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

Last Approval: 2/8/2023
Next Review Due By: February 2024

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 orthotic devices with myoelectric power 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.

The MyoPro® orthosis (brace) is a custom-fabricated myoelectric upper extremity orthosis that uses weak electromyographic signals generated by paretic muscles to assist movement of an impaired arm. The individual has total control over their hand, wrist, elbow, and arm, while the myoelectric arm brace amplifies weak muscle signals to assist in upper limb movement. There is no use of electrical stimulation or invasive procedures (Myomo Inc., 2022). The noninvasive sensors on the surface of the skin read the nerve signals and activate small motors in the orthosis, allowing the patient to move their arm or hand. A therapist, prosthetist or orthoptist is able to adjust gain or the amount of assistance, signal boost, thresholds, and range of motion. Potential users include patients with 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

MyoPro myoelectric orthotic (brace), manufactured by Myomo, is a class II FDA registered 510(k) exempt device. Three models of MyoPro 2s 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 motor and a multi-articulating wrist (MAW) 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 (MAW), and a powered 3-jawchuck grasp.

COVERAGE POLICY

Myoelectric upper extremity orthotic devices (e.g., MyoPro) **is 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.*

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.

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 were 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 Fugi-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.

SUPPLEMENTAL INFORMATION

Orthosis: An appliance or apparatus used to improve the function of movable body parts. This differs from a prosthetic device which are 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

CPT Codes – N/A

HCPCS Codes

HCPCS	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

02/08/2023	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

Government Agencies

1. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database (search: MyoPro, Myomo, myoelectric, orthosis, and orthotic). Available from CMS. Accessed January 2023.
2. Food and Drug Administration (FDA). Myomo e100. Premarket Notification 510(k). 510(k) No. K062631. Rockville, MD. Available from FDA. Published April 12, 2007. Accessed January 2023.

Evidence Based Reviews and Publications

1. Hayes. Evidence Analysis Research Brief: MyoPro orthosis (Myomo, Inc.) for upper extremity paralysis/paresis after stroke. Available from Hayes. Published Oct 4, 2021. Archived Nov 4, 2022. Registration and login required.
2. Hayes. Evidence Analysis Research Brief: MyoPro orthosis (Myomo Inc.) to improve upper extremity function and elbow range of motion in patients with cerebral palsy. Available from Hayes. Updated Aug 17, 2022. Registration and login required.
3. Myomo, Inc. Myomo therapy. Available from Myomo. Published 2008. Accessed January 2023.

Peer Reviewed Publications

1. McCabe JP, Henniger D, et al. Feasibility and clinical experience of implementing a myoelectric upper limb orthosis in the rehabilitation of chronic stroke patients: A clinical case series report. PLoS One. 2019 Apr 12;14(4):e0215311. doi: 10.1371/journal.pone.0215311.
2. Page SJ, Griffin C, White S. Efficacy of myoelectric bracing in moderately impaired stroke survivors: A randomized, controlled trial. Journal of rehabilitation medicine. 2020 Feb 7;52(2):jrm00017. doi: 10.2340/16501977-2644.

3. Peters H, Page S, Persch A. Giving them a hand: Wearing a myoelectric elbow-wrist-hand orthosis reduces upper extremity impairment in chronic stroke. Archives of physical medicine and rehabilitation. 2017 Sep;98(9):1821-1827. doi: 10.1016/j.apmr.2016.12.016.
4. Willigenburg NW, McNally MP, et al. Portable myoelectric brace use increases upper extremity recovery and participation but does not impact kinematics in chronic, poststroke hemiparesis. J Mot Behav. 2017 Jan-Feb;49(1):46-54. doi: 10.1080/00222895.2016.1152220.

Other Peer Reviewed and National Organization Publications (used in the development of this policy)

No guidance located on myoelectric upper extremity orthoses or MyoPro located. NICE recommends access to orthotics in both cerebral palsy guidelines; however, the Myopro device is not referenced.

1. National Institute for Health and Care Excellence (NICE). Available from NICE. Accessed January 2023
    a. Stroke rehabilitation in adults. Clinical guideline [CG162]. Published: June 12, 2013. In development [GID-NG10175] Expected Publication October 18, 2023.
    b. Cerebral palsy in adults. NICE guideline [NG119]. Published January 15, 2019.
    c. Cerebral palsy in under 25s: assessment and management. NICE guideline [NG62]. Published: January 25, 2017
2. Winstein CJ, et al.; on behalf of the American Heart Association Stroke Council, Council on Cardiovascular and Stroke Nursing, Council on Clinical Cardiology, and Council on Quality of Care and Outcomes Research. Guidelines for adult stroke rehabilitation and recovery: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2016; 47: e98–e169. doi: 10.1161/STR.0000000000000098.
3. Dunaway S, Dezsi DB, Perkins J, Tran D, Naft J. Case report on the use of a custom myoelectric elbow-wrist-hand orthosis for the remediation of upper extremity paresis and loss of function in chronic stroke. Mil Med. 2017 Jul;182(7):e1963-e1968. doi: 10.7205/MILMED-D-16-00399.
4. Hoenig H, Colon-Emeric C. Overview of geriatric rehabilitation: Patient assessment and common indications for rehabilitation. Available from UpToDate. Updated December 2, 2021. Accessed January 2023.
5. Kim GJ, Rivera L, Stein J. Combined clinic-home approach for upper limb robotic therapy after stroke: a pilot study. Arch Phys Med Rehabil. 2015; 96(12):2243-2248.
6. Page SJ, Hill V, White S. Portable upper extremity robotics is as efficacious as upper extremity rehabilitative therapy: a randomized controlled pilot trial. Clin Rehabil. 2013 Jun;27(6):494-503. doi: 10.1177/0269215512464795.
7. Stein J, Narendran K, McBean J, et al. Electromyography-controlled exoskeletal upper-limb-powered orthosis for exercise training after stroke. Am J Phys Med Rehabil. 2007 Apr;86(4):255-61. doi: 10.1097/PHM.0b013e3180383cc5.

APPENDIX

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