# Molina Clinical Policy
# Power Enhanced, Robotically Assisted, and Microprocessor Upper and Lower Extremity Orthoses: MEDICARE
# Policy No. 350b

**Last Approval: 10/21/2026**
**Next Review Due By: February 2027**

## DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment. Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of the Federal government or CMS for Medicare. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

## OVERVIEW

Extremity deficits or weakness can be caused by a myriad of disease processes, including stroke, trauma, brachial plexus injury, cerebral palsy, or other progressive neurological diseases. These deficits are often improved through physical therapy, particularly repetitive task practice, to train the affected extremity. However, in some cases, additional interventions, such as orthoses, may be needed to support extremity function. Orthoses are external devices that are used to improve the function of weak or injured body parts. They are distinct from prosthetic devices, which are designed to replace missing body parts. Standard, non-powered orthotic devices typically provide support and stabilization through the use of static or dynamic splinting or bracing.

**Power enhanced, robotically assisted, and/or microprocessor orthoses** integrate technology into an orthotic to help patients regain function of weak or injured body parts. They combine the structure of a standard upper limb orthotic device with microprocessors, muscle sensors, an electric motor, and/or hydraulics to assist in extremity movement. They're designed to enable individuals to self-initiate and control movements of a partially paralyzed or weakened extremity using their own muscle signals via electromyographic sensors (e.g., Myopro), via EEG neural signals (e.g., IpsiHand), or through sensors and applications via smartphone (e.g., Neuro HiSWING R+, Carbonhand).

**Regulatory Status**

The following is a non-exhaustive list of power enhanced, robotically assisted, and/or microprocessor orthotic examples.

MyoPro system (Myomo Inc.) received FDA approval via the 510(k) Premarket process in 2007 under product code OAL and 510(k) number K062631. It is classified as powered, emg-triggered, exercise equipment intended as an electromechanically powered device intended to facilitate movement and increase range of motion for stroke patients. There are multiple newer models on the market (e.g., MyoPro 2, MyoPro 2+), all with their own enhancements.

IpsiHand (Neurolutions Inc.) received FDA approval via the De Novo process in 2021 under product code QOL and De Novo number DEN2000046. It is classified as an electroencephalography (EEG)-driven upper extremity powered exerciser intended to facilitate muscle re-education and for maintaining or increasing range of motion in the upper extremity of chronic stroke patients (≥ 6 months post-stroke) undergoing rehab.

Neuro HiSWING R+ is registered with the FDA as an external joint, knee brace intended as an orthotic to assist with pathological gait due to insecurities when standing and walking. It is exempt from the 510(k) Premarket process as a Class 1 medical device under registration number 3011404939.

Carbonhand is registered with the FDA as a powered hand, external limb component intended to assist with grip strength in patients with reduced grip strength or impaired hand function. It is exempt from the 510(k) Premarket process as a Class 1 medical device under registration number 3027241828.

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## COVERAGE POLICY

Power enhanced, robotically assisted, and/or microprocessor upper and/or lower extremity orthoses (e.g., MyoPro, IpsiHand, Carbonhand, Neuro HiSWING R+) are considered **experimental, investigational, and unproven** for all indications, including but not limited to stroke, trauma, brachial plexus injury, cerebral palsy, or any other neurological or neuromuscular disease or injury, due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

*Note: These devices are distinct from prosthetic devices, which replace or compensate for missing body parts*

**All prior authorization requests for covered benefits are reviewed for medical necessity on an individual basis.**

**DOCUMENTATION REQUIREMENTS:** Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

## SUMMARY OF MEDICAL EVIDENCE

There is a paucity of literature in the peer-reviewed publications to assess safety, efficacy, long-term outcomes, and patient management associated with the use of power enhanced, robotically assisted, and/or microprocessor orthotic examples. The literature currently consists of case reports, retrospective observational studies, and a few randomized controlled trials (RCTs) with small patient populations and short-term outcomes. Additional well-designed, large-scale clinical studies evaluating this technology following stroke and other neurological injuries are required to establish its clinical efficacy and safety.

