MEDICAL POLICY

Medical Policy Title	**Orthotics**
Policy Number	**1.01.25**
Current Effective Date	July 17, 2025
Next Review Date	July 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

This policy does not address knee braces. Please see Nationally Recognized InterQual Standards for Knee Braces.

I. Orthotic devices are considered **medically appropriate** when prescribed by a qualified provider for therapeutic support, protection, restoration, 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;

D. Trusses.

II. Custom orthotic devices are considered **not medically necessary** if activities of daily living can be performed with standard orthotic devices. If 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. Duplicate orthotics are considered **not medically necessary**; more than one (1) orthotic device per body part used for the same function is considered a matter of convenience for the member.

IV. The following enhanced devices to improve the functioning of an impaired body part are considered **investigational**:

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, EksoNR, and Indego personal exoskeletons).

RELATED POLICIES

Corporate Medical Policy

1.01.18 External Prosthetic Devices

1.01.32 Cranial Orthotics

1.01.41 Foot Orthotics

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Coverage for orthotics is contract dependent unless required by Federal or State mandates.

II. Foot orthotics are not addressed in this policy.

III. Orthotics used solely for sports or work-related activities may be 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), are **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 **EITHER** of the following are met:

   A. The patient has experienced a change in his or her physiological condition;

   B. There has been irreparable change in the device's condition, or in a part of the device, due to normal wear and tear;

      1. Required repairs would exceed the cost of a replacement device, or the parts that need to be replaced.

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

VIII. 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 the OttoBock E-MAG Active, 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 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. 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. 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 Ekso Bionics and they now offer the Ekso Indego Personal exoskeleton to enable those with SCI a functional independence in their home and community. Ekso Bionics also offers the EksoNR which is available at certified rehabilitation centers.

SUPPORTIVE LITERATURE

Electronic/Electromagnetic Activated Stance Control KAFO Devices

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 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.

Ruetz et al (2024) conducted an industry sponsored, international multicenter, randomized controlled, cross-over clinical trial which compared a traditional KAFO device with a C-Brace microprocessor stance and swing control orthosis (Ottobock SE & Co. KG, Duderstadt, Germany) for individuals with lower limb paresis. Traditional KAFO users were evaluated with a C-Brace trial tool to check whether the potential participant was able to use the C-brace functions. Participants able to meet inclusion criteria were randomized to either start with their traditional KAFO or the C-Brace. Participants had to commit to use the C-Brace at least 1 hour per day 5 days per week. Participants starting with the C-Brace used it at home for a 3 month period, followed by a 1 month washout period of using their own KAFO, followed by another 3 month C-Brace home use period. Participants starting with their own KAFO continued their use for 3 months and then used the C-Brace for a 3 month period. In total, 149 participants were enrolled, 102 individuals were randomized, and 76 participants completed the protocol. Participants mean age was 55.8 years including 57 males and 45 females. The primary outcome measure in this study was the Berg Balance Scale (BBS), a 14-item

performance-based instrument, to assess balance with the orthosis. Higher scores represent better balance, and BBS scores <45 have been found to indicate an increased risk of falling in the elderly and scores <40 have been shown to demonstrate an almost 100% fall risk. Secondary physical performance outcome measures included the Dynamic Gait Index (DGI), the 6-minute walk test (6MWT), and the Stair Assessment Index (SAI). With the C-Brace, the BBS improved by3.3 ± 6.3 points ($p < 0.0001$). Significantly fewer participants presented BBS scores <40 indicative of increased fall risk (16 vs. 36, $p = 0.018$). Mean falls reduced from 4.0 ± 16.8 to 1.1 ± 3.3 ($p = 0.002$). Outcomes for function, mobility, and quality of life showed significant improvements with the C-Brace. In the 6MWT, the differences between the C-Brace and baseline KAFO use were not statistically significant. The distance walked with KAFO use was significantly longer than at baseline but did not reach the level of clinical meaningfulness. This study was limited by the Covid-19 pandemic and closures of the research sites during the study time. A total of 32 individuals chose to terminate their study participation or had to be withdrawn by the local investigators. Another limitation of this study was only including participants with a baseline BBS score <45.

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 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. 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 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.

