HIGHMARK Delaware
HEALTH OPTIONS

CLINICAL MEDICAL POLICY	
Policy Name:	Myoelectric Upper Extremity Orthoses
Policy Number:	MP-075-MD-DE
Responsible Department(s):	Medical Management
Provider Notice Date:	04/01/2019
Issue Date:	05/06/2019
Effective Date:	05/06/2019
Annual Approval Date:	03/12/2020
Revision Date:	N/A
Products:	Highmark Health Options Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 5

DISCLAIMER

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options does not provide coverage for the myoelectric powered upper-extremity orthotics under the Company's Medicaid products.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Orthosis
Orthosis is an appliances 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
These are orthotic devices that combine the structure of a standard arm orthotic with microprocessors, muscle sensors and electric motors with an external power source.

PROCEDURES

1. Highmark Health considers the use of an upper extremity myoelectric orthoses investigational and not medically necessary for all indications, including but not limited to use by members with stroke, trauma or neurological disorders. This device is not to be confused with prosthetic devices that are used to replace or compensate for missing limbs or other body parts.

2. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

3. Place of Service
   The place of service for myoelectric upper extremity orthoses is outpatient.

GOVERNING BODIES APPROVAL

On April 12, 2007 the FDA approved premarket notification 510(k) (K062631) for the Myomo e 100. The device classification includes EMG triggered powered exercise equipment OAL, powered exercise equipment, and limb orthosis. The indication for the device was for stroke patients undergoing rehabilitation to facilitate stroke rehabilitation by muscle re-education and maintain or increasing range of motion.

Additional information is available at:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm.

CODING REQUIREMENTS

Non-covered Procedure Codes

HCPCS Codes	Description
L3999	Upper limb orthosis, not otherwise specified

*These procedure codes will not be reimbursed without Medical Director approval.

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE

In 2013, the Christopher & Dana Reeve Foundation reported that there are nearly 1 in 50 people in the United States leaving with paralysis, which is approximately 5.4 million people. The leading cause of paralysis is stroke (33.7%), followed by spinal cord injury (27.3%) and multiple sclerosis (18.6%). Treatment of upper extremity paralysis can include: surgical procedures, occupational and/or physical

therapy programs, medication, electrical stimulation, braces and orthotics. A recent innovation is the use of myoelectric orthoses.

Upper extremity myoelectric orthoses are devices that are designed to support an arm that is weak or deformed by neurologic impairments as seen in stroke or brachial plexus injuries. As in several types of orthoses, certified prosthetist or orthotists (CPO) create molds and take precise measurements of the user's arm and forwards that information to a fabrication facility. Once completed, the orthosis is returned to the CPO who then adjusts the device and calibrates the software to properly amplify the user's EMG signals.

An example of myoelectric orthoses is the MyoPro (Myomo). According to the manufacturer, this custom fabricated orthotic weights approximately 2 to 4 pounds, has manual wrist articulation, and myoelectric initiated bi-directional elbow movement. The device can enable patients to self-initiate and control movements of a partially paralyzed or weakened arm using their own muscle signals. There is no electrical stimulation or invasive procedures utilized. The robotic brace serves to supplement and enhance the movement of the user.

In an observational cohort study, Peters and Page (2016) reported outcomes on the use of a fabricated myoelectric elbow-wrist-hand orthosis in 18 subjects with chronic, moderate, stable impaired stroke survivors. Outcomes were measured with the upper extremity Fugi-Meyer Scale, a battery of functional tasks and the Box and Block test. Subjects exhibited significantly reduced upper extremity impairment using the orthosis such as increased quality in performing all functional tasks, increases in feeding and drinking as wall a decreases in time required to grasp a cup.

In 2016 Willigenburg and colleagues reported on an 8 week randomized controlled trial of 12 subjects who were post-stroke survivors. The trial sought to compare behavioral and kinematic outcomes using either standard treatment of repetitive task-specific task practice compared to the use of the Myomo e100. The myoelectric orthotic group scored higher on the Stroke Impact Scale which included self-reported measurements on perception of recovery. The standard group scored higher on kinematic peak hand velocity outcomes. The authors concluded that the use of the myoelectric orthotic increase perceptual improvement but the orthotic was as effective as standard manual treatment when evaluating kinematics. The researchers that further well-designed studies with larger sample and control groups are necessary.