***Randomized Controlled Trials***

Page et al. (2020) published the results of a single-blinded RCT involving 34 participants (n = 34) exhibiting chronic, moderate, stable, post-stroke, upper extremity hemiparesis. Participants were randomized by a computer-generated number table to receive one of the following three interventions: Myomo combined with repetitive, task-specific practice (RTP), RTP only, or Myomo therapy only. Of the 34 participants, 31 completed the study and were analyzed. The main outcome of this study was the Upper Extremity section of the Fugl-Meyer (FM) assessment, which evaluated upper extremity impairment. The Arm Motor Activity Test (AMAT) was the secondary outcome of this study and was utilized to determine if there were any changes in activity limitations. Regarding the primary outcome measure, all three groups showed almost identical score increases of around +2 points, indicating no differences in the extent of change. For the secondary outcome measure, the two groups using the Myomo showed almost identical score increases of about +1 point each, while the RTP group had a score increase of +2.6 points. The between-group comparison for FM and AMAT indicated no significant differences between the groups on all measures (FM: H = 0.376, p = 0.83; AMAT: H = 0.978, p = 0.61) The study found that RTP using a myoelectric device resulted in motor improvements similar to those seen with traditional hands-on therapies involving direct therapist guidance and hand-over-hand assistance. Importantly, the duration of therapist contact was the same for both groups. Future research will be necessary to evaluate if myoelectric bracing can be a viable alternative to labor-intensive upper extremity training, or if it could be used as a supplementary strategy with comparable effectiveness to manual therapy for individuals with moderate stroke impairments.

Willigenburg et al. (2016) compared behavioral and kinematic outcomes of post-stroke survivors with moderate upper extremity impairment in an 8-week randomized controlled trial. The 12 subjects were randomly assigned to either the standard treatment of repetitive task-specific practice (n=5) or the use of the Myomo e100 myoelectric upper extremity orthotic with repetitive task-specific practice (n=7). Individuals who used the myoelectric orthotic performed better on the Stroke Impact Scale, which included self-reported measurements on recovery perceptions (p=0.032) and daily

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activities (p=0.061). The standard treatment group outperformed the control group in terms of kinematic peak hand velocity during the reach-up task (p=0.018). There were no significant differences in the remaining kinematic outcomes, which included elbow extension and shoulder flexion. The researchers concluded that using a myoelectric orthotic increases the perception of improvement; however, when evaluating kinematics, myoelectric orthotics were just as effective as standard manual treatment. The study's limitations include a small sample size, treatment stability issues, and a short duration.

***Systematic Reviews and Meta-Analyses***

Richards et al. (2025) conducted a systematic review to investigate the use of upper-extremity myoelectric orthoses in individuals with upper limb weakness or paralysis due to stroke or traumatic brain injury. Ten studies met the inclusion criteria, including 1 RCT and the remainder being non-randomized experimental, prospective single-arm, or retrospective studies. Five studies (n = 76) focused on compensatory use and task performance with and without the device, all of which showed that participants could complete more tasks or parts of tasks while using the device than without it. In general, the studies reported improvements in motor function, gross manual dexterity, and the ability to perform simulated activities of daily living (ADLs) such as grasping, feeding, and object manipulation. For example, Peters et al. (2017) reported an 8.72-point improvement in the FM Assessment for Upper Extremity when using the device, which surpassed the minimal clinically important difference for this measure. Five studies evaluated device use as part of a restorative motor rehabilitation program, which had mixed results. The median standardized difference for the FM Assessment was 1.8 overall (1.5 for stroke-only participants) and 0.9 for the Modified Ashworth Scale (MAS), indicating significant improvements in motor function and spasticity. Higher improvements tended to be observed in participants with moderate baseline impairment and in studies with more hours of motor practice (30-50 hours). The one RCT, by Page et al. (2020), showed no significant benefit of including a upper-extremity myoelectric orthotic device over conventional task practice. The authors concluded that these devices show promise as compensatory tools to improve functional activity performance in individuals with upper extremity paresis due to stroke or traumatic brain injury. However, the current body of evidence, which is limited by very small sample sizes, single-group designs, and heterogeneity protocols, prevents broad conclusions.

