



Medical Necessity Guideline MyoPro Upper Limb Compensatory Device

Medical Necessity Guideline (MNG) Title: MyoPro Upper Limb Compensatory Device		
MNG #: (KH to Populate)	☒ CCA Senior Care Options (HMO D-SNP) (MA) ☒ CCA One Care (Medicare-Medicaid) (MA) ☒ CCA Medicare Preferred (PPO) (MA & RI) ☒ CCA Medicare Value (PPO) (MA & RI) ☒ CCA Medicare Maximum (HMO D-SNP) (RI) ☐ CCA Medicare Excel (HMO POS) (MI) ☐ CCA Medicare Maximum (HMO D-SNP) (MI) ☐ CCA Medicare Excel (HMO) (CA)	Prior Authorization Needed? ☒ Yes (always required) ☐ Yes (only in certain situations. See this MNG for details) ☐ No
Benefit Type: ☒ Medicare ☐ Medicaid	Approval Date: 9/12/2024	Effective Date: 11/18/2024
Last Revised Date:	Next Annual Review Date: 9/12/2025	Retire Date:

OVERVIEW:

The MyoPro Motion E and Motion W devices, L8701, and the MyoPro Motion G device, L8702, are prescription upper limb compensatory devices utilized to increase the ability to perform functional tasks with an affected limb. The myoelectric powered upper-extremity orthotic, determined by Medicare to be a brace, is custom fabricated to each patient for optimum comfort and performance. The user voluntarily activates movement of the brace with their remaining electromyography (EMG) muscle signal, and the device detects weak muscle activity from the affected muscle groups.

The orthotic device (brace) weighs about 1.8 kilograms (4 pounds), has manual wrist articulation, and myoelectric initiated bi-directional elbow movement. As the use of robotic devices for therapy has been reported, a therapist or prosthetist/orthoptist can adjust the gain (amount of assistance), signal boost, thresholds, and range of motion. Potential users include patients with traumatic brain injury, spinal cord injury, brachial plexus injury, amyotrophic lateral sclerosis, and multiple sclerosis.



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DEFINITIONS:

Electromyography (EMG): Muscle response, or electrical activity, due to a nerve's stimulation of the muscle, sometimes referred to as myoelectric activity.

MyoPro 2 Motion E: A powered elbow with static rigid wrist support.

MyoPro 2 Motion G: An elbow-wrist-hand orthosis (EWHO) with a powered elbow, passively adjustable multi-articulating wrist (MAW), and a powered, 3-jaw-chuck grasp.

MyoPro 2 Motion W: An elbow-wrist orthosis with a powered elbow and a multi-articulating wrist (MAW) with flexion/extension and supination/pronation. The passive MAW may be prepositioned by the user to increase task-specific function.

DECISION GUIDELINES:

Clinical Coverage Criteria:

The MyoPro 2 is indicated for use by all of the following (1-3):

1. Members aged 18 years and older diagnosed with:
 - a) Long-term muscle weakness; or
 - b) Partial paralysis

The above conditions (a or b) may be due to any of the following:

- CVA stroke; or
 - Brachial plexus injury; or
 - Traumatic brain or spinal cord injury; or
 - ALS; or
 - Other neuromuscular disease or injury.
2. Members that, per user assessment and clinician evaluation:
 - a) Meet physical size specifications; and
 - b) Demonstrate the capacity to use the device, including sufficient cognitive abilities.
 3. Members for whom there is no other medical service or device, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly.

NOTE: It is recommended that all new MyoPro users attend Occupational or Physical therapy to develop proficiency and independence with their MyoPro.



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LIMITATIONS/EXCLUSIONS:

The use of MyoPro 2 is contraindicated for any the following:

1. Insufficient myoelectric signal output from at least one muscle group needed to activate the desired powered joint (for example, biceps or triceps signal to extend the affected elbow).
2. Severe shoulder subluxation.
3. Excessive pain in shoulder, arm or hand during facilitated range of motion.
4. During recovery from acute injury such as trauma, infection, or skin condition.
5. Upper extremity contracture(s) that prevent functional movement to benefit from the orthosis.
6. Rigid spasticity in the affected muscle groups.
7. Physical size/measurements that do not meet specifications of the manufacturer.
8. Cognitive or behavioral impairment that would inhibit safe use of the orthosis/brace.
9. Other medical issue which interferes with safe use of the device for functional improvement.
10. Home or clinical environment close to areas with high flammability risk.

CODING:

When applicable, a list(s) of codes requiring prior authorization is provided. This list is for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment.

CPT/HCPCS CODE	CODE 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

Disclaimer

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses evidence based InterQual® criteria, when available, to review prior authorization requests for medical necessity. This Medical Necessity Guideline (MNG) applies to all CCA Products unless a more expansive and applicable CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), or state-specific medical necessity guideline exists. Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis by considering the individual member's health care needs. If at any time an applicable CMS LCD or NCD or state-specific MNG is more expansive than the criteria set forth herein, the NCD, LCD, or state-specific MNG criteria shall supersede these criteria.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. This Medical Necessity Guideline is subject to all applicable Plan Policies



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and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

This Medical Necessity Guideline is not a rigid rule. As with all CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity (supporting literature (full text preferred) should be attached to the request), or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

RELATED REFERENCES:

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3. MassHealth 130 CMR 450.000: 130 CMR: DIVISION OF MEDICAL ASSISTANCE ADMINISTRATIVE AND BILLING REGULATIONS. 4/1/2024. <https://www.mass.gov/doc/130-cmr-450-administrative-and-billing-regulations/download>
4. U.S. Food and Drug Administration. CFR - Code of Federal Regulations Title 21. Last Updated: 03/22/2024. Accessed 9/11/2024. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRsearch.cfm?FR=882.5050>
5. DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services (CMS). Second Biannual 2023 Healthcare Common Procedure Coding System (HCPCS) Public Meeting. <https://www.cms.gov/files/document/hcpcs-public-meeting-agenda-non-drug-and-non-biological-items-and-services-november-29-2023.pdf>
6. DEPARTMENT OF HEALTH AND HUMAN SERVICES Centers for Medicare & Medicaid Services 42 CFR Parts 409, 410, 414, 424, 484, 488, and 489. Final Rule [FR Doc. 2023-24455 Filed: 11/1/2023 4:15 pm; Publication Date: 11/13/2023. <https://public-inspection.federalregister.gov/2023-24455.pdf>
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<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8404626/>
11. DEPARTMENT OF HEALTH & HUMAN SERVICES. Original Premarket Notification 510(k) Summary. K062631. April 12, 2007. https://www.accessdata.fda.gov/cdrh_docs/pdf6/k062631.pdf
12. U.S. Food and Drug Administration (FDA) Product Classification.
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpdc/classification.cfm?id=5604>
13. NIH National Library of Medicine. Access GUDID DEVICE: MyoPro 2+ (00855846007153) Motion G Left - 28462 rev1. <https://accessgudid.nlm.nih.gov/devices/00855846007153>
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REVISION LOG:

REVISION DATE	DESCRIPTION
9/12/2024	New MNG

APPROVALS:

David Mello, MD

CCA Senior Clinical Lead [Print]

Signature

Senior Medical Director, Utilization
Management and Medical Policy

Title [Print]

9/12/2024

Date

Nazlim Hagmann, MD

CCA CMO or Designee [Print]

Signature

Chief Medical Officer

Title [Print]

9/12/2024

Date