Anthem

Medical Policy

Subject: Home Video-Assisted Robotic Rehabilitation Systems
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Description/Scope

This document addresses the home use of video-assisted robotic rehabilitation systems, which combine the use of robotic-assisted movement therapy with interactive video-assisted programs to complement physical rehabilitation programs for individuals with movement disorders. Such systems include the Motus Nova Stroke Rehab Recovery at Home, also known as the Motus Hand or Motus Foot devices (Motus Nova, Atlanta, GA).

Note: For further information on similar technologies, please see the following related document:

- DME.00052 Brain Computer Interface Rehabilitation Devices
- OR-PR.00005 Upper Extremity Myoelectric Orthoses

Position Statement

Investigational and Not Medically Necessary:

Home video-assisted robotic rehabilitation systems are considered **investigational and not medically necessary** for all indications.

Rationale

Use of video-assisted robotic rehabilitation systems has been described in the literature and used in the facility setting for several decades (Dohle, 2013; He, 2023; Hesse, 2008; Krebs, 2008; Kutner, 2010; Lo, 2020; Park, 2020). The health impact of such devices is unclear, with mixed results reported. More recently, the use of such devices in the home has been proposed. However, there has been relatively little peer-reviewed published studies describing clinical outcomes as a result of home use.

Wolf (2015) described the results of a prospective, single-blinded, multisite, randomized controlled trial (RCT) involving 99 participants with hemiparesis and limited access to upper extremity rehabilitation. Participants were randomized to rehabilitation using either a combination of InMotion Robotics® Hand Mentor™ Pro (BIONIK Laboratories Corp., Watertown, MA) plus home exercise for 3 hours/day, 5 days per week, for 8 weeks (n=51) or home exercises alone at an identical dosage (n=48). A total of 10 subjects (10%) were lost to follow-up. There were no significant differences between groups with regard to time spent in therapeutic interventions (p=0.68), overall Action Research Arm Test (ARAT) results (p=0.147), and the Fugl-Meyer Assessment of Motor Assessment After Stroke (FMA) (p=0.594). Results in Wolf Motor Function Test (WMFT) performance time on total and fine motor tasks, and number of total and fine motor tasks not completed were significantly in favor of the control group (p=0.12 overall). The authors concluded that there were no significant differences between groups with regard to change in motor function over time.

Housley (2016) reported the results of a case series study involving 20 mostly rural participants with post-stroke hemiparesis treated with at home rehabilitation with the InMotion Robotics Hand Mentor or Foot Mentor™ device. Each participant was instructed to start at a low daily activity level (1 hour) and progress to the standard 2-hour therapy dosage within the first week, and remain at that level for the 3-month study duration. No adverse events were reported. Upper extremity ARAT scores improved by an average of 9.22 points (30.06%, p=0.046), which were noted as both a statistically and clinically significant improvement in upper extremity function. Participants using the foot device demonstrated a 29.03% increase in gait speed (0.31 to 0.40 m/s) which was noted to be a small but clinically significant improvement (p=0.197). No significant improvements in 6-minute walking distance were reported (p=0.153), nor were there any noted

changes with regard to Functional Independence Measure (FIM) results (p=0.642). While some benefits were reported, they need to be validated in more robust trials producing generalizable results.

Cherry (2017) reported the results of a pilot case series study involving 10 participants with post-stroke hemiparesis who underwent home robotic rehabilitation with the InMotion Robotics Hand Mentor or Foot Mentor devices in the home setting. Qualitative, self-reported data was collected regarding device use. The reported benefits included convenience, self-reported increased mobility, improved mood, and use as an outlet for physical and mental tension and anxiety. No objective health outcome data were provided, and this study does not provide generalizable data to inform the benefits of home video-assisted robotic rehabilitation systems.

The largest and most robust trial to date was an observer-blinded RCT published by Rodgers (2020). Their report included the results of a National Institute for Health Research (UK)-funded health technology assessment investigating the use of robotic-assisted training of the upper extremities using the Massachusetts Institute of Technology-Manus robotic gym system (BIONIK Laboratories Corp., Watertown, MA). The study involved 770 participants who were randomized to robotic-assisted training (n=257), enhanced upper limb therapy (EULT, n=259), or usual care (n=254). Participants were followed for 6 months. The robotic-assisted training program consisted of 45 minutes of face-to-face therapy, 3 days a week for 12 weeks, in addition to usual care. EULT consisted of 45 minutes of face-to-face therapy, 3 days per week for 12 weeks, in addition to usual care. Usual care involved a minimum of 45 minutes of each appropriate therapy for a minimum of 5 days a week at a level that enables the individual to meet their rehabilitation goals. Therapy continued for as long as each individual continued to benefit from and to tolerate therapy. The loss to follow-up was 21%, with 79% of participants having full data sets available at 6 months. Full completion of the EuroQol-5 Dimensions, 5-level version, questionnaire (EQ-5D-5L) was accomplished by 82% of participants at 6 months. The mean difference in Quality Adjusted Life Years (QUALYs) between each of the intervention groups (robotic-assisted training and EULT) and usual care was very small and was not statistically significant. The authors concluded that “Robot-assisted training did not improve upper limb function compared with usual care. Although robotic-assisted training improved upper limb impairment, this did not translate into improvements in other outcomes.”

The most recent version of the American Heart Association/American Stroke Association guidelines for adult stroke rehabilitation and recovery (Winstein, 2016) includes the following statement regarding robotic-assisted rehabilitation, “Robot-assisted movement training to improve motor function and mobility after stroke in combination with conventional therapy may be considered.” This is a Class IIb recommendation, which indicated that the benefit from the treatment outweighs risks, but that “additional studies with broad objectives needed; additional registry data would be helpful.” The Level of Certainty of treatment effect was rated as “A”, indicating “Multiple populations evaluated.” and “Data derived from multiple randomized clinical trials or meta-analyses”. Their overall classification indicates that the “Recommendations usefulness/efficacy less well established” and that there is “Greater conflicting evidence from multiple randomized trials or meta-analyses.”

The U.S Department of Veterans Affairs/U.S. Department of Defense (VA/DOD, 2024), *Management of Stroke Rehabilitation*, addresses the use of robotic-assisted rehabilitation, saying, “There is insufficient evidence to recommend for or against robotic-assisted therapy to improve upper or lower extremity motor outcomes.” The strength of evidence for this recommendation is “Neither for nor against.”

It should be noted that neither of these documents specifically address the use of home video-assisted robotic rehabilitation systems.

Background/Overview

Robotic rehabilitation devices use a supporting structure for a part of the body integrated with devices that detect and augment movement via sensors, motors, and actuators. The intention of such devices is to support and reinforce movement through repetitive task practice for a person who has limited movement. Such devices are widely used in the rehabilitation setting to help individuals who have experienced a stroke or other medical condition or trauma impacting neurological and muscle function. These types of devices may be applied to a specific part of a person’s body, such as an arm or leg, or to multiple body parts at once. Video-assisted robotic rehabilitation systems involve the combination of a robotic rehabilitation device with a computerized video interface, similar to a video game, that is intended to lead the person receiving rehabilitation through various activities that involve the use of the body part being treated. The intent is to encourage and reinforce use and movement of the body part to improve strength and promote development of neural pathways involved in the movement itself. Up until recently, the use of such devices has been limited to the office and facility setting. Use of video-assisted robotic rehabilitation systems in the home has become a therapeutic option as smaller, portable devices have entered the market.

Such devices are classified as Class I devices and do not