MEDICAL POLICY DRAFT

MEDICAL POLICY DETAILS	
Medical Policy Title	**Orthotics**
Policy Number	**1.01.25**
Category	**~~Equipment/Supplies~~ Contract Clarification**
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, 4/20/23**
Current Effective Date	**~~04/21/22~~ 4/20/23**
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.*~~ • ***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 (including Medicare HMO-Dual Special Needs Program (DSNP) 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.*** • ***If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.***

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~~ **custom** 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.

III. Based upon our criteria and the lack of peer-reviewed literature, the following enhanced devices have not been medically proven to be effective and, therefore, are considered investigational to improve the functioning of an impaired body part.

- **A. electronic/electromagnetic activated stance control KAFO devices (e.g., OttoBock E-Mag Active, OttoBock 17B500 Sensor Walk, and OttoBock C-Brace)**
- **B. myoelectric and/or power enhanced upper extremity orthotic device (e.g., MyoPro arm brace)**
- **C. powered exoskeleton orthosis (e.g., ReWalk, EskoNR, and Indego personal exoskeletons)**

*Refer to Corporate Medical Policy #1.01.14 Surgical Stockings **and Compression Garments**.*

*Refer to Corporate Medical Policy #1.01.18 **External** 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** 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; 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.

Electronic/electromagnetic activated stance control KAFO devices

Electronic devices use microprocessors with specialty orthotic braces to reportedly provide assistance in walking. Examples of these include but may not be limited to ~~Both~~ the OttoBock E-MAG Active, ~~and~~ The Sensor Walk, **and the C-Brace Orthotronic** electronic knee-ankle-foot orthotics (KAFO). The Ottobock 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 Ottobock 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. The Ottobock Sensor Walk received **510(k) Food and Drug Administration (FDA) approval in 2006 classified as an electronic stance control KAFO limb brace. The Ottobock C-Brace Orthotronic is a KAFO that utilizes a microprocessor in the orthotic and offers a more natural gait pattern compared to locked KAFOs and traditional stance control KAFOs. According to their website, the C-Brace consists of individually fabricated thigh, calf, and foot components. An ankle joint or individual spring element connects the foot and calf components. The sensor system continuously measures the flexion of the knee joint and its angular acceleration. This lets the C-Brace detect the user's current walking phase, so it can regulate the hydraulic resistances as well as control the flexion and extension of the knee joint.**

Myoelectric and/or power enhanced upper extremity orthotic device

Myoelectric powered upper extremity orthotics use microprocessors and electronics to provide assistance with movement of extremity. They can also use sensors on the muscles to help self-initiate movement. 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. **Myomo Inc. received 510(k) FDA approval for the Myomo e100 in 2007 classified as EMG-triggered powered exercise equipment, an electromechanically powered device intended to facilitate movement and increase range of motion for stroke patients. This device is intended for stroke patients undergoing rehabilitation and would be included as part of prescribed physical therapy to enable stroke patients to exercise independently otherwise they would be unable to do so.**

Powered exoskeleton orthosis

ReWalk is a wearable robotic exoskeleton that provides powered hip and knee motion to enable individuals with spinal cord injury (SCI) to stand upright and walk. ReWalk is the first exoskeleton to receive FDA clearance for personal and rehabilitation use in the United States and was granted 510(k) FDA approval in 2014 for a new classification code PHL. Indego (Parker Hannifin) was approved by the FDA through the 510(k) process in 2016 classified as a powered exoskeleton. The FDA determined that this device was substantially equivalent to existing devices, citing ReWalk as a predicate device. Indego Therapy is an adjustable, lower-limb powered exoskeleton that can be custom-sized and perfectly fitted to patients in less than five minutes. Indego Therapy enables individualized gait therapy for patients with lower extremity weakness or paralysis (such as complete/incomplete spinal cord injury and stroke). In December 2022 Indego was acquired by Esko Bionics and they now offer the Esko Indego Personal exoskeleton to enable those with SCI a functional independence in their home and community. Esko Bionics also offers the EskoNR which is available at certified rehabilitation centers.

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, servomotor) 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.

Electronic/electromagnetic activated stance control KAFO devices

The evidence is limited in peer-reviewed literature for stance control orthotic devices and studies have not shown these devices to be superior in health outcomes compared to standard measures. The published studies are limited to few randomized controlled trials and small case studies which many are supported by the manufacturers. In a randomized, cross-over study (Deems-Dluhy, et al. 2021, Clinical Trial No. NCT02089880) 18 participants were trained on use of a stance control orthosis (SCO) or a microprocessor controlled orthosis (MPO) which was the OttoBock C-Brace for this study. All participants currently used a unilateral KAFO or SCO for impairment due to neurologic or neuromuscular disease, orthopedic disease, or trauma. After an acclimation and training period of one month, participants used the first device in their home for another month and were then evaluated. Participants then crossed over to the other device group (SCO or MPO), received a month of acclimation and training, followed by home trial and evaluations. Outcomes measured included the 6-minute walk test (6MWT), 10-m walk test, Berg Balance Scale (BBS), functional gait assessment (FGA), hill assessment index, stair assessment index (SAI), Five Times Sit to Stand Test, crosswalk test, Modified Falls Efficacy Scale (mFES), Orthotic and Prosthetic User's Survey (OPUS), and World Health Organization Quality of Life (WHQOL)-BREF Scale. Standard patient-reported and performance measures of function and metabolic cost during walking were assessed at baseline with their own device and after training and use of each of the study devices. Significant changes were observed in participants' self-selected gait speed (P=.023), BBS (P=.01), FGA (P=.002), and SAI (P<.001) between baseline and post-MPO assessment. During the 6MWT, persons using the MPO walked significantly longer (P=.013) than when using their baseline device however, there were no significant differences in oxygen consumption and heart rate values measured during the 6MWT across all the groups. Participants reported higher quality of life scores in the OPUS (P=.02) and physical health domain of the WHOQOL-BREF (P=.037) after using the MPO. Participants reported fewer falls when wearing the MPO (five) versus a SCO (38) or locked KAFO (15). However, there were no significant gains in balance confidence as measured by the mFES from baseline to tests with the MPO and SCO. This study was limited by its high rate of withdrawal and consequently small sample size with limited statistical power.