Chang et al (2024) conducted an industry sponsored, retrospective study to evaluate the outcomes from the use of a custom MyoPro orthosis in individuals 65 years and older with upper limb impairment secondary to stroke. The Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire was administered to individuals who have chronic stroke both before and after receiving their myoelectric orthosis. Nineteen participants were recruited nationwide from Myomo, Inc.'s patient database who had the orthosis for at least 6 months and had completed a pre-orthosis DASH assessment. Participants were 78.9% male and 52.6% White. All the MyoPro users in this study were 65 years and older (median of 68.0 years), had chronic stroke (at least 1.6 years since stroke onset) and received their MyoPro at a mean of 11.7 months before completing their post-MyoPro DASH questionnaire. After using the MyoPro, participants had a mean improvement (decrease) in DASH score of 18.07, 95% CI 5 (225.41, 210.72), adjusted for eight (8) covariates. This large change in DASH score was statistically significant and clinically meaningful as participants self-reported an improvement with engagement in functional tasks. The authors concluded that the use of the MyoPro increases independence in functional tasks as reported by the validated DASH outcome measure for older participants with chronic stroke. Limitations of this study include its Myomo Inc funded and retrospective study design, the inclusion of only four females, and small sample size.

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 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.

Spungen et al (2024) published results of a randomized controlled trial conducted at 15 Veterans Affairs medical centers in the United States from 2016 to 2021. The study aimed to examine if use of a wheelchair plus an exoskeleton compared with the use of only a wheelchair led to clinically meaningful net improvements in patient-reported outcomes for mental and physical health. Participants were veterans with spinal cord injury (SCI) and were randomized 1:1 to either standard of care (SOC) with wheelchair use or SOC plus at-will use of an US Food and Drug Administration (FDA) cleared exoskeletal-assisted walking (EAW) device (ReWalk Robotics Inc) for 4 months in the home and community. The primary outcomes were measured with the Veterans RAND 36-Item Health Survey (MCS/VR-36) and the Spinal Cord Injury–Quality of Life (SCI-QOL) assessment tools. The primary outcomes were measured at baseline, post randomization after advanced EAW training sessions, and at 2 months and 4 months (primary end point) in the intervention period. A total of 161 veterans with SCI were randomized to the EAW (n = 78) or SOC (n = 83) group; 151 (94%) were male, the median age was 47 (IQR, 35-56) years, and median time since SCI was 7.3 (IQR, 0.5 to 46.5) years. The FDA requires a trained companion to accompany the personal exoskeletal device user. Each participant had up to three (3) companions who trained with them during the EAW training sessions. The proportions of successes were not statistically significant between the EAW and SOC groups for the MCS/VR-36 (EAW:12 of 78 [15.4%] vs SOC:14 of 83 [16.9%]; relative risk, 0.91; 95% CI, 0.45-1.85) and SCI-QOL physical and medical health domain (EAW:10 of 78 [12.8%] vs SOC:11 of 83 [13.3%]; relative risk, 0.97; 95% CI, 0.44-2.15).

The EAW group reported using the exoskeletal device a mean (SD) of 86 (46) minutes per week (range, 0-248 minutes per week) for 7.7 (5.3) weeks (range, 0-16 weeks). The mean (SD) cumulative total step count ranged from 4321 (4654) to 6192 (10 707) steps per month (range across all EAW participants, 250-57 766 steps per month), which is a mean (SD) distance of 1.53 (0.02) miles per month (range, 0.07-16.40 miles per month).The authors reported that device use was lower than expected primarily due to the FDA-mandated companion being unavailable 43.9% of the time (177 of 403 instances). Other nonuse reasons were illness (70 [17.4%]), being busy (58 [14.4%]), travel (37 [9.2%]), and inclement weather (24 [6.0%]). During the post-randomization

period, 18 serious adverse events (SAEs) and 157 adverse events (AEs) occurred in the EAW group and 28 SAEs and 165 AEs in the SOC group. Two EAW-related foot fractures and nine (9) unrelated fractures (mostly during wheelchair transfers) were reported. The study was limited by the high number of screen failures and withdrawals and the low amount of device use during the study period. The authors concluded the study showed home and community use of this first-generation personal exoskeleton in the SCI population failed to support improved quality of life.

