X3 Microprocessor Knee

Reimbursement Reference Guide
X3 Microprocessor Knee
Reimbursement Reference Guide
Effective: November 1, 2014

X3 Microprocessor Knee
The 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 X3. Therefore a miscellaneous code must be used to describe it until a new HCPCS code can be secured.

The following HCPCS Code is applicable to X3 and recommended for all payers (excluding Medicare):

**LONG DESCRIPTION:** L5999 Ottobock 3B5-X3 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, Dynamic Stability Control for Intuitive Standing and Transitional Gait, Loading Flexed Knee to Traverse Obstacles and Stairs; Corrosion Resist with IPX7 Waterproof Rating; Protective Cover, Running Mode and Mute Mode.

**SHORT DESCRIPTION:** Ottobock 3B5-X3 Adaptive Microproc Ctrl Knee dynamic stability, stairs/obstacle, waterprf, run

**Medicare:**
When billing Medicare for X3 use:

L5856 (instead of L5999), L5828, L5845, L5848, L5930(K4 only)

Note: We do not recommend billing L5999 to Medicare.

**Veterans Administration:**
When billing the VA for X3 use:

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

**Manufacturer Suggested Retail Price (MSRP) 2014 (MSRP)**

For the X3 is $115,000.

**FDA Status**
X3 Microprocessor Knee is a Class II exempt device. FDA believes that the device does not present risks that require premarket notification (510(k)) review to assure its safety and effectiveness; therefore, safety and effectiveness research is not required for this device. However, X3 Microprocessor 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 listing number of the device is E206060, product code ISW.

**X3 Warranty**
Three-year manufacturer warranty (extendable to six years); includes:

- Repair costs*
- Incidental corrosion
- Service inspection in the 24th month
- Service unit for use during repairs and service inspections

*Superficial damage and damage resulting from negligence or improper use are not included.

**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.
X3 Microprocessor Knee Features and Benefits

Autoadaptive Microprocessor-Control of (Hydraulic) Swing & Stance Phase

- Simulated physiologic rule sets run by a microprocessor, provide autoadaptive swing and stance phase control, predicted by multi-modal proprioceptive input (six separate sensors, including a gyroscope and an accelerometer).
- The X3 microprocessor adjusts resistances to improve the patient’s swing phase timing, step length, and ground clearance, while decreasing muscular effort needed to walk with varied cadence (different from traditional microprocessor knees which are programmed with pre-set and default resistances).
- Minimizes gait deviations (hip hiking, vaulting, excessive hip extension and excessive hip flexion) for reducing stress to the sound-side hip and knee joints and prosthetic side hip joint and lower back.
- Provides controlled speed (the patient controls the speed). The knee adjusts resistance dependent on speed and toe clearance, and improves gait symmetry.
- Adapts to the patient (not the other way around); reducing cognitive stress, reliance on muscular strength and unnatural muscle movements.

Obstacles and Stairs Feature

- The X3 allows the patient to walk up stairs step-over-step with a prosthetic knee that bends to maximize clearance of the stair with each step. (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).
- This same function allows the patient to step over obstacles in a secure fashion, supported by a stable, flexed knee at loading. (The traditional method for traversing obstacles is to swing the prosthetic leg around the obstacle).

Dynamic Stability Control for Intuitive Standing and Transitional Gait (i.e. Safe multidirectional movement in confined spaces)

- The X3 allows intuitive standing, backward walking, multi-directional motion, and transitional gait by controlling the switch from swing to stance. (If the patient’s knee flexes unexpectedly, the X3 helps prevent a fall).
- Provides stability in crowds and confined areas, because if its ability to transition from stance into swing phase while taking small steps.
- 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 backwards).
- Allows the patient to carry items up to 25 pounds without impacting the release of stance. For example, the patient can carry small children, pets, or items such as trays, shopping bags, laundry baskets, briefcases, and suitcases without worrying that the knee might collapse.
- Allows the patient to intuitively stand on a flexed and stable knee on level, uneven, or inclined surfaces (ramps or hills). (With traditional prosthetic knees people with limb loss must use hip extension to stabilize the knee or cognitively ensure that their center of mass stays ahead of their knee axis to prevent unexpected flexing of the prosthetic knee).

Stance Flexion Yielding

- The X3 provides Hydraulic resistance against knee flexion (bending), allowing controlled, partial knee flexion, in early stance phase, during weight bearing, thus providing shock absorption and reduced impact.
X3 Microprocessor Knee Features and Benefits

Stance Flexion Yielding (continued)

- This feature allows the patient to walk down hills and ramps with a bent knee. People can also use the hydraulics to descend stairs step over step, minimizing prosthetic side hip and lower back stress while transferring weight to the prosthesis.
- Provides support when sitting down into a chair.

Stance Extension Damping

- The X3 provides progressive hydraulic resistance during stance and swing phase extension. Progressive resistance minimizes the need for patients to exert muscular effort during uncontrolled extension of the knee.

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 Functionality

- Walk2Run feature: The 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 running mode can also be 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.

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 lo.min 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 At this time, it is not recommended to bill miscellaneous code L5999 to Medicare 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).