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

Last Approval: 2/14/2024
Next Review Due By: February 2025

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

Myoelectric controlled upper-extremity orthotic devices use neurologic sensors, microprocessor units, and electric motors to provide self-initiated movement of the affected upper extremity. This device is designed to enable individuals to self-initiate and control movements of a partially paralyzed or weakened arm using their own muscle signals (Hayes 2023).

The MyoPro is a custom-fabricated, non-invasive myoelectric orthosis (brace) that assists an individual with upper extremity deficits to move their arm or hand. The user must be able to generate detectable electromyographic signals in the impaired extremity to use the MyoPro. The device is powered by an external battery pack. Electromyographic sensors located in the device are positioned over muscles in the upper and lower arm. The MyoPro detects and amplifies electromyographic (myoelectric) signals generated by paretic muscles, activating small motors within the orthosis to assist the user to complete the desired movement (Hayes 2023). There is no use of electrical stimulation or invasive procedures (Myomo Inc. 2023). A therapist, prosthetist or orthoptist can adjust gain or the amount of assistance, signal boost, thresholds, and range of motion. Potential users include patients with stroke, traumatic brain injury, spinal cord injury, brachial plexus injury, multiple sclerosis, or cerebral palsy. The MyoPro is reportedly the first myoelectric orthotic available for home use.

Regulatory Status

MyoPro myoelectric orthotic (brace), manufactured by Myomo Inc., is a class II FDA registered 510(k) exempt device. Three models of the MyoPro 2 are available. All MyoPro 2s are elbow-wrist-hand orthoses, featuring powered joints:

- 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+ myoelectric orthotic (brace), manufactured by Myomo Inc., has an updated user interface, customization for speed control, an improved design for increased comfort, application, and grasp ability (Myomo Inc. 2023). Two models of 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+) **are considered experimental, investigational, and unproven** for all indications, including but not limited to use by individuals with stroke, trauma, brachial plexus injury, cerebral palsy, or any other neurological or neuromuscular disease or injury.

There is insufficient literature in the peer-reviewed publications to assess safety, efficacy, long-term outcomes, or patient management associated with the use of the myoelectric upper extremity orthotic devices (e.g., MyoPro Orthosis) for upper extremity paralysis or paresis.

**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, or 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 with small patient populations that report short-term outcomes. These studies have a small number of participants and short-term follow-up. Additional well-designed, large-scale clinical studies evaluating the benefits and risks of this technology following stroke and other neurological injuries are required to establish its clinical efficacy and safety conclusively.

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 TBI (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: Fugl-Meyer for upper limb (primary outcome measure), active and passive range of motion, Modified Ashworth Scale 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 Fugl-Meyer, Modified Ashworth Scale, 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 TBI 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.

Page et al. (2020) published the results of a small randomized controlled trial involving 34 subjects (n = 34) exhibiting chronic, moderate, stable, post-stroke, upper extremity hemiparesis. Subjects were randomized by a computer-generated number table to receive: Myomo combined with repetitive, task-specific practice or Myomo therapy only. Of the 34 subjects, 31 completed the study and were analyzed. Using the Arm Motor Activity Test, the researchers concluded that further studies are needed to show if myoelectric bracing may be a possible alternative to training.

McCabe et al. (2019) performed a retrospective analysis of data to demonstrate feasibility of the implementation of an upper limb myoelectric orthosis for the treatment of persistent moderate upper limb impairment following stroke (>6 months). Nine patients (>6 months post stroke) participated in treatment at an outpatient Occupational Therapy department utilizing the MyoPro myoelectric orthotic device. Group therapy was provided at a frequency of 1-2 sessions per week (60-90 minutes per session). Patients were instructed to perform training with the device at home on non-therapy days and to continue with use of the device after completion of the group training period. Outcome measures included Fugl-Meyer Upper Limb Assessment (FM) and modified Ashworth Scale (MAS). According to the results, patients demonstrated clinically important and statistically significant improvement of 9.0±4.8 points on a measure of motor control impairment (FM) during participation in group training. Muscle tone improved for muscles with MAS >1.5 at baseline. The study had several limitations, including the inconsistency with which testing was completed and the variability in treatment doses across different patients. Furthermore, this was a retrospective study of clinical care provided to a small, heterogeneous group of stroke survivors, and data on patients' adherence to the home exercise program was not available. However, because this was a real-world clinical setting rather than a controlled trial, the data may be more representative of clinical practice patterns in chronic stroke. Finally, only impairment measures were reported, limiting the interpretation of results in terms of function and quality of life. To better understand how the device affects patient care and functional performance, more robust measurement across multiple domains is required.

Peters et al. (2017) conducted an observational cohort study of 18 participants with moderate upper extremity impairment following stroke to test behavioral outcomes. Outcomes were measured with the upper extremity Fugl-Meyer Scale, a battery of functional tasks, and the Box and Block test. Participants demonstrated significantly reduced upper extremity impairment using the orthosis, such as increased quality in performing all functional tasks, increases in feeding and drinking, and a decrease in the time required to grasp a cup. When participants wore the orthotic, their Fugl-Meyer scores increased by an average of 8.72 points, exceeding the minimal clinically significant difference. Many activities, including elbow extension, grasping items, finger extension, and manual dexterity, yielded statistically significant results; however, the authors concluded that additional large samples and control groups are required in well-designed studies.

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. The researchers noted that this is the first study of its kind on portable myoelectric orthotic kinematics, and that further research is required.

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 (NICE 2019, 2017). NICE recommends additional research in both populations.

SUPPLEMENTAL INFORMATION

Orthosis: An appliance or apparatus used to improve the function of movable body parts. This differs from a prosthetic device which is intended to replace or compensate for a missing limb or body part.

Myoelectric Orthoses: Orthotic devices that combine the structure of a standard upper limb orthotic device with microprocessors, muscle sensor, and an electric motor of a myoelectric device.

CODING & BILLING INFORMATION

HCPCS (Healthcare Common Procedure Coding System) Codes

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

02/14/2024	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.

REFERENCES

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*