MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Orthotics**
Policy Number	**1.01.25**
Category	**Equipment/Supplies**
Original Effective Date	**09/16/99**
Committee Approval Date	**06/27/02, 07/24/03, 06/24/04, 06/23/05, 06/22/06, 04/26/07, 04/24/08, 04/23/09, 04/29/10, 04/28/11, 04/2612, 02/28/13, 04/24/14, 04/23/15, 04/28/16, 04/27/17, 04/26/18, 04/25/19, 04/23/20, 04/22/21, 4/21/22**
Current Effective Date	**04/21/22**
Archived Date	**N/A**
Archived Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, orthotic devices are considered **medically appropriate** when prescribed by a qualified provider for therapeutic support, protection, or restoration of an impaired body part, or to improve the functioning of an impaired body part. Orthotics are devices that are rigid or semi-rigid. Examples of orthotic devices include:
   A. braces for leg, arm, neck, back and shoulder;
   B. corsets for back or for use after special surgical procedures;
   C. splints for extremities; and
   D. trusses.

II. Custom orthotic devices with enhanced or robot-assisted features (e.g., those that contain electronic features for stance control, such as the OttoBock E-MAG Active, OttoBock 17B500 Sensor Walk Electronic knee ankle foot orthosis [KAFO], or the MyoPro arm brace [Myomo, Inc]) are considered to be **not medically necessary** if activities of daily living can be performed with standard orthotic devices. If enhanced devices are requested, the specific overall medical condition of the member is considered in order to determine medical necessity. Detailed clinical information is required for consideration of coverage when non-standard orthotic devices are requested.

Refer to Corporate Medical Policy #1.01.14 Surgical Stockings.

Refer to Corporate Medical Policy #1.01.18 Prosthetic Devices.

Refer to Corporate Medical Policy #1.01.32 Cranial Orthotics.

Refer to Corporate Medical Policy #1.01.41 Foot Orthotics.

Refer to nationally recognized InterQual standards for Knee Braces.

POLICY GUIDELINES

I. Coverage for orthotics is contract dependent unless required by federal or state mandates. Please contact your local Customer Care (Member/Provider) Department to determine coverage under a member's subscriber contract.

II. Foot orthotics are not addressed in this policy.

III. Orthotics used solely for sports or work-related activities are considered not medically necessary or **ineligible for coverage**, based upon the member's subscriber contract.

IV. Orthotics containing convenience or luxury features (e.g., combination brace with an ice pack, braces with microprocessor components), where there exists a reasonably feasible, and medically appropriate standard alternative pattern of care, are considered **not medically necessary** or **ineligible for coverage**, based upon the member's subscriber contract.

V. Necessary repairs and maintenance of covered orthotic devices are **eligible for coverage**, unless covered by a manufacturer's warranty or purchase agreement. Adjustments to covered orthotics are **eligible for coverage** if ordered by a physician and necessary due to normal wear, or when required by a change in the patient's condition.

VI. Replacement of a medically necessary orthotic is **eligible for coverage** if when:
   A. The patient has experienced a change in his or her physiological condition; or
   B. Required repairs would exceed the cost of a replacement device, or the parts that need to be replaced; ~~or~~ and
   C. There has been irreparable change in the device's condition, or in a part of the device, due to normal wear and tear.

VII. Replacement or repair needed due to misuse or neglect is **ineligible for coverage**.

VIII. Duplicate orthotics are considered **not medically necessary**; more than one orthotic device per body part used for the same function is considered a matter of convenience for the member

