ottobock.

Genium.
Reimbursement Guide.

January 2024

Product Information.
January 2024.

The 3B1-3 *Genium* prosthetic knee 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* is able to monitor the user's motion possibilities at any given time.

FDA Status.

Under FDA's regulations, the *Genium* Microprocessor Controlled Prosthetic Knee is a Class I device, exempt from the premarket notification [510(k)] requirements. *Genium* prosthetic knee has met all applicable general control requirements which include Establishment Registration (21CFR 807), Medical Device Listing (21 CFR part 807), applicable Quality System Regulation (21CFR part 820), Labeling (21CFR part 801), and Medical Device Reporting (21 CFR Part 803). The *Genium* prosthetic knee is listed under JOINT, KNEE, EXTERNAL LIMB COMPONENT; Product Code is ISY, Listing Number is E253231.

Health Canada Compliance.

The *Genium* Microprocessor Controlled Prosthetic Knee 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.

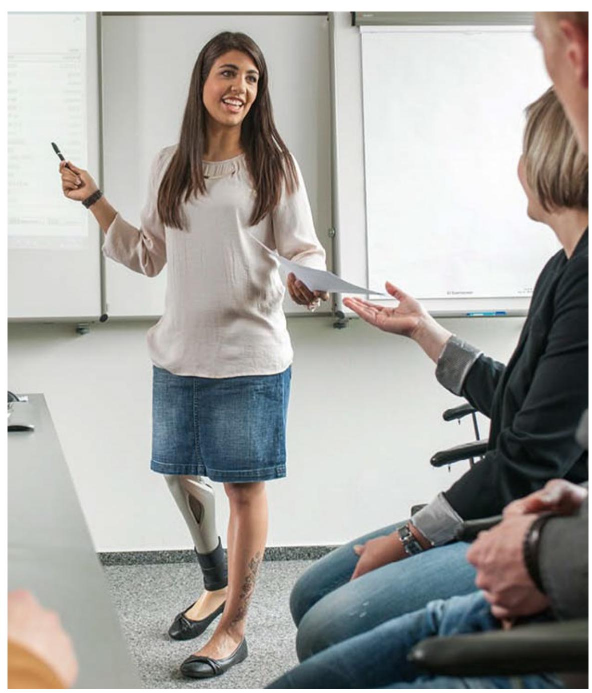
Genium comes with a three-year manufacturer warranty (extendable to six years) which includes:

- 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* Warranty for details.

Who Can Provide a *Genium*?

The *Genium* 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 Service**s** 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* (U.S.only).

[1] Coding

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

[1] L5999

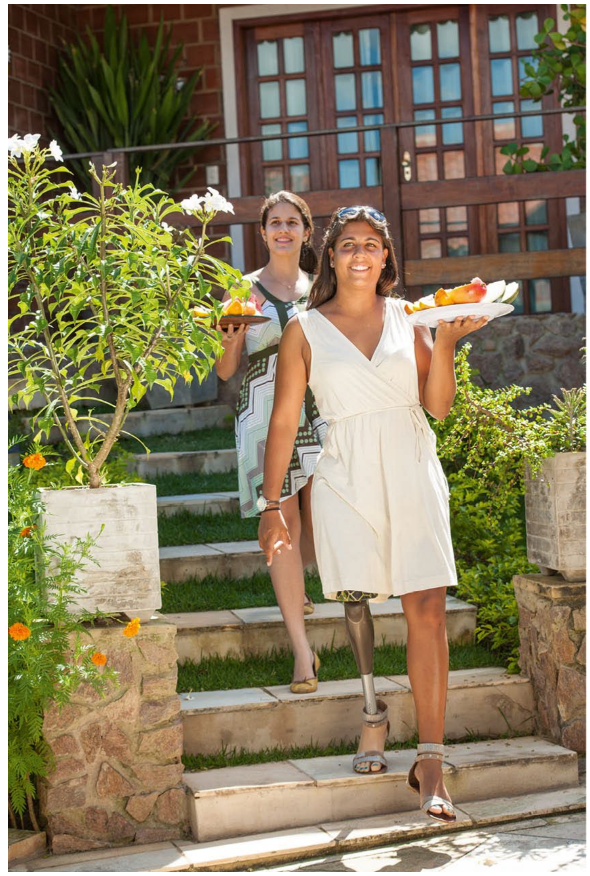
Addition to lower extremity endoskeletal system, Ottobock 3B1-3 *Genium* adaptive microprocessor-controlled swing and stance phase knee, with stance flexion; stance extension damping; simulated-physiologic rule sets, predicted by multi-modal proprioceptive input; loading flexed knee to traverse obstacles and stairs; dynamic stability control 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 control unit feature for intuitive standing and backwards walking, IP 67 weatherproof, 5 additional programmable modes; includes battery and charger.

[1] Short narrative description for *Genium* for use on claim.

L5999 Addition to LL prosthesis Ottobock 3B1-3 *Genium* prosthetic knee, MSRP $_________

[2] Manufacturer Suggested Retail Price (MSRP)

$101,000



[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.

Hydraulic Swing and Stance Phase.

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, consequently, 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 *Genium* 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 *Genium*'s simulated physiologic rule sets allow optimized prosthetic gait (OPG) with a nearly physiologic pre-flexion of the knee at heel strike.

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.

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.

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."

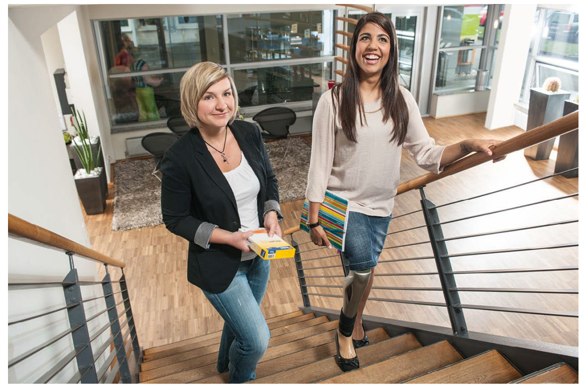
Pre-flexion facilitates a consistent positioning of the foot for step-over-step stair descent, resulting in more confidence and prosthetic side weight bearing.

Incline to Decline The improvements in safety and gait patterns in slope ambulation also facilitate the negotiation of uneven terrain that is basically a permanent switchover between inclines and declines.

Obstacles and Stairs Function.

Obstacles The *Genium* 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* is safe while loaded bent past the obstacle. 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* 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 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 *Genium* 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. 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* 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* 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.

Walking Speed 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.

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

Walk2Run feature The *Genium*'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.

Inertial Motion Unit.

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*.

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 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.

Stumble Recovery Feature.

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 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.

Additional Features.

Supported Ramp Descent Stance flexion on the *Genium* 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 *Genium* 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 *Genium* 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 *Genium* 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/Genium X3 **Bibliography.**

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