

Subject: MyoPro Orthosis (Myomo, Inc.) for Upper Extremity Paralysis/Paresis		Original Effective Date: 12/10/19
Policy Number: MCP-350	Revision Date(s):	
MCPC Approval Date: 12/10/19	Review Date:	

DISCLAIMER

This Molina clinical policy is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina clinical policy document and provide the directive for all Medicare members.

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

The MyoPro® orthosis (brace) is designed to enable individuals to support and assist movement of a weak or deformed hand and arm. Patients can self-initiate and control movement of a partially paretic upper limb using their own myoelectric signals. Similar to how a myoelectrically controlled prosthetic operates, the MyoPro orthosis utilizes surface EMG sensing technology to enable volitional motion of the impaired limb. When the user tries to move their extremity, sensors in the orthosis detect, process, and amplify the weak myoelectric signal, which activates motors to move the extremity in the desired direction. The user is in complete control of their own extremity; the orthosis assists with movement only once a signal is detected. According to the manufacturer website, the MyoPro is the only product on the market to help restore function for those who still have their arms and hands but are unable to use them. The Myomo e100 (Myomo Inc.) was cleared through the FDA 510(k) Premarket Notification ([K062631](#)) process on April 12, 2007.²

RECOMMENDATION

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.

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 are needed that show consistent improvements in relevant outcome measures.

Stein et al., (2007) reported the results 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. Patients 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.¹⁴

A Cochrane systematic review (Mehrholz et al, 2008, 2012, 2015 & last update 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. Randomised 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.¹¹

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. ¹⁰

Willigenberg et al (2019) 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. ¹⁶

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
	N/A

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

ICD-10	Description: [For dates of service on or after 10/01/2015]
	Any/All

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Government Agency

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Peer Reviewed Publications

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22. Advanced Medical Review (AMR): Policy was reviewed and vetted by AMR practicing physician board certified in Physical Med & Rehab, Pain Management. 10/4/19.

Review/Revision History:

2019: New Policy