Molina Clinical Policy
MyoPro Orthosis / Myoelectric Upper Extremity Orthoses
Policy No. 350

Last Approval: 02/11/2026
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 a State, the Federal government or CMS for Medicare and Medicaid Members. 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

Upper 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 may be needed to support upper extremity function. For example, 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 or non-functioning body parts. Standard, non-powered orthotic devices typically provide support and stabilization through the use of static or dynamic splinting or bracing.

Myoelectric controlled upper extremity orthotic devices (e.g. MyoPro) combine the structure of a standard upper limb orthotic device with microprocessors, muscle sensors, and an electric motor to assist in extremity movement. The MyoPro devices are custom-fabricated, non-invasive myoelectric orthoses that assist individuals with upper extremity deficits in performing self-initiated movement of the affected upper extremity. They're designed to enable individuals to self-initiate and control movements of a partially paralyzed or weakened arm using their own muscle signals. Electromyographic sensors located in the device are positioned over muscles in the upper and lower arm. The MyoPro detects and amplifies electromyographic signals generated by paretic muscles, activating small motors within the orthosis to assist the user to complete the desired movement; therefore, the user must be able to generate detectable electromyographic signals in the impaired extremity to use the MyoPro. There is no use of electrical stimulation or invasive procedures. A therapist, prosthetist or orthotist can adjust gain or the amount of assistance, signal boost, thresholds, and range of motion. The MyoPro is reportedly the first myoelectric orthotic available for home use (Hayes 2025; Myomo 2017).

Regulatory Status

The primary system on the market is the MyoPro system (Myomo Inc.), which was originally FDA-cleared in 2007 through the 510(k) premarket notification process under product code OAL and 510(k) number K062631. Newer generations include the MyoPro 2, MyoPro 2+, and MyoPro 2x, which contain components exempt from the pre-market notification requirement depending on the device classification. Three models of the MyoPro 2 are available:

- MyoPro 2 Motion E: A powered elbow with static rigid wrist support.
- MyoPro 2 Motion W: A powered elbow and a multi-articulating wrist with flexion/extension and supination/pronation. The passive multi-articulating wrist may be pre-positioned by the user to increase task-specific function.
- MyoPro 2 Motion G: A powered elbow, a multi-articulating wrist, and a powered 3-jawchuck grasp.

The MyoPro 2+ has an updated user interface, customization for speed control, an improved design for increased comfort, application, and grasp ability. The MyoPro 2x is the newest model that offers improved arm and hand functioning. Two models of the MyoPro 2+ are available:

- MyoPro 2+ Motion W: A powered elbow and a multi-articulating wrist with flexion/extension and supination/pronation. The passive MAW may be pre-positioned by the user to increase task-specific function.
- MyoPro 2+ Motion G: A powered elbow, a multi-articulating wrist, and a powered 3-jawchuck grasp.

COVERAGE POLICY

Myoelectric upper extremity orthotic devices (e.g., MyoPro and MyoPro 2 systems) 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

**Myoelectric orthotic devices are distinct from prosthetic devices, which replace or compensate for missing limbs or other body parts*

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 the myoelectric upper extremity orthoses. The literature currently consists of case reports, retrospective observational studies, and a few randomized controlled trials (RCTs) with small patient populations with 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 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

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.

Pundik et al. (2022) conducted a mixed cohort pilot study of 13 individuals to evaluate the MyoPro as a tool for motor learning-based therapy for chronic upper limb weakness. The participants had chronic moderate or severe weakness due to stroke (n = 7) or traumatic brain injury (n = 6). They participated in a single group interventional study with two phases, in-clinic, and a home exercise program. The in-clinic phase consisted of eighteen sessions, twice a week, 27 hours of in person therapy and a home exercise program. The home phase consisted of practice of the home exercise program. There was no control group. Treatment was customized to the patient based on their abilities. Participants were educated on the MyoPro and motor learning-based therapy. Tasks included grasp/release, hand to mouth movements, forward reaching movements, bimanual tasks, and fine motor manipulation of objects. Training to the device progressed during the study, as did motor learning-based exercises without the MyoPro. Data was collected on the identified weeks, with the patient using the device. The following scales/tools were used to collect the data: FM for upper limb (primary outcome measure), active and passive range of motion, MAS to assess muscle tone, Chedoke Arm and Hand Inventory to assess activities of daily living, Craig Handicap Assessment and Rehabilitation Technique) objectively evaluates five observable behaviors, Orthotic and Prosthetic User's Survey patient reported device satisfaction and Orthosis utilization, full and partial movements recorded by the MyoPro software. Patient self-

reported changes in arm performance were recorded as well. Improvements were observed on FM MAS, Range of Motion, and Chedoke Arm and Hand Activity Inventory. Orthotic and Prosthetic User's Survey demonstrated satisfaction with the device throughout study participation. The stroke and traumatic brain injury cohorts both responded to the intervention. The study size was small in size, there was no blinding, and no comparison group was included. The authors concluded that based on the encouraging results in impairment and function, further study using a randomized controlled design is warranted.

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

CODING DISCLAIMER: Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

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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