***Non-randomized Studies, Retrospective Reviews and Other Evidence***

Kottnik et al. (2024) conducted a prospective intervention study evaluating 63 participants that used the Carbonhand for six weeks at home. Carbonhand system consists of a wearable glove that enhances a user's grip based on voluntary, active initiation of the system. All patients had chronic self-perceived hand function problems due to a variety of disorders including acquired brain injury, osteoarthritis, rheumatoid arthritis, spinal cord injury, and other neurological disorders. Participants completed five assessments at different time points, three pre-assessments, one post-assessment immediately after the completion of the six week intervention, and one follow-up assessment four weeks after the intervention completion. Primary outcome of maximal hand grip strength was assessed with a dynamometer. Secondary outcome measures were pinch strength of thumb with index, middle and ring fingers, and hand function via the Jebsen Taylor Hand Function Test (JTHFT) and Action Research Arm Test (ARAT). All measures were performed without the glove on the most affected side and assessed during each assessment. Grip strength significantly improved between pre- and post- assessments (+1.9 kg, CI 0.8 to 3.1; p = 0.002) and between pre- and follow-up assessments (+1.7 kg, CI 0.5 to 2.8; p = 0.012). Pinch strength slightly improved but did not reach statistical significance. Timed performance on JTHFT significantly improved after six-week glove use between pre- and follow-up assessments (p = 0.020) and between pre- and follow-up assessments (p = 0.002). Individual variation was high across all outcomes assessed. Use time varied from around 20 minutes total use time to more than 186 hours total use over six weeks. This total use time variation may be do to reported mild adverse events in 33 of the 63 patients. The events reported were increased pain, muscle aches, stiffness, skin irritation, and tingling of the hand/fingers. The authors concluded that the use of Carbonhand had a positive therapeutic effect.

Rustamov et al. (2024) conducted a prospective study on 30 patients to evaluate the brain computer interface IpsiHand system in chronic stroke patients. The IpsiHand system utilizes electroencephalographic (EEG) signals from the unaffected side of the brain to control a wearable exoskeleton around the affected extremity. Additionally, the authors included 26 patients from two other studies with the same experimental design to analyze in totality (Advarra Study: NCT04338971,16 patients; Washington University Study: NCT03611855, 10 patients). Primary outcome assessed was motor function, evaluated using the Upper Extremity Fugl-Meyer (UEFM) assessment. Secondary outcomes included the Action Research Arm Test (ARAT), Arm Motor Ability Test (AMAT), Motricity Index, Gross Grasp (Hand Grip Dynamometer), and Modified Ashworth Scale (MAS) at the wrist and elbow scores. It is important

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to note that patients in the Rustamov study received concurrent botox injections in the affected extremity. All patients were at least 6 months post stroke. The minimal clinically significant change in the UEFM score was at least 5.25 point increase, of which a total of 18 of 26 patients reached or exceeded. ARAT score changes were significant, $F(3,75) = 16.32$, $P < .001$. AMAT score changes were significant, $F(3,75) = 26.13$, $P < .001$. Motricity Index score changes were significant, $F(3,75) = 19.48$, $P < .001$. Gross Grasp score changes were significant, $F(3,75) = 5.06$, $P = .003$. Elbow and Wrist MAS scores did not prove significant, $F(3,75) = 2.06$ and 0.02, $P = .11$ and.92, respectively, excluding significant changes across BCI therapy sessions. Botox injections did not significantly change motor function scores.

