

3B5-3 Genium® X3

Reimbursement Guide



Quality for life

Genium X3 Reimbursement Guide

Product Information

May 2019

The 3B5-3 Genium X3 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 X3 is able to monitor the user's motion possibilities at any given time. Additionally, the X3 is rated for both IP68 (water proof 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 X3 Microprocessor-Controlled Prosthetic Knee is a Class I device, exempt from the premarket notification [510(k)] requirements. The Genium X3 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 part 820), Labeling (21CFR part 801), and Medical Device Reporting (21 CFR Part 803). The Genium X3 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 X3 comes with a three-year manufacturer warranty (extendable to six years) which includes:

- Repair costs*
- Service inspection in months 12 and 24
- Service unit during the repair and service inspections

* Superficial damage and damage resulting from improper use, intent, negligence or force majeure are not covered. See Genium X3 Warranty for details.

Who Can Provide a Genium X3?

The Genium X3 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.



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Billing for the Genium X3 (U.S. only)

¹Coding

At this time there is not an existing Healthcare Common Procedure Coding System (HCPCS) code to describe the 3B5-3 Genium X3 adaptive microprocessor-control feature. Until there is new coding for this feature, we recommend using a miscellaneous code to describe it.

L5828 Single Axis, Fluid (hydraulic), Swing and Stance Phase Knee.

L5845 Stance flexion feature, adjustable

L5848 Fluid Stance Extension, Dampening feature

²L5999 Ottobock 3B5-3 Genium X3 Prosthetic Knee; Adaptive Microprocessor-Controlled Swing and Stance Phase feature, with Simulated-Physiologic Rule Sets, predicted by Multi-Modal Proprioceptive Input. Includes 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), Stumble Recovery, Stance release on ramps, Transition to running, Weight compensation for stance release, Inertial Motion Unit (IMU) control feature for intuitive standing, sitting support, and walking backwards; Corrosion resist with IP68 waterproof and IP66 water jet ratings; Protective cover; Running mode, mute mode, plus 5 programmable activity modes, includes battery and charger.

² Short Description of L5999 Used on a claim:

L5999 Adaptive MP feature on Ottobock 3B5-3 Genium X3 Prosthetic Knee

³Manufacturer Suggested Retail Price (MSRP)

The 2019 MSRP for the L5999 Adaptive MP feature is \$115,000

¹The 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.

³The 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).

3B5-3 Genium X3 Features and Benefits

Hydraulic Swing and Stance Phase Knee

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 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.

Optimized Prosthetic Gait (OPG) with Pre-Flex

Physiologic Rule Sets: The 3B5-3 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, the 3B5-3 Genium X3’s simulated physiologic rule sets allow 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).

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 descent (1-6).

Step-Over-Step: Pre-flexion supports easier and more physiologic step-over-step slope ascent by reducing the need to “climb up over the limb” (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).

Incline to Decline: 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).

References for OPG with Pre-Flex

1. Lura DJ, Wernke MM, Carey SL, Kahle JT, Miro RM, Highsmith MJ. Differences in knee flexion between the Genium and C-Leg microprocessor knees while walking on level ground and ramps. *Clin Biomech (Bristol, Avon)*. 2015 Feb;30(2):175-81. doi: 10.1016/j.clinbiomech.2014.12.003. Epub 2014 Dec 13.
2. 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. *J Prosthet Orthot* 2014; 26(3): 134-143.
3. Highsmith MJ, Kahle JT, Lura DJ, Lewandowski AJ, Quillen WS, Kim HS. Stair ascent and ramp gait training with the Genium knee. *Technol Innov* 2014; 15: 349-258.
4. Highsmith MJ, Kahle JT, Miro RM, Lura DJ, Dubey RV, Carey SL, Quillen WS, Mengelkoch LJ. Perceived differences between the Genium und the C-leg microprocessor prosthetic knees in prosthetic-related function and quality of life. *Technol Innov* 2014; 15: 269-375.
5. Kannenberg A, Zacharias B, Mileusnic M, Seyr M. Activities of daily living: Genium Bionic Prosthetic Knee compared with C-Leg. *J Prosthet Orthot* 2013; 25(3): 110-117.

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- Bellmann M, Schmalz T, Ludwigs E, Blumentritt S. Immediate effects of a new microprocessor-controlled prosthetic knee joint: a comparative biomechanical evaluation. *Arch Phys Med Rehabil* 2012; 93(3): 541-549.

