Anthem

Medical Policy

Subject: Upper Extremity Myoelectric Orthoses
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Description/Scope

This document addresses the use of upper extremity myoelectric orthoses (for example, the MyoPro®, MyoMo, Inc., Cambridge, MA), which are intended to augment the function of individuals with upper arm weakness or partial paralysis due to neurological conditions, trauma, or other problems. Such devices use neurologic sensors, microprocessor units, and electric motors to provide self-initiated movement of the affected limb. These devices should not be confused with prosthetic devices, which are intended to replace or compensate for a missing limb or other body part.

Note: For more information regarding upper extremity myoelectric devices, please refer to:

- CG-OR-PR-05 Myoelectric Upper Extremity Prosthetic Devices

Position Statement

Investigational and Not Medically Necessary:

The use of myoelectric upper extremity orthotic devices is considered **investigational and not medically necessary** for all indications, including but not limited to use by individuals with stroke, trauma, or neurological disorders.

Rationale

In 2013, Page and others published the results of a small randomized controlled trial (RCT) involving 16 subjects with chronic, stable, moderate upper extremity impairment. Subjects were assigned to undergo administered repetitive task-specific practice with or without the use of the Myomo e100 myoelectric upper limb orthosis (n=8 in each group). After the intervention, both groups exhibited nearly identical Fugl-Meyer Assessment of Motor Recovery After Stroke score increases of approximately 2.1 points; the group using the orthotic exhibited larger score changes on all but one of the Canadian Occupational Performance Measure and Stroke Impact Scale subscales, including a 12.5 point increase on the Stroke Impact Scale recovery subscale. The authors conclude that therapist-supervised repetitive task-specific practice integrating the Myomo device is as efficacious as manual practice in subjects with moderate upper extremity impairment. The generalizability of this study is limited by the small sample size, as well as other methodological issues. Further investigation on the clinical utility and health outcomes is needed.

Klamroth-Marganska and colleagues (2014) conducted an 8-week prospective, multicenter, parallel-group randomized trial involving 77 subjects diagnosed with single cerebrovascular accident and moderate to severe arm paresis. Subjects were randomly assigned into two groups: robotic therapy (n=39) or conventional therapy (n=38). Both groups applied therapy 3 times a week for 8 weeks (total of 24 sessions). The primary outcome showed a significant difference in the Fugl-Meyer Assessment of the upper extremity motor function (p=0.041). An increase of 5 or more points was noted in 34% of the robotic therapy group and 26% of the conventional therapy group. Lesser progress was noted in the mean strength from the robotic therapy group (p=0.017). The researcher noted that the difference between the two groups was small (0.78 points in the Fugl-Meyer Assessment of the upper extremity) and significance was weak (p=0.41). Before a final conclusion can be drawn, additional investigation with severely affected subjects should be conducted.

In a 2015 pilot study, Kim and colleagues used a nonrandomized pretest-posttest design to evaluate an upper extremity myoelectric orthotic on 11 post-stroke individuals. After undergoing supervised training on the use of a Myomo mPower 1000 myoelectric upper extremity orthotic, subjects completed and logged self-initiated home therapy sessions for 6 weeks. The orthotic was fitted with an accelerometer that recorded motion data. Paired t-test results showed a statistically significant improvement on the Fugl-Meyer Assessment Upper Extremity scale (t=3.32; p=0.01), the Motor Activity Log Amount of Use subscale (t=4.40; p=0.002), and the Motor Activity Log How Well subscale (t=4.02; p=0.004). At a 12-week follow-up, statistical significance dropped but was still present for the Motor Activity Log Amount of Use subscale (t=2.61; p=0.035) and Motor Activity Log How Well subscale (t=2.47; p=0.043). Results for the Arm Ability Test, Box and Blocks test and Modified Ashworth scale were not statistically significant and none of the results from the study met the minimal clinically important difference. Limitations of the study include a small sample size, limited capture of data by the accelerometer, and lack of a control group. Some subjects reported skin irritation or technical difficulties during the study. Two subjects dropped out due to technical problems.

Willigenburg and colleagues (2016) conducted an 8-week RCT to compare behavioral and kinematic outcomes of post-stroke survivors with moderate upper extremity impairment. The researchers assigned 12 subjects 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). The individuals who used the myoelectric orthotic scored higher on the Stroke Impact Scale which included self-reported measurements on recovery perceptions (p=0.032) and activities of daily living (p=0.061). The standard treatment group scored higher on kinematic peak hand velocity during the reach-up task (p=0.018). No significant differences between the groups were found on the remaining kinematic outcomes which included elbow extension and shoulder flexion. The researchers concluded the use of the myoelectric orthotic increases the perception of improvement; however, myoelectric orthotics were as effective as the standard manual treatment when evaluating kinematics. Limits of the study include small sample size, stability of treatment issues and short duration. The researchers note that this is the first known study of its kind on portable myoelectric orthotic kinematics and further investigation is needed.