PROFESSIONAL GUIDELINE(S)

The American Physical Therapy Association (APTA) published guidelines for improving locomotor function after a chronic stroke, incomplete spinal cord injury or brain injury (Hornby 2020). Their recommendations for use of robotic assisted or exoskeleton devices are as follows:

- "Robotic-Assisted Walking Training Following Acute-Onset Central Nervous System (CNS) Injury: Based on the preponderance of evidence for individuals poststroke and incomplete spinal cord injury (iSCI) and limited evidence in traumatic brain injury (TBI), clinicians should not perform walking interventions with exoskeletal robotics on a treadmill or elliptical devices to improve walking speed and distance in individuals greater than 6 months following acute-onset CNS injury as compared with alternative interventions (evidence quality: I-II; recommendation strength: strong for stroke and iSCI).
- Strong evidence (six (6) level 1 and one (1) level 2 articles) indicates that walking training with robotics compared with walking training alone does not result in greater walking speed or distance in people in the chronic stages following stroke, iSCI, and TBI."

The APTA published guidelines for the use of ankle-foot orthoses (AFO) and functional electrical stimulation (FES) post-stroke to improve body function and mobility (Johnston 2021). Their recommendations based on findings from 122 included meta-analysis, systematic reviews, randomized controlled trials, and cohort studies are as follows:

- Strong evidence exists that AFO and FES can each increase gait speed, mobility, and dynamic balance.
- Moderate evidence exists that AFO and FES increase quality of life, walking endurance, and muscle activation.
- Weak evidence exists for improving gait kinematics.
- AFO or FES should not be used to decrease plantar flexor spasticity.

Guidelines for Adult Stroke Rehabilitation and Recovery: A Guideline for Healthcare Professionals from the American Heart Association/American Stroke Association (Winstein 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.

REGULATORY STATUS

The Ottobock Sensor Walk received 510(k) Food and Drug Administration (FDA) approval in 2006 classified as an electronic stance control KAFO limb brace.

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.

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.

Ekso and EksoGT (Ekso Bionics) were approved by the FDA through the 510(k) process in 2016 classified as lower extremity powered exoskeletons. They were approved to perform ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for patients with hemiplegia due to stroke or a spinal cord injury.

EksoNR (Ekso Bionics) was approved by the FDA through the 510(k) process in 2020 as a substantially equivalent device. Like the EksoGT, the EksoNR is intended to be used in a rehabilitation institution under the supervision of a trained physical therapist. The indications for use are spinal cord injury, stroke, and acquired brain injury, including traumatic brain injury. The indications were expanded in 2022 through the 510(k) process to include multiple sclerosis as an indication.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

HCPCS Codes

Code	Description
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components, and electronics, not otherwise classified
E0738 (E/I)	Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, includes microprocessor, all components, and accessories
E0739 (E/I)	Rehabilitation system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors
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 (Personal Exoskeleton System)
L0120- L0720	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)
L1320	Thoracic, pectus carinatum orthosis, sternal compression, rigid circumferential frame with anterior and posterior rigid pads, custom fabricated
L1600-L1755, L1900-L2861	Orthotic devices - lower limb (code range)

Code	Description
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”)
L3470	Heel, Thomas extended to ball
L3161	Foot, adductus positioning device, adjustable
L3650-L3766, L3806- L3809 L3900-L3956	Orthotic devices - upper limb
L3960-L3967	Shoulder-elbow-wrist-hand orthosis (SEWHO) (code range)
L3971-L3978	Shoulder-elbow-wrist-hand-finger orthosis (SEWHO) (code range)
L3980-L3995	Upper extremity fracture orthosis, humeral (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

Code	Description
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
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
Multiple Codes	

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Ankle-Foot/Knee-Ankle-Foot Orthosis (LCD L33686) [accessed 2025 Jun 5]

Ankle-Foot/Knee-Ankle-Foot Orthoses (Policy Article A52457) [accessed 2025 Jun 5]

Knee Orthoses (LCD L33318) [accessed 2025 Jun 5]

Knee Orthoses (Policy Article A52465) [accessed 2025 Jun 5]

Spinal Orthoses: TLSO and LSO (LCD L33790) [accessed 2025 Jun 5]

Spinal Orthoses: TLSO and LSO (Policy Article A52500) [accessed 2025 Jun 5]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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 HISTORY/REVISION	
Committee Approval Dates	
10/18/01, 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, 04/26/12, 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, 04/21/22, 06/22/23, 06/20/24, 06/26/25	
Date	**Summary of Changes**
06/26/25	• Annual review, policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
10/18/01	• Original effective date