ADMINISTRATIVE POLICY STATEMENT
OHIO MEDICAID

Policy Name	Policy Number	Date Effective
Experimental or Investigational Item or Service - Myoelectric Upper Extremity Orthosis	AD-0826	07/01/2021-06/30/2022

Policy Type			
Medical	**ADMINISTRATIVE**	Pharmacy	Reimbursement

Administrative Policy Statements 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.

Administrative 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 Administrative Policy Statement. If there is a conflict between the Administrative 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.

Table of Contents

Administrative Policy Statement 1
A. Subject 2
B. Background 2
C. Definitions 2
D. Policy 3
E. Conditions of Coverage 3
F. Related Policies/Rules 3
G. Review/Revision History 3
H. References 3

A. Subject

Experimental or Investigational Item or Service - Myoelectric Upper Extremity Orthosis

B. Background

Experimental or Investigational items or services are not covered.

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 orthosis is considered experimental and investigational because there is insufficient evidence of its effectiveness.

C. Definitions

- **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.
- **Orthosis** – A brace.
- **Experimental or Investigational Items or Services** or **Experimental or Investigational** – 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; OR
  - 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; OR
  - 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; OR
  - 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; OR
  - 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; OR
  - 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; OR

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

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. Myoelectric upper extremity orthosis is considered experimental, investigational, and are unproven for all indications including to restore function to arms and hands paralyzed or weakened by cerebrovascular accident stroke, brachial plexus injury, cerebral palsy or any other neurological or neuromuscular disease or injury.

III. Myoelectric upper limb and hand devices are not covered. This includes but is not limited to:
   A. MyoPro
   B. LUKE Arm
   C. Otto Bock myoelectric prosthesis
   D. LTI Boston Digital Arm System
   E. DEKA Arm System
   F. SensorHand
   G. Bebionic

E. Conditions of Coverage

NA

F. Related Policies/Rules

Experimental or Investigational Technologies

G. Review/Revision History

	DATES	ACTION
Date Issued	01/06/2021	
Date Revised	03/03/2021	Updated definition
Date Effective	07/01/2021	
Date Archived	06/30/2022	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy

H. References

1. Hoenig, H & Colon-Emeric, C. (2020, January 13). Overview of geriatric rehabilitation: patient assessment and common indications for rehabilitation. Retrieved July 9, 2020 from www.uptodate.com
2. Hayes. (2020, May 28). MyoPro Orthosis (Myomo Inc.) to Improve upper Extremity Function and Elbow Range of Motion in Patients with Cerebral palsy. Retrieved July 9, 2020 from www.hayesinc.com
3. Federal Drug Administration. (2007, April 12). Premarket Notification 510(k) Summary K062631. Retrieved July 9, 2020 from www.fda.gov
4. Hayes. (2020, July 21). Evidence Analysis Research Brief MyoPro Orthosis (Myomo Inc.) for Upper Extremity paralysis/Paresis After Stroke. Provided to CareSource on July 21, 2020.

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