Kim and colleagues (2015) reported the results of a small nonrandomized study on the use combined clinic-home base electromyography-controlled wearable robotic elbow brace in stroke patients. A total of eleven subjects were enrolled in this study with nine individuals completing the study. The participants received in-clinic training by an occupational therapist followed by a 6 week home program using the robotic device. The authors reported that Fugi-Meyer Assessment UE scores showed significant improvement from baseline to discharge and that the participants reported continued improvement in 3 month follow up.

In a study performed at the Department of Veterans Affairs rehabilitation research and development center (Lum et al. 2002), 27 subjects with chronic hemiparesis participated in robot-assisted movement training compared to conventional techniques of rehabilitation. While the robot group had larger improvements during the 2 month study, the authors reported that at the 6 month follow-up, the groups no longer differed in terms of Fugi-Meyer testing. In conclusion it was stated that further research into the use of robotic manipulation for motor rehabilitation is necessary.

Medicare

In November 2014 the (DME MACs) have evaluated the MyoPro upper extremity assist device and determined that it falls with the DME benefit category. On May 5, 2014 the PDAC (Medicare Pricing, Data Analysis and Coding) published a joint DME MAC reminder that states this item definitely falls within the DME benefit versus the Brace benefit and the product is to be coded as A9300-exercise equipment. Note: Exercise equipment is noncovered by Medicare. Claims for A9300 will be denied as noncovered (no Medicare benefit). This article was retired and replace on December 3, 2014 which states supplier are to submit claims for the MyoPro using DME miscellaneous code E1399. The brace is classified under the capped-rental payment methodology as it does not meet the requirements to be categorized as an inexpensive or routinely purchased item. This article was last update August 16, 2018.

In May 2018, the manufacture announced that CMS published favorable preliminary decision in establishing two new Level II HCPCS codes (L codes) to describe the microprocessor-controlled, custom fabricated upper extremity brace. At the time of this medical policy's development, no new L codes were identified.

The available data indicates that the use of the myoelectric upper extremity orthosis may offer perceptual improvement, however, it is not clear from the research the device is any more effective compared to standard manual treatment. The majority of clinical trials revealed small sample sizes (the largest study was comprised of 18 participants), participants were primarily limited to stroke victims, performance on testing results were inconsistent, and trials were of limited duration. Results of these trails cannot be generalized to all other upper extremity monoplegia. Therefore, the evidence is insufficient to determine the effects of technology on health outcomes and an investigational coverage determination is warranted.

POLICY SOURCE(S)

ECRI Institute. Health Technology Assessment information. Product Brief. 2017. MyoPro arm orthosis (Myomo, Inc.) for stroke rehabilitation. Accessed on October 8, 2018.

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. Accessed on October 8, 2018.

Unicare Medical Policy. Upper extremity myoelectric orthoses. August 29, 2018. Accessed on October 8, 2018.

Willigenburg NW, McNally MP, Hewitt TE, Page SJ. Portable myoelectric brace use increases upper extremity recovery and participation but does not impact kinematics in chronic, post-stroke hemiparesis. J Mot Behav. 2017; 49(1):46-54. Accessed on October 9, 2018.

Christopher & Dana Reeve Foundation. Stats about paralysis. Accessed on October 9, 2018.

Brown DW, Roberts K. Application of external power in brachial plexus injury management: a case study. From MEC '08 Measuring Success in Upper Limb Prosthetics. New Brunswick, Canada. August 13-15, 2008.

Lum PS, Burgar CG, Shor PC, Majmundar M, Van der Loos M. Robot-assisted movement training compared with conventional therapy techniques for the rehabilitation of upper-limb motor function after stroke. Arch Phys Med Rehabil. 2002 Jul;83(7):952-9. Accessed on October 10, 2018.

Policy History

Date	Activity
10/08/2018	Initial policy developed
03/12/2019	QI/UM Committee approval
05/06/2019	Provider effective date