Molina Clinical Policy
MyoPro Orthosis for Upper Extremity Paralysis / Paresis: Policy No. 350

Last Approval: 2/9/2022
Next Review Due By: February 2023

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

The MyoPro® orthosis (brace) is a powered hand and elbow orthosis designed to provide individuals support and assistance with movement of a weak or paralyzed hand and arm. Using the device, patients can self-initiate and control movement of a partially paretic upper limb using their own myoelectric signals. Sensors in the orthosis detect, process, and amplify weak myoelectric signals generated when a user attempts to initiate movement in their extremity. The amplified signals then activate motors within the device to move the extremity in the desired direction. The orthosis assists with movement only once a signal is detected, allowing the user control of their own extremity. The Myomo e100 (Myomo Inc.) was cleared through the FDA 510(k) Premarket Notification (K062631) process on April 12, 2007. The current MyoPro 2 device as a Listed FDA Class-2, 510-K exempt device.

COVERAGE POLICY

The MyoPro orthosis **is considered experimental, investigational, and unproven** when used to help restore function to arms and hands paralyzed or weakened by CVA stroke, 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 MyoPro Orthosis for upper extremity paralysis/paresis.

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 MyoPro Orthosis for upper extremity paralysis/paresis. At the current time the literature consists prospective comparative studies, prospective uncontrolled studies and case reports. These studies have a small number of participants and short-term follow-up. Additional studies with larger numbers of participants showing consistent improvements in relevant outcome measures are needed.

Stein et al. (2007) evaluated the efficacy of the Myomo e100 device on 6 stroke patients with severe chronic hemiparesis. Each patient used the device for a total of 18 hrs. of exercise therapy (2 to 3 hrs. per week) for a period of 6 weeks. The average age of the patients was 53 years, and the average time since their stroke was 3.67 years. A 7th patient did not have sufficient EMG signals to control the device. Subjects performed exercises including a defined set of functional tasks (moving blocks or turning light switches on or off) with the robotic brace. They were able to control the motorized brace to assist in these motions. Assessment by both the Fugl-Meyer scale and the modified

Ashworth scale (a measure of muscle spasticity) showed improvement in upper extremity motor function. The authors concluded that the EMG-controlled powered elbow orthoses show promise as a new modality for assisted exercise training after stroke but that further studies are needed to confirm these preliminary results.

A Cochrane systematic review (Mehrholz et al, 2018) evaluated the evidence of the effectiveness of electromechanical and robot-assisted training to assess the safety and effectiveness for improving activities of daily living, arm function, and arm muscle strength in people after stroke. Randomized controlled trials comparing electromechanical and robot-assisted arm training for recovery of arm function with other rehabilitation or placebo interventions, or no treatment, for people after stroke were reviewed. 45 trials (involving 1619 participants) were included in the 2018 update of the review. Electromechanical and robot-assisted arm training improved activities of daily living scores (SMD 0.31, 95% confidence interval (CI) 0.09 to 0.52, P = 0.0005; I^2 = 59%; 24 studies, 957 participants, high-quality evidence), arm function (SMD 0.32, 95% CI 0.18 to 0.46, P < 0.0001, I^2 = 36%, 41 studies, 1452 participants, high-quality evidence), and arm muscle strength (SMD 0.46, 95% CI 0.16 to 0.77, P = 0.003, I^2 = 76%, 23 studies, 826 participants, high-quality evidence). Electromechanical and robot-assisted arm training did not increase the risk of participant dropout (RD 0.00, 95% CI -0.02 to 0.02, P = 0.93, I^2 = 0%, 45 studies, 1619 participants, high-quality evidence), and adverse events were rare. The authors concluded that people who receive electromechanical and robot-assisted arm training after stroke might improve their activities of daily living, arm function, and arm muscle strength. However, the results must be interpreted with caution although the quality of the evidence was high, because there were variations between the trials in: the intensity, duration, and amount of training; type of treatment; participant characteristics; and measurements used.

McCabe et al. (2019) performed a retrospective study 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 (p = 0.0005) on a measure of motor control impairment (FM) during participation in group training. It was feasible to administer the training in a group setting with the MyoPro, using a 1:4 ratio (therapist to patients). Muscle tone improved for muscles with MAS >1.5 at baseline.

Willigenberg et al. (2017) examined the efficacy of an 8-week regimen combining repetitive task-specific practice (RTP) with a myoelectric brace (RTP+Myomo) on paretic upper extremity (UE; use in valued activities, perceived recovery, and reaching kinematics) in 12 subjects (4 men; M age = 53.5 years; mean time poststroke = 61.7 months). Seven subjects were administered RTP+Myomo therapy, and 5 were administered RTP only. Both groups participated in individualized, 45-min therapy sessions occurring 3 days/week over an 8-week period. The arm, hand ability, activities of daily living, and perceptions of recovery subscales of the Stroke Impact Scale (SIS), as well as UE reaching kinematics, assessed before and after the intervention. Subjects in the RTP+Myomo group showed greater improvements on all SIS subscales, with the recovery scale reaching statistical significance (p = .03). Subjects in the RTP-only group showed a greater increase in hand velocity in the reach up task (p = .02), but no changes were observed in the range of shoulder flexion or elbow extension during reaching. None of the changes in kinematic outcome measures significantly correlated with any of the changes in SIS subscales. RTP integrating myoelectric bracing may be more beneficial than RTP only in improving self-reported function and perceptions of overall recovery. The authors observed no changes in the range of elbow extension, and no relationship between self-reported improvements and changes in reaching kinematics.