Chang et al. (2023) conducted a small three-month prospective single arm cohort observational study of 18 individuals affected with chronic arm weakness post stroke (hemiparesis) to compare task performance with and without a myoelectric arm orthosis. The main inclusion criteria were adults who were first time users of a myoelectric arm orthosis post stroke for upper extremity impairment, medically stable, had adequate passive range of motion of the shoulder, elbow, wrist, and fingers and were able to generate a detectable electromyography signal. Four tasks associated with common activities of daily life: grasp/release and elbow flexion/extension were selected due to their applicability to MyoPro's functionality. Participants were custom fitted with a MyoPro orthosis. Prior to receiving the device, all participants were evaluated for the ability to complete the study's selected tasks. All participants (except #12) were not able to complete the tasks with their paretic arm. As an observational study, no training or therapy was provided to the participants, therefore it was unknown how much and what type of therapy or training the participants had received for the orthosis. Post fitting, participants completed research sessions on a regular basis at: 2 weeks, 1 month, 2 months and 3 months over video calls at home. Tasks were completed with and without the MyoPro orthosis. Total completion time and success in task completion was analyzed for each participant, using longitudinal linear mixed effect models. Results demonstrated that participants could be successful in completing the selected tasks using the MyoPro orthosis. "Higher probability of success and reduced time to complete functional tasks were observed with MyoPro as compared without the MyoPro." Participants self-reported increased confidence and ability to complete tasks using the device. Authors note that the sample size was small, the timeframe was short, and participant training and therapy were unknown. They recommend studying the MyoPro over a longer period of time to determine optimal training on the device, determine which tasks are successfully completed with larger sample sizes to identify variable that predict and increase in function with the MyoPro.

**National and Specialty Organizations**

The **National Institute for Health and Care Excellence (NICE)** guidelines for *stroke* do not recommend the use of robot-assisted arm training post-stroke due to a lack of benefit in the current published literature (NICE 2023). NICE guidelines for *cerebral palsy* mention there is a lack of published evidence establishing the effectiveness of orthotic devices in this patient population and recommends additional research in both adults and children (NICE 2017, 2019).

## CODING & BILLING INFORMATION

**HCPCS (Healthcare Common Procedure Coding System)**

| Code | Description |
|---|---|
| **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 |
| **A8005** | Powered, cable driven grip assist glove, hand, finger, includes microprocessor, pressure sensors, all components and accessories, custom fitted [Effective 04/01/2026] |
| **A8006** | Powered, cable driven grip assist glove, hand, finger, includes pressure sensors, glove replacement only [Effective 04/01/2026] |
| **E0738** | Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, includes microprocessor, all components and accessories |
| **L2221** | Addition to lower extremity orthosis, ankle system, microprocessor-controlled feature plantarflexion and/or dorsiflexion, includes power source [Effective 04/01/2026] |

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## APPROVAL HISTORY

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|---|---|
| **10/21/2026** | Policy revised. Added “All prior authorization requests for covered benefits are reviewed for medical necessity on an individual basis." to coverage section. |
| **04/15/2026** | Policy adopted by Medicare UM committee. |
| **04/08/2026** | Policy revised. Coverage criteria expanded to include any power enhanced, robotically assisted, and/or microprocessor upper and lower extremity orthoses as E/I/U. Title changed to “Power Enhanced, Robotically Assisted, and Microprocessor Upper and Lower Extremity Orthoses” |
| **02/11/2026** | Policy reviewed. No change to coverage criteria. |
| **02/12/2025** | Policy reviewed**.** No changes to coverage criteria. Updated Summary of Medical Evidence and References. |
| **02/14/2024** | Policy reviewed, no changes to criteria. Updated Overview, Summary of Medical Evidence, and References sections. IRO Peer Review on January 17, 2024, by a practicing physician board-certified in Pain Management, Physical Medicine, and Rehabilitation. |
| **02/08/2023** | Policy reviewed, updated references. Revised title to ‘MyoPro Orthosis / Myoelectric Upper Extremity Orthoses.” Overview, summary of evidence, and references updated. |
| **02/09/2022** | Policy reviewed, no changes. References updated. New policy template. |
| **02/09/2021** | Policy reviewed, updated references. |
| **12/09/2020** | Policy reviewed, no new peer reviewed literature or clinical studies identified. |
| **12/10/2019** | New policy. IRO Peer Review. Policy reviewed on October 4, 2019, by a practicing physician board-certified in Physical Medicine and Rehabilitation, Pain Management. |

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