Myoelectric and/or power enhanced upper extremity orthotic device

The published peer-reviewed studies for upper limb myoelectric orthotic devices are limited. They include studying the devices in a rehabilitation setting for training and further studies are needed for the home setting. 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 one week to five 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.

In a single group interventional, study, (Pundik, et al. 2022 Clinical Trial No. NCT03215771) 13 patients with moderate to significant arm weakness due to stroke or TBI were evaluated after using the MyoPro. The in-clinic phase consisted of two weekly sessions each lasting 1.5 hours under the direction of a physical therapist trained in the application of motor learning-based upper limb intervention and use of the MyoPro. Sessions were divided into 45 minutes of training in the device and 45 minutes of training outside of the device. A customized home exercise program (HEP) was devised to complement in-clinic practice and consisted of in-device and out-of-device exercises tailored to the individual's needs. The participants took the MyoPro home from therapy sessions to practice during non-therapy days. At the conclusion of the in-clinic phase, individuals transitioned to the home phase during which they were instructed to complete their customized HEP as prescribed for nine weeks with the MyoPro. The study did not include a control group. Outcomes were collected at baseline and at weeks three, five, seven, nine, 12, 15, and 18. Statistics included mixed model regression analysis. Statistically significant and clinically meaningful improvements were observed on Fugl-Meyer (+7.5 points). Gains were seen at week three, increased further through the in-clinic phase and were maintained during the home phase. Statistically significant changes in Modified Ashworth Scale, range of motion, and Chedoke Arm and Hand Activity Inventory were seen early during the in-clinic phase. Orthotic and Prosthetic User's Survey demonstrated satisfaction with the device throughout study participation. Both stroke and TBI participants responded to the intervention. Limitations of this study include a small sample size, lack of a control group, no blinding was employed, and was a cohort of mixed diagnoses with a range of impairments. The authors concluded the study showed MyoPro might be a useful tool for motor learning in individuals with chronic stroke and TBI. Further study using a randomized controlled design is warranted.

Powered exoskeleton orthosis

The published peer-reviewed studies for powered exoskeletons are limited outside of the rehabilitation setting. Further study is needed to determine the benefits of these devices outside of the institutional setting. There are insufficient studies comparing exoskeleton devices with conventional therapy and treatment. A systematic review (Tamburella et al. 2022) compared commercial powered exoskeletons (EXOs) (Ekso, ReWalk, Indego, HAL and Rex devices) in individuals with spinal cord injury (SCI). Forty one RCTs and non RCT studies included 566 participants in their review. The most investigated domain was walking, followed by cardiorespiratory/metabolic responses, spasticity, balance, quality of life, human–robot interaction, robot data, bowel functionality, strength, daily living activity, neurophysiology, sensory function, bladder functionality and body composition/bone density domains. The most frequent adverse events were skin lesions, while the less frequent ones were the presence of extreme fatigue, falls, bone fractures or muscle strain. There were limitations noted such as poor or moderate methodological quality of the studies included, participant cohorts were heterogenous and small, interventions were variable, and the heterogeneity of control groups and follow up assessments. The authors concluded it is not possible to draw general conclusions about the effects of EXOs usage due to the lack of high-quality studies. However, the strengths and weaknesses of EXOs are starting to be defined, even considering the different types of adverse events that EXO training brought about. EXO training showed to bring significant improvements over time, but whether its effectiveness is greater or less than conventional therapy or other treatments is still mostly

unknown. High-quality RCTs are necessary to better define the pros and cons of the EXOs available today. Studies of this kind could help clinicians to better choose the appropriate training for individuals with SCI.

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.*
- ***Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).***

CPT Codes

Code	Description
No codes	

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HCPCS Codes

Code	Description
K1007 **(E/I)**	Bilateral hip, knee, ankle, foot **(HKAFO)** 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)~~
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)
L2006 (E/I)	**Knee ankle foot device, any material, single or double upright, swing and stance phase microprocessor control with adjustability, includes all components (e.g., sensors, batteries, charger), any type activation, with or without ankle joint(s), custom fabricated ("Ottobock C-Brace") (effective 01/01/2020)**
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

Code	Description
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
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 **(E/I)**	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 **(E/I)**	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, **OttoBock C brace, ReWalk robotic exoskeleton,** MYOMO mPower 1000 arm brace.

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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&