swimming and Showering.

The 3B5-4 *Genium X4* is ideal for patients working in or near water and allows unprecedented contact with water including showering, swimming, boating, fishing and more.

Submergible: The 3B5-4 *Genium X4* has undergone stringent testing and is water and corrosion resistant (IP 68), which allows the prosthesis to be submerged.

Waterjets: The 3B5-4 *Genium X4* can be exposed to stronger jets of water as well (IP66). As a result, the *Genium X4* can be thoroughly rinsed after spending time in chlorinated or salt water.

Corrosion Resistant: The 3B5-4 *Genium X4* is constructed with corrosion resistant materials (titanium, hard anodized aluminum, stainless steel, coatings) and can be used in fresh, salt, and chlorinated water.

Rugged Protection.

The **Rubber Protector** on the 3B5-4 *Genium X4* was designed in cooperation with users at Walter Reed and Brook Army Medical Centers and protects the joint against impacts and scratches. The X4 protector is optional but recommended to help protect the X4 from damage and can be replaced by the user if worn out.

Additional Features.

Supported Ramp Descent: Stance flexion on the 3B5-4 *Genium X4* increases resistance as the knee angle increases. This causes slower and more controlled walking down ramps and stairs.

Supported Sitting: Flexion resistance is customizable on the 3B5-4 Genium X4, depending on the patient's need for support. If the knee joint is in a sitting position for more than one second, the flexion resistance is reduced depending on the setting. This promotes adjustable freedom of movement when sitting.

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: The 3B5-4 *Genium X4* has a Cockpit app compatible with both Android and iOS phones. With this app the user can switch between activities. The Cockpit app also allows the user to check battery life and view step counts.

Intuitive Cycling: Two full revolutions of uninterrupted pedaling activates this function on Genium X4. Deactivation and default back to stance occurs when stepping off the bike, supporting the ability to safely exercise on a bike both indoors and outdoors.

Locked Stance Phase: New amputees and individuals requiring a knee blocked to unnecessary bending can use this function for multi-tasking or standing on moving/unstable surfaces (bus, boat, train, plane). Swing phase flexion will not occur unless a deliberate step is taken with the sound limb.

Intuitive Slope Adaptation During Descents: The knee detects the slope angle using a slope indicator during swing of the previous step and adapts the level of resistance automatically. Early detection leads to an increased level of support and stability during loading for each step down, shallow ramps, and steep hills.

Evidence Essentials.

Genium microprocessor knees.

	Mobility need or deficit of the patient	Evidence for benefits of the *Genium* compared to *C-Leg*
Mobility	Patient feels limited in activities of daily living (ADL) and overall mobility	- **Significant improvement in total score of Physical Functional Performance Test (10 ADLs), and subdomains Upper Body Function, Upper Body Strength, Lower Body Strength and Balance, scores no longer different from able-bodied individuals.** (Highsmith et al., 2016B; Mileusnic et al, 2019) - **Significantly improved perceived ease and safety of ADLs.** (Hahn et al., 2016; Kannenberg et al., 2013; Mileusnic et al, 2019) - **Significant improvements AMP scores and step-activity derived functional level.** (Highsmith et al., 2016A and 2016B; Mileusnic et al, 2019)
Mobility	Patient has difficulty with long-distance ambulation	- **Significant reduction of stance-phase braking forces.** (Bellmann et al., 2012; Schmalz et al., 2014) - **Optimized swing control with constant knee swing flexion angle of 64° across walking speed.** (Bellmann et al., 2012; Schmalz et al., 2014; Mileusnic et al, 2019) - **Best correction of kinematic and kinetic gait deviations and compensatory mechanisms compared to NMPK and C-Leg.** (Varrecchia et al., 2019)
Mobility	Patient has difficulty negotiating stairs and clearing bigger obstacles	- **Patients rated stair ascent and descent and clearing bigger obstacles significantly easier.** (Hahn et al., 2016; Highsmith et al., 2014B; Kannenberg et al., 2013; Mileusnic et al, 2019) - **Many patients improve quality of stair ascent to reciprocal (step-over-step) gait pattern that can also be used for stepping over bigger obstacles.** (Aldridge et al., 2014; Bellmann et al., 2012A and 2012B; Highsmith et al., 2014A and 2016A; Mileusnic et al, 2019; Schmalz et al., 2014)

Mobility	Patient has difficulty negotiating slopes and uneven terrain	- **Significantly increased self-selected walking speed and quality of slope descent.** (Bell et al., 2016; Mileusnic et al, 2019) - **Significantly improved gait symmetry and quality and unloading of the sound limb during slope descent.** (Bellmann et al., 2012; Highsmith et al., 2016A, Lura et al., 2017; Schmalz et al., 2014; Mileusnic et al, 2019) - **Significantly improved knee swing flexion (toe clearance during slope descent.** (Bellmann et al., 2012; Highsmith et al., 2016A, Lura et al., 2017; Mileusnic et al, 2019; Schmalz et al., 2014) - **Patients rated slope and uneven terrain ambulation significantly easier and safer.** (Hahn et al., 2016; Highsmith et al., 2014B; Kannenberg et al., 2013; Mileusnic et al, 2019)
Mobility	Patient has difficulty standing still for longer periods of time, especially on slopes and hills	- **Significantly increased weight-bearing on the prosthetic side while standing still on level ground and slopes.** (Bellmann et al., 2012; Highsmith et al., 2014B) - **Patients rate ADLs that require standing significantly easier and safer.** (Hahn et al., 2016; Kannenberg et al., 2013; Mileusnic et al, 2019)
Musculo-skeletal pain	Patient suffers from joint and back pain due to gait asymmetry and excessive loading	- **Significant improvement in gait symmetry and, thus, loading of the locomotor system.** (Bellmann et al, 2012A; Highsmith et al., 2016C; Lura et al.; 2017; Mileusnic et al, 2019; Schmalz et al., 2014) - **Best correction of kinematic and kinetic gait deviations and compensatory mechanisms compared to NMPK and C-Leg.** (Varrecchia et al., 2019)

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