



MEDICAL POLICY STATEMENT

Ohio Medicaid

Policy Name & Number	Date Effective
Myoelectric Upper Extremity Orthosis-OH MCD-MM-1560	03/01/2024
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject**Myoelectric Upper Extremity Orthosis****B. Background**

Experimental or Investigational items or services are not covered.

An upper limb myoelectric orthosis is a robotic assisted brace. It is proposed that the device self-initiates movement using the member's own muscle signals. Upper limb myoelectric orthoses are considered experimental and investigational because there is insufficient evidence of their effectiveness. These devices should not be confused with prosthetic devices, which are intended to replace or compensate for a missing limb or other body part.

The intent of this policy is to address requests that require medical necessity review in accordance with OAC 5160-1-01.

C. Definitions

- **Experimental or Investigational Items or Services** - Medical, surgical, diagnostic, psychiatric, substance use disorders treatment or other health care services, technologies, equipment, supplies, treatments, procedures, therapies, biologics, drugs, or devices (each a "Health Care Item" or "Service") that, at the time CareSource has made a determination regarding coverage in a particular case, are:
 - Not approved by the United States Food and Drug Administration (FDA) to be lawfully marketed for the proposed use,
 - Not identified in the American Hospital Formulary Service or the United States Pharmacopoeia Dispensing Information as appropriate for the proposed use, or
 - Determined by the FDA to be contraindicated for the specific use,
 - Subject to review and approval by any institutional review board or other body serving a similar function for the proposed use, and such final approval has not been granted,
 - The subject of an ongoing clinical trial that meets the definition of a Phase 1, 2 or 3 clinical trial set forth in the FDA regulations, regardless of whether the trial is actually subject to FDA oversight,
 - Provided as part of a clinical research protocol or clinical trial or is provided in any other manner that is intended to evaluate the safety, toxicity, or efficacy of the drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply,
 - Provided pursuant to informed consent documents that describe the drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply as experimental or investigational, or otherwise indicate that the safety, toxicity, or efficacy of the drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply is under evaluation.

NOTE: Devices that are FDA approved under the Humanitarian Use Device exemption are not considered to be experimental or investigational.

- **Orthosis** – A brace, sling, or splint often made from thermoplastics, casting, and metal.
- **Upper Limb Myoelectric Orthosis** – Device that combines a standard upper limb orthotic device with microprocessors, muscle sensor, and an electric motor of a myoelectric device.

D. Policy

- I. Any drug, biologic, device, diagnostic, product, equipment, procedure, treatment, service, or supply used in or directly related to the diagnosis, evaluation, or treatment of a disease, injury, illness, or other health condition which CareSource determines in its sole discretion to be experimental or investigational is not covered by CareSource.
- II. The use of myoelectric upper extremity orthotic devices is considered investigational and not medically necessary for all indications including, but not limited to, restoration of function to arms and hands paralyzed or weakened by cerebrovascular accident, brachial plexus injury, cerebral palsy, or any other neurological or neuromuscular disease or injury.
- III. Myoelectric upper limb and hand orthotic devices are not covered. This includes, but is not limited to, the following:
 - A. MyoPro
 - B. MyoPro 2

E. Conditions of Coverage

NA

F. Related Policies/Rules

Experimental, Investigational and Other Non-Covered Service

G. Review/Revision History

DATES		ACTION
Date Issued	10/25/2023	New Policy. Approved at Committee.
Date Revised		
Date Effective	03/01/2024	
Date Archived		

H. References

1. Evolving Evidence Review: MyoPro Orthosis (Myomo Inc.) for Upper Extremity Paralysis/Paresis After Stroke. Hayes; 2023. Accessed September 26, 2023. www.hayesinc.com

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.

2. Medicaid Medical Necessity: Definitions and Principles, OHIO ADMIN. CODE 5160-1-01 (2022). Accessed October 17, 2023. [www. codes.ohio.gov](http://www.codes.ohio.gov)
3. Medicare coverage of items and services in category a and b investigational device exemption (IDE) studies. US Centers for Medicare and Medicaid Services. January 1, 2015. MLN Matters MM8921. Accessed September 26, 2023. www.cms.gov
4. Premarket Notification 510(k) Summary K062631. Federal Drug Administration. April 12, 2007. Accessed September 26, 2023. www.fda.gov
5. Jensen EF, Raunsbæk J, Lund JN, et al. Development and simulation of a passive upper extremity orthosis for amyoplasia. *J Rehabil Assist Technol Eng*. 2018;5. doi:10.1177/2055668318761525
6. Pundik S, McCabe J, Kesner S, et al. Use of a myoelectric upper limb orthosis for rehabilitation of the upper limb in traumatic brain injury: A case report. *J Rehabil Assist Technol Eng*. 2020;7:1-11. doi:10.1177/2055668320921067

ODM Approved 11/30/2023