Obstacles and Stairs Function

Obstacles: The 3B5-3 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 3B5-3 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.

Stair Ascension: The 3B5-3 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).



References for Obstacles and Stairs feature

- 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. *J Prosthet Orthot* 2014; 26(3): 134-143.
- Aldridge Whitehead JM, Wolf EJ, Scoville CR, Wilken JM. Does a microprocessor-controlled knee affect stair ascent strategies in persons with transfemoral amputation? *Clin Orthop Rel Res* 2014; Feb 11 [epub ahead of print]
- Highsmith MJ, Kahle JT, Lura DJ, Lewandowski AJ, Quillen WS, Kim HS. Stair ascent and ramp gait training with the Genium knee. *Technol Innov* 2014; 15: 349-258.
- Kannenbergh A, Zacharias B, Mileusnic M, Seyr M. Activities of daily living: Genium Bionic Prosthetic Knee compared with C-Leg. *J Prosthet Orthot* 2013; 25(3): 110-117.
- Bellmann M, Schmalz T, Ludwigs E, Blumentritt S. Immediate effects of a new microprocessor-controlled prosthetic knee joint: a comparative biomechanical evaluation. *Arch Phys Med Rehabil* 2012; 93(3): 541-549.

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- Bellmann M, Schmalz T, Ludwigs E, Blumentritt S. Stair ascent with an innovative microprocessor-controlled exoprosthetic knee joint. *Biomed Tech* 2012; 57(6): 435-444.

Dynamic Stability Control

Multi-Directional Walking: 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).

Crowds and Confined Areas: The Genium X3 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).

Walking Speed: 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).

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

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.

References for the Dynamic Stability Control feature

- Lura DJ, Wernke MM, Carey SL, Kahle JT, Miro RM, Highsmith MJ. Differences in knee flexion between the Genium and C-Leg microprocessor knees while walking on level ground and ramps. *Clin Biomech (Bristol, Avon)*. 2015 Feb;30(2):175-81. doi: 10.1016/j.clinbiomech.2014.12.003. Epub 2014 Dec 13.
- 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. *J Prosthet Orthot* 2014; 26(3): 134-143.
- Highsmith MJ, Kahle JT, Miro RM, Lura DJ, Dubey RV, Carey SL, Quillen WS, Mengelkoch LJ. Perceived differences between the Genium and the C-leg microprocessor prosthetic knees in prosthetic-related function and quality of life. *Technol Innov* 2014; 15: 269-375.
- Kannenbergh A, Zacharias B, Mileusnic M, Seyr M. Activities of daily living: Genium Bionic Prosthetic Knee compared with C-Leg. *J Prosthet Orthot* 2013; 25(3): 110-117.
- Bellmann M, Schmalz T, Ludwigs E, Blumentritt S. Immediate effects of a new microprocessor-controlled prosthetic knee joint: a comparative biomechanical evaluation. *Arch Phys Med Rehabil* 2012; 93(3): 541-549.

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.

Intuitive Stance: 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

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collapse. In this situation, the user will uncomfortably stand with the hip extended in order to attempt to stabilize the knee.

Backwards Walking: 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

1. Highsmith MJ, Kahle JT, Miro RM, Lura DJ, Dubey RV, Carey SL, Quillen WS, Mengelkoch LJ. Perceived differences between the Genium und the C-leg microprocessor prosthetic knees in prosthetic-related function and quality of life. *Technol Innov* 2014; 15: 269-375.
2. Kannenberg A, Zacharias B, Mileusnic M, Seyr M. Activities of daily living: Genium Bionic Prosthetic Knee compared with C-Leg. *J Prosthet Orthot* 2013; 25(3): 110-117.
3. Bellmann M, Schmalz T, Ludwigs E, Blumentritt S. Immediate effects of a new microprocessor-controlled prosthetic knee joint: a comparative biomechanical evaluation. *Arch Phys Med Rehabil* 2012; 93(3): 541-549.

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.

Stance Flexion Yielding

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.

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.



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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 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) or feet with axial compression (e.g. 1C61 Triton Vertical Shock) are required.

Swimming and Showering

The 3B5-3 Genium X3 is ideal for patients working in or near water and allows unprecedented contact with water including showering, swimming, boating, fishing and more.



Submergible: The 3B5-3 Genium X3 has undergone stringent testing, and is water and corrosion resistant (IP 68), which allows the prosthesis to be submerged.

Waterjets: The 3B5-3 Genium X3 can be exposed to stronger jets of water as well (IP66). As a result, the X3 can be thoroughly rinsed after spending time in chlorinated or salt water.