IX. Replacement or repair covered under a homeowner policy, or similar insurance is **ineligible for coverage.**

DESCRIPTION

Orthopedic or orthotic devices (collectively called "orthotics") are rigid or semi-rigid device used to support, restore or protect body function. Orthotics may also redirect, eliminate, or restrict motion of an impaired body part.
Both the OttoBock E-MAG Active and The Sensor Walk are electronic knee-ankle-foot orthotics (KAFO). The E-MAG Active contains a gyroscope that monitors the orientation of the user's limb (whether it is at heel off, heel strike, etc.) which helps users achieve a more natural gait, thereby reducing compensatory movements that can lead to degenerative conditions. This KAFO should not be used in patients with spasticity, knee flexion contracture greater than 15°, hip flexor and extensor strength less than grade 3. The Sensor Walk contains a microprocessor, used to determine the appropriate time to engage and disengage the knee joint restraint mechanism, which provides additional stability for patients who have weak or absent quadriceps, or knee instability while ambulating. However patients must be able to exhibit a steppage gait, have hip flexor strength (grade 3), and have enough muscle strength in their torso or pelvis to swing the device forward while walking.
According to the manufacturer's website (Myomo, Inc), the MyoPro is a Myoelectric Arm Orthosis designed to support a weak or deformed arm. The MyoPro can enable individuals to self-initiate and control movements of a partially paralyzed or weakened arm using their own muscle signals. When the user tries to bend the affected arm, sensors in the brace detect the weak muscle signal, which activates the motor to move the arm in the desired direction. The user is completely controlling the arm; the brace amplifies their weak muscle signal to help bend and move the arm. No electrical stimulation or invasive procedures are employed.

RATIONALE

Guidelines for Adult Stroke Rehabilitation and Recovery: A Guideline for Healthcare Professionals from the American Heart Association/American Stroke Association (Winstein, et al. 2016) recommend rehabilitation following stroke to be delivered by a multidisciplinary team of healthcare providers with training in neurology, rehabilitation nursing, OT, PT,

and speech therapy. A component of the rehabilitation therapy may be robotic and electromechanics-assisted training devices. These devices have been used in an effort to promote gait recovery after stroke or to improve upper extremity function after stroke. Benefits from the robot-assisted therapy are observed in patients within the first three months after stroke and in those patients who are unable to walk. However, the evidence from systematic reviews is mixed regarding whether the benefits are significantly improved over conventional gait training. Robot-assisted movement training to improve motor function and mobility after stroke in combination with conventional therapy may be considered (Recommendation: IIb; Level of evidence: A). Mechanically-assisted walking (treadmill, electromechanical gait trainer, robotic device, servo-motor) with body weight support may be considered for patients who are non-ambulatory or have low ambulatory ability early after stroke (Recommendation: IIb; Level of evidence: A). Additional studies are needed to determine the optimal device, training protocols, and patient selection to maximize benefits. For individuals with moderate to severe upper limb impairment, robotic therapy has been shown to benefit ADLs and arm function but not arm muscle strength. Many of the studies compared robot-assisted therapy to usual care and not to dose-matched exercise. The studies that did compare robot-assisted therapy with dose-matched exercise showed minimal or no differences in the efficacy between the two therapies. Overall, robotic therapy appears to provide some benefit for upper extremity motor abilities and participation but is of uncertain utility compared with dose-matched conventional upper limb exercise therapies.

The Robot-Assisted Training for the Upper Limb after Stroke (RATULS) multi-center trial (Rogers, et al. 2020), randomized patients with upper limb impairment after stroke to three different rehabilitation programs: robot-assisted training, an enhanced upper limb therapy program based on repetitive practice of functional tasks, and usual care. Participants. A total of 770 adults, within 1 week to 5 years post-stroke with upper limb impairment were randomized to one of the outpatient therapies which were performed for 45 minutes, three times per week for 12 weeks. Upper limb functional recovery success, the upper limb impairment, activities of daily living, and quality of life were assessed by the Action Research Arm Test, the Fugl-Meyer Assessment, Barthel Activities of Daily Living Index, and the Stroke Impact Scale at three and six months. Upper limb functional recovery success was greater for the enhanced upper limb therapy group (50%) compared to the robot-assisted training group (44%) and usual care (42%). The enhanced upper limb therapy group and the robot-assisted training group had less upper limb impairment, better mobility, and better performance in activities of daily living compared to usual care at three and six months. However, the enhanced upper limb therapy group outperformed the robot-assisted training group in all of these areas with the exception of upper limb function. Both the robot-assisted training and enhanced upper limb therapy group were acceptable therapies for the participants and therapists. The trial concluded that robot-assisted training did not improve upper limb function after stroke when compared with an enhanced upper limb therapy program or with usual care.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
No codes	