SUPPLEMENTAL INFORMATION

None.

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

2/9/2021	Policy reviewed, updated references.
12/9/2020	Policy reviewed, no new peer reviewed literature or clinical studies identified.
12/10/2019	New policy.

REFERENCES

Government Agencies

1. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. Available from CMS. Accessed December 13, 2021.
2. Food and Drug Administration (FDA). Myomo e100. Summary of Safety and Effectiveness. 510(k) No. K062631. Rockville, MD. Available from FDA. Published April 12, 2007. Accessed December 13, 2021.

Evidence Based Reviews and Publications

1. AMR Peer Review. Policy reviewed on October 4, 2019 by an Advanced Medical Reviews (AMR) practicing physician board-certified in Physical Medicine and Rehabilitation, Pain Management.
2. Hayes. Evidence analysis research brief: MyoPro orthosis (Myomo, Inc.) for upper extremity paralysis/paresis after stroke. Available from Hayes. Published November 2018. Updated July 2020. Accessed Dec. 13, 2021. Registration and login required.
3. Hayes. Evidence analysis research brief: Robotic rehabilitation of upper extremities in patients with degenerative neurological conditions. Available from Hayes. Updated May 2019. Accessed December 13, 2021. Registration and login required.
4. 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 May 2020. Accessed Dec. 13, 2021. Registration and login required.
5. Hoenig H, Colon-Emeric C. Overview of geriatric rehabilitation: Patient assessment and common indications for rehabilitation. Available from UpToDate. Updated December 2, 2021. Accessed December 13, 2021.
6. Myomo, Inc. Myomo therapy. Available from Myomo. Published 2008. Accessed December 14, 2021.

Peer Reviewed Publications

1. Bermúdez I, Badia S, Lewis E, Bleakley S. Combining virtual reality and a myoelectric limb orthosis to restore active movement after stroke: A pilot study. International Journal on Disability and Human Development. 2014 Aug;13(3):393-399. doi: 10.1515/ijdhd-2014-0333. Accessed December 14, 2021.
2. Brackenridge J, Bradnam LV, et al. A review of rehabilitation devices to promote upper limb function following stroke. Neuroscience and Biomedical Engineering. 2016 Mar;4(1):25-42. doi: 10.2174/2213385204666160303220102. Accessed December 14, 2021.
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. Accessed December 14, 2021.
4. Duret C, Mazzoleni S. Upper limb robotics applied to neurorehabilitation: an overview of clinical practice. NeuroRehabilitation. 2017;41(1):5-15. doi: 10.3233/NRE-171452. Accessed December 14, 2021.
5. Gandolfi M, Valè N, et al. Effects of high-intensity robot-assisted hand training on upper limb recovery and muscle activity in individuals with multiple sclerosis: a randomized, controlled, single-blinded trial. Front Neurol. 2018 Oct 24;9:905. doi: 10.3389/fneur.2018.00905. Accessed December 14, 2021.
6. Kwakkel G, Kollen BJ, Krebs HI. Effects of robot-assisted therapy on upper limb recovery after stroke: A systematic review. Neurorehabil Neural Repair. 2008 Mar-Apr;22(2):111-121. doi: 10.1177/1545968307305457. Accessed December 14, 2021.

7. 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. Accessed December 14, 2021.
8. Mehrholz J, Platz T, Kugler J, Pohl M. Electromechanical and robot-assisted arm training for improving arm function and activities of daily living after stroke. Cochrane Database of Syst Rev. 2008;(4):CD006876. Updated 2012, 2015, 2018. doi: 10.1002/14651858.CD006876.pub5. Accessed December 14, 2021.
9. 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. Accessed December 14, 2021.
10. 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. Accessed December 14, 2021.
11. 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. Accessed December 14, 2021.
12. 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. Accessed December 14, 2021.
13. Weber LM, Stein J. The use of robots in stroke rehabilitation: A narrative review. NeuroRehabilitation. 2018;43(1):99-110. doi: 10.3233/NRE-172408. Accessed December 14, 2021.
14. 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. Accessed December 14, 2021.

National and Specialty Organizations

1. Management of Stroke Rehabilitation Working Group. Management of stroke rehabilitation. VA/DOD Clinical Practice Guideline. VA/DOD Evidence Based Practice. Version 2.0, 2010. Washington, DC: Veterans Health Administration, Department of Defense; 2010. Available from VA. Accessed December 14, 2021.
2. National Institute for Health and Care Excellence (NICE). Clinical guidance: Stroke rehabilitation in adults. In development [GID-NG10175] Expected Publication December 14, 2022. Available from NICE. Accessed December 14, 2021.
3. 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. Accessed December 14, 2021.

APPENDIX

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