Peters and colleagues (2017) performed an industry designed and supported observational cohort study to test behavioral outcomes on 18 subjects who had moderate upper extremity impairment following stroke. Each subject performed a series of tests including the Fugl-Meyer Assessment and the Box and Blocks test. The subjects completed the tests in the same order with and without wearing a MyoPro Motion-G myoelectric upper extremity orthotic. The Fugl-Meyer scores were an average of 8.72 points higher (p<0.0001) when participants wore the orthotic and the scores exceeded the minimal clinically important difference. In addition, Box and Blocks test scores were higher for the individuals wearing the orthotic (z=3.42; p<0.001). The researchers found that statistically significant results were demonstrated for many activities including elbow extension, grasping items, finger extension, and manual dexterity.

Limitations include a small sample size and a change in study design. The researchers note that this is the first study comparing subjects with or without a myoelectric brace. Well-designed studies with large samples and control groups are needed.

Page and colleagues (2020) published a small randomized controlled trial involving 34 subjects exhibiting chronic, moderate, stable, post-stroke, upper extremity hemiparesis. The subjects were randomized by a computer-generated number table to receive: Myomo combined with repetitive, task-specific practice; repetitive, task-specific practice only; or Myomo therapy only. Of the 34 subjects, 31 completed the study and were analyzed. Using the Fugl-Meyer Impairment scale (FM), the following score change was noted: Myomo combined with repetitive, task-specific practice = +2.37; repetitive, task-specific practice only = +2.84; and Myomo only = +2.78. Using the Arm Motor Activity Test (AMAT), the following score change was noted: Myomo combined with repetitive, task-specific practice = +1.75; repetitive, task-specific practice only = +2.56; and Myomo only = +0.86. The researchers concluded that further studies are needed to show if myoelectric bracing may be a possible alternative to upper extremity training.

Background/Overview

Upper extremity myoelectric orthoses (for example, the MyoPro) are devices that combine the structure of a standard arm orthotic device with the microprocessors, muscle sensors and electric motor of a myoelectric device. This type of device is designed to enable individuals to self-initiate and control movements of a partially paralyzed or weakened arm using their own muscle signals. When the user tries to bend their arm, sensors in the brace detect the weak muscle signal, which activates the motor to move the arm in the desired direction. The user is completely controlling their own arm; the brace amplifies their weak muscle signal to help bend and move their arm. It has been proposed that with the brace, a paralyzed individual, such as one who has suffered a stroke or other neuromuscular disorder, may be able to perform activities of daily living including feeding, reaching, and lifting.

Definitions

Orthosis: An orthopedic appliance or apparatus used to support, align, prevent, or correct deformities, or to improve function of movable parts of the body. These types of devices are not prosthetic devices, which are intended to replace or compensate for a missing limb or other body part.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

HCPCS

L3999	Upper limb orthosis, not otherwise specified [when specified as an upper extremity myoelectric orthosis]
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 Diagnosis

	All diagnoses

References

Peer Reviewed Publications:

1. 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.
2. Klamroth-Marganska V, Blanco J, Campen K, et al. Three-dimensional, task-specific robot therapy of the arm after stroke: a multicentre, parallel-group randomised trial. Lancet Neurol. 2014; 13(2):159-166.
3. Page S, Griffin C, White S. Efficacy of myoelectric bracing in moderately impaired stroke survivors: A randomized, controlled trial. J Rehabil Med. 2020 Feb 7; 52(2):jrm00017.
4. 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; 27(6):494-503.
5. Peters HT, Page SJ, Persch A. Giving them a hand: wearing a myoelectric elbow-wrist-hand orthosis reduces upper extremity impairment in chronic stroke. Arch Phys Med Rehabil. 2017; 98(9):1821-1827.
6. Willigenburg NW, McNally MP, Hewett TE, Page SJ. Portable myoelectric brace use increases upper extremity recovery and participation but does not impact kinematics in chronic, poststroke hemiparesis. J Mot Behav. 2017; 49(1):46-54.

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MyoMo
MyoPro

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review.
Reviewed	05/12/2022	MPTAC review.
Reviewed	05/13/2021	MPTAC review. Updated Rationale and References sections.
	04/01/2021	Updated Coding section with corrected descriptors for L8701, L8702.

	10/01/2020	Updated Coding section with 10/01/2020 HCPCS changes; revised descriptors for L8701, L8702.
Reviewed	05/14/2020	MPTAC review. Updated Rationale and References sections.
Reviewed	06/06/2019	MPTAC review.
	12/27/2018	Updated Coding section with 01/01/2019 HCPCS changes; added L8701, L8702.
Reviewed	07/26/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated References section.
Reviewed	08/03/2017	MPTAC review. Updated Rationale and References sections.
Reviewed	08/04/2016	MPTAC review. Updated Rationale and Reference sections. Removed ICD-9 codes from Coding section.
Reviewed	08/06/2015	MPTAC review.
New	08/14/2014	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.