



## CLINICAL UM POLICY FOR COVERAGE DETERMINATION

Policy Title:	Policy – Myoelectric Controlled Upper-Limb Orthoses (MyoPro)	Number & Version:	UM-MYOPRO
Functional Unit:	Utilization Management	Effective Date:	07/10/2023
Policy Owner (Title):	Director, Utilization Management	Page Number:	1 of 3

### I. POLICY STATEMENT and PURPOSE

The purpose of this policy is to describe the circumstances under which Myoelectric Controlled Upper-Limb Orthoses (e.g. MyoPro Orthosis) would or would not be considered medically necessary for members under the guidelines used for clinical review of organizational determinations.

### II. BACKGROUND

A Myoelectric Controlled Upper-Limb Orthosis (MyoPro Orthosis) is a myoelectric-controlled powered orthosis (brace) designed to help restore upper extremity function to patients experiencing paresis or partial paralysis following neuromuscular injury or disease (Hayes, 2023). It was designed to be used to address upper limb impairment after a stroke to improve performance of activities of daily living by providing support, limiting unsafe motion, and enhancing the functional movement of paralyzed or weak upper limbs (Hoppe-Ludwig, 2021).

Per Hayes Evolving Evidence Review “based on a review of full-text clinical practice guidelines and position statements, guidance appears to confer **no/unclear support** for the use of the MyoPro orthosis for upper extremity paralysis/paresis after stroke (Hayes, 2023).

### III. SCOPE

This Policy applies to Myoelectric Controlled Upper-Limb Orthoses.

### IV. DEFINITIONS

**Orthosis (Orthoses – plural):** A type of off-the shelf, custom-fit, or custom fabricated brace used to counteract limb impairment by improving function after a stroke or other neurological injuries (Hoppe-Ludwig, 2021).

**Medically Necessary** – Covered Services rendered by a Health Care Provider that the Plan determines are:

- 1) Safe and effective
- 2) Not experimental or investigational
- 3) Appropriate for patients,
  - a) including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is—
    - i) furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member,
    - ii) furnished in a setting appropriate to the patient's medical needs and condition,
    - iii) ordered and furnished by qualified personnel,



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- iv) one that meets, but does not exceed, the patient's medical need; and
- v) is at least as beneficial as existing and available medically appropriate alternatives.

### V. **OWNERSHIP & TRAINING**

The Director of Utilization Management is responsible for administration, oversight, and training regarding performance under this Policy.

### VI. **PROTOCOLS / COVERAGE POLICY**

The Myoelectric Controlled Upper-Limb Orthosis (MyoPro) device is considered NON-covered / NOT medically necessary. There is currently insufficient evidence to establish the use of the device as superior over traditional treatment.

### VII. **REGULATORY REFERENCES / CITATIONS**

CMS National Coverage Determinations (NCDs)	None
CMS Local Coverage Determinations (LCDs)	None
CMS Articles	None

### VIII. **PROFESSIONAL REFERENCES / CITATIONS**

1. Hayes, Evolving Evidence Review. March 6, 2023. MyoPro Orthosis (Myomo Inc.) for Upper Extremity Paralysis/Paresis After Stroke. Accessed at: <https://evidence.hayesinc.com/report/eer.myopro4579> on April 26, 2023.
2. Hoppe-Ludwig, S., Armitage, J., Turner, K. L., O'Brien, M. K., Mummidisetty, C. K., Koch, L. M., Kocherginsky, M., & Jayaraman, A. (2021). Usability, functionality, and efficacy of a custom myoelectric elbow-wrist-hand orthosis to assist elbow function in individuals with stroke. *Journal of rehabilitation and assistive technologies engineering*, 8, 20556683211035057. <https://doi.org/10.1177/20556683211035057> Accessed at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8404626/> on April 26, 2023.
3. McCabe, J. P., Henniger, D., Perkins, J., Skelly, M., Tatsuoka, C., & Pundik, S. (2019). 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*, 14(4), e0215311. <https://doi.org/10.1371/journal.pone.0215311>. Accessed at: <https://pubmed.ncbi.nlm.nih.gov/30978249/> on April 26, 2023.
4. Page, S., Griffin, C., & White, S. (2020). Efficacy of myoelectric bracing in moderately impaired stroke survivors: A randomized, controlled trial. *Journal of rehabilitation*



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5. Page, S. J., Hill, V., & White, S. (2013). Portable upper extremity robotics is as efficacious as upper extremity rehabilitative therapy: a randomized controlled pilot trial. *Clinical rehabilitation*, 27(6), 494–503. <https://doi.org/10.1177/0269215512464795> . Accessed at: <https://pubmed.ncbi.nlm.nih.gov/23147552/> on April 26, 2023.
6. Peters, H. T., Page, S. J., & Persch, A. (2017). Giving Them a Hand: Wearing a Myoelectric Elbow-Wrist-Hand Orthosis Reduces Upper Extremity Impairment in Chronic Stroke. *Archives of physical medicine and rehabilitation*, 98(9), 1821–1827. <https://doi.org/10.1016/j.apmr.2016.12.016> . Accessed at: <https://pubmed.ncbi.nlm.nih.gov/28130084/> on April 26, 2023.
7. Willigenburg, N. W., McNally, M. P., Hewett, T. E., & Page, S. J. (2017). Portable Myoelectric Brace Use Increases Upper Extremity Recovery and Participation But Does Not Impact Kinematics in Chronic, Poststroke Hemiparesis. *Journal of motor behavior*, 49(1), 46–54. <https://doi.org/10.1080/00222895.2016.1152220> . Accessed at: <https://pubmed.ncbi.nlm.nih.gov/27749154/> on April 26, 2023.



### **IX. RELATED POLICIES / PROCEDURES**

None

### **X. ATTACHMENTS**

None

### **APPROVALS:**

	Printed Name	Signature
Senior Medical Director, UM:	<u>Michael Fusco, MD</u>	
Corporate Chief Medical Officer (QMMC Chair):	<u>Debbie Zimmerman, MD</u>	

### **VERSION HISTORY:**

Version #	Date	Author	Purpose/Summary of Major Changes
01	04/26/2023	Gina Vehige	Original; FINAL Approved by MMC 6/30/2023; Effective 07/10/2023