HCPCS Codes

Code	Description
K1007	Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors (ReWalk Personal Prosthetic Exoskeleton System) (Effective 10/1/2020)

Code	Description
K1015	Foot, adductus positioning device, adjustable (effective 4/1/2021)
L0112-L0710	Cervical-thoracic-lumbar-sacral orthotic devices (code range)
L0810-L0861	Halo procedure (code range)
L0970-L0984	Additions to spinal orthosis (code range)
L1000–L1310	Orthotic devices, scoliosis procedures (code range)
L1600-L1755, L1900-L2861	Orthotic devices - lower limb (code range)
L3470	Heel, Thomas extended to ball
L3650-L3766, L3806- L3809 L3900-L3956	Orthotic devices - upper limb
L3960-L3995	Shoulder-elbow-wrist-hand orthosis (SEWHO) (code range)
L4000-L4210	Replacement and repairs of orthotic device (code range)
L4350	Ankle control orthosis, stirrup style, rigid, includes any type interface (e.g., pneumatic, gel), prefabricated, off-the-shelf
L4360	Walking boot, pneumatic and/or vacuum with or without joints, with or without interface material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L4361	Walking boot, pneumatic and/or vacuum, with or without joints, with or without interface material, prefabricated, off-the-shelf
L4370	Pneumatic full leg splint, prefabricated, off-the-shelf
L4386	Walking boot, nonpneumatic with or without joints, with or without interface material prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L4387	Walking boot, nonpneumatic, with or without joints, with or without interface material, prefabricated, off-the-shelf
L4392	Replacement soft interface material, static AFO
L4394	Replace soft interface material, foot drop splint
L4396	Static or dynamic ankle-foot orthotic, including soft interface material, adjustable for fit, for positioning, may be used for minimal ambulation, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L4397	Static or dynamic ankle foot orthosis, including soft interface material, adjustable for fit, for positioning, may be used for minimal ambulation, prefabricated, off-the-shelf
L4398	Foot drop splint, recumbent positioning device, prefabricated, off-the-shelf

Code	Description
L4631	Ankle-foot orthotic (AFO), walking boot type, varus/valgus correction, rocker bottom, anterior tibial shell, soft interface, custom arch support, plastic or other material, includes straps and closures, custom fabricated
L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)
L8701	Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated
L8702	Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated

ICD10 Codes

Code	Description
Several	

KEY WORDS

Brace, Orthosis, Orthotic, Splint, OttoBock E-MAG Active KAFO, OttoBock Sensor Walk Electronic KAFO, MYOMO mPower 1000 arm brace.

REFERENCES

Rogers H, et al. Robot-assisted training compared with an enhanced upper limb therapy programme and with usual care for upper limb functional limitation after stroke: the RATULS three-group RCT. Health Technol Assess 2020 Oct;24(54):1-232.

Winstein CJ, et al. Guidelines for Adult Stroke Rehabilitation and Recovery: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. Stroke 2016 Jun;47(6):e98-e169.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for Ankle-Foot/Knee-Ankle-Foot Orthosis. Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33686&ContrId=389&ver=28&ContrVer=1&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=1&bc=AAQAAAIAAAAA&

There is currently a Local Coverage Determination (LCD) for Spinal Orthoses: TLSO and LSO. Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33790&ver=20&CntrctrSelected=389*1&Cntrctr=389&s=41&DocType=1&bc=AAgAAAQAgAAA&