Corrosion Resistant: The 3B5-3 Genium X3 is constructed with corrosion resistant materials (titanium, hard anodized aluminum, stainless steel, coatings).

Rugged Protection

The **Rubber Protector** on the 3B5-3 Genium 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.

Additional Features

Supported Ramp Descent: Stance flexion on the 3B5-3 Genium X3 increases resistance as the knee angle increases. This causes a slower and more controlled walking down ramps and stairs

Deliberate Stance Function: When enhanced stability is needed (e.g. bilateral, hip disarticulation, etc.), the 3B5-3 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.

Supported Sitting Function: Flexion resistance on the 3B5-3 Genium X3 can be set to be increasing or constant depending on the patient's need.

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 3B5-3 Genium X3 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.

Genium X3 Clinical Studies

1. Lura DJ, Wernke MW, Carey SL, Kahle JT, Miro RM, Highsmith MJ. Crossover study of amputee stair ascent and descent biomechanics using Genium and C-Leg prostheses with comparison to non-amputee control. *Gait Posture* 2017; 58: 103-107. [Download](#)
2. Highsmith MJ, Klenow TD, Kahle JT, Wernke MM, Carey SL, Miro RM, Lura DJ, Sutton BS. Effects of the Genium knee system on functional level, stair ambulation, perceptive and economic outcomes in transfemoral amputees. *Technol Innov* 2016; 18: 139-150. [Download](#)
3. Highsmith MJ, Kahle JT, Miro RM, Cress EM, Lura DJ, Quillen WS, Carey SL, Dubey RV, Mengelkoch LJ. Functional performance differences between Genium and C-Leg prosthetic knees and intact knees. *J Rehabil Res Dev* 2016;53(6):753-766. [Download](#)
4. Highsmith MJ, Klenow TD, Kahle JT, Wernke MM, Carey SL, Miro RM, Lura DJ. Effects of the Genium microprocessor knee system on knee moment symmetry during hill walking. *Technol Innov*. 2016 September; 18(2-3): 151–157. doi:10.21300/18.2-3.2016.151. [Download](#)
5. Hahn A, Lang M, Stuckart C. Analysis of clinically important factors on the performance of advanced hydraulic, microprocessor-controlled exo-prosthetic knee joints based on 899 trial fittings. *Medicine*. 2015; 95:45. [Download](#)
6. Bell EM, Pruziner AL, Wilken JM, Wolf EJ. Performance of conventional and X2(r) prosthetic knees during slope descent. *Clin Biomech (Bristol, Avon)* 2016 Mar; 33: 26-31. doi: 10.1016/j.clinbiomech.2016.01.008. Epub 2016 Feb 2. [Download](#)
7. Lura DJ, Wernke MM, Carey SL, Kahle JT, Miro RM, Highsmith MJ. Differences in knee flexion between the Genium and C-Leg microprocessor knees while walking on level ground and ramps. *Technol Innov*, 2014; 15: 359–368; *Clin Biomech (Bristol Avon)*. 2015 Feb; 30(2): 175-81. doi: 10.1016/j.clinbiomech.2014.12.003. Epub 2014 Dec 13. [Download](#)
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11. Highsmith MJ, Kahle JT, Lura DJ, Dubey RV, Carey SL, Quillen WS, Mengelkoch LJ. Short and mid-distance walking and posturography with a novel microprocessor knee. *Technol Innov*, 2014; 15: 359–368. [Download](#)
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13. Bellmann M, Schmalz T, Ludwigs E, Blumentritt S. Immediate effects of a new microprocessor-controlled prosthetic knee joint: a comparative biomechanical evaluation. Arch Phys Med Rehabil. 2012 Mar;93(3):541-9. doi: 10.1016/j.apmr.2011.10.017. [Download](#)
14. Aldridge Whitehead JM, Wolf EJ, Scoville CR, Wilken JM. Does a microprocessor-controlled prosthetic knee affect stair ascent strategies in persons with transfemoral amputation? Clin Orthop Relat Res. 2014 Feb; DOI 10.1007/s11999-014-3484-2. [Download](#)
15. Bellmann M, Schmalz T, Ludwigs E, Blumentritt S. Stair ascent with an innovative microprocessor-controlled exoprosthetic knee joint. Biomed Tech (Berl). 2012 Dec;57(6):435-44. doi: 10.1515/bmt-2011-0029. [Download](#)

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