Meridium microprocessor-controlled foot and ankle
Reimbursement Reference Guide, July 1, 2016

Meridium
The Meridium Microprocessor-Controlled prosthetic foot and ankle is designed for transtibial and transfemoral prosthetic users, both limited and full community ambulators.

The Meridium utilizes a complex sensory system (including an inertial motion unit) along with sophisticated rule sets that allow for real-time adaptive adjustments to the user’s walking speed and ground conditions, whether on slopes, stairs or varying terrain including a intuitive standing lock on all surfaces. This occurs over the full ROM (14 degrees dorsiflexion and 22 degrees plantarflexion). This is a big plus for the user during everyday activities, making both greater flexibility and enhanced stability possible.

Coding and Billing for Private Pay 1, 2, 3
Currently there are no existing HCPCS codes that adequately describe the Meridium. In the meantime, HCPCS code L5999 is available to use for the Meridium until coding can be obtained.

Long Description:
L5999 Ottobock XXX=X
Meridium  Microprocessor-Controlled prosthetic foot and ankle, with Simulated-Physiologic Rule Sets, Real-time Adaptation over full ROM feature with separate control of dorsal and plantar flexion resistances allows for consistent performance with varying gait speeds, real-time terrain recognition and adaptation with adjustments at every step for full foot flat on stairs, inclines, ramps, and uneven terrain; Automatic adaptation to barefoot walking and different shoe types; Inertial Motion Unit Control Feature for intuitive standing lock on all surfaces, includes power source and charger.

Short Description:
L5999 Ottobock XXX=X
Meridium, Adaptive over ROM, Microprocessor Ctrl Foot–Ankle

Manufacturer Suggested Retail Price (MSRP) is $60,000.

Warranty
Meridium microprocessor ankle foot comes with a three-year manufacturer warranty. During the warranty period, repair costs are covered except for those associated with damages resulting from improper use.

FDA Status
Under FDA’s regulations, the Meridium Microprocessor-Controlled prosthetic foot and ankle is a Class I medical device and exempt from the premarket notification [510(k)] requirements. Given the low risk of Class I medical devices, FDA determined that General Controls are sufficient to provide reasonable assurance of the device’s safety and effectiveness; therefore, safety and effectiveness research is not required for this device.

The Meridium 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 Meridium is listed under External Limb Prosthetic Component; Product Code ISH; Listing Number E253230.

1 The product/device “Supplier” (defined as an O&P Practitioner or O&P patient care facility) 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 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).
Meridium
Microprocessor-Controlled Foot and Ankle
Features and Benefits

Real-time Adaptation over full Range of Motion
- Separate control of dorsiflexion (14°) and plantarflexion (22°).

4 – Axis Kinematics
- Meridium’s 4-axis design allows movement of ankle, foot and separate toe section resulting in excellent adaptability, more similar to natural gait and reduced need for compensatory movements.

Walking Speed changes
- Real-time adaptation combined with Meridium’s 4-axis design provides almost natural rollover, resulting in better control of walking speed.
- Compare this to conventional prosthetic feet which have stiff ankles and only partially mimic the function of an ankle joint.
- When the user changes walking speed, the dorsiflexion resistance automatically adjusts itself to the change in forces, allowing the user to easily vary gait speed without feeling any change in the foot’s behavior.

Increased Foot clearance during swing
- During the swing phase, the foot remains in the dorsiflexion position to provide greater ground clearance which requires less compensatory movements and allows better gait symmetry. This prevents the tip of the foot from getting caught and may help to reduce stumbles and falls.

Expanded Full-Surface Contact with the Ground
- Meridium allows for expanded, full-surface contact with the ground for improved stability and traction when walking on level ground, uneven terrain, and slopes.

Walking on Hills and Slopes
- Plantar flexion and rollover are adjusted in real time according to the incline and dorsiflexion resistance supports consistent rollover across the wide range of motion.
- With each step, the foot moves to a full-surface (flat on the ground) position as the user walks up or down the slope.
- Real-time adjustment and wide range of motion allow the user to place an equal load on both legs, and enables a more uniform gait symmetry.
- When descending a slope, this full-surface contact prevents undesired acceleration, providing additional safety. The user also finds it easier to control knee flexion, because less flexion moment occurs.
- The dorsiflexion position also provides greater ground clearance when walking up slopes. This prevents the tip of the foot from getting caught and may help to reduce stumbles and falls.

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Walking on Uneven Ground

- The advantages of real-time adjustment are particularly evident on uneven surfaces such as cobblestones, grass, forest paths, and other similarly structured surfaces. With every step, the dorsiflexion and plantar flexion angles are fully and immediately adapted to the walking surface. The improved contact with the ground increases the user’s safety.
- Smaller obstacles are therefore no longer perceived as a problem, but rather as if they had been smoothed over.

Stairs

- The Meridium recognizes the movement pattern when walking on stairs and adjusts both dorsiflexion and rollover angle, in real time, step by step.
- This allows up to full surface contact meaning that on stairs the patient doesn’t have to roll over the edge of the step anymore which provides additional stability. Benefit to the user is enhanced safety and stability.

Intuitive Stance

- Meridium can differentiate between walking and standing based on the situation.
- Meridium provides intuitive stance on both level ground and slopes and the user maintains the same level of stability in either case.
- Dorsiflexion is locked for stable standing and immediately returns to adaptation for walking once movement is sensed.

Backwards Walking

- The Meridium adapts in real-time to the movement pattern when walking backwards. Controlled lowering of heel down to the ground for full foot flat and ease of rolling over backwards.

Relief Function

- This function automatically lowers the foot to the floor when a load is placed on the heel for a prolonged period and allows the foot to be flat on the floor while sitting or standing. Helpful when in areas with minimal leg room, such as public transportation, or theaters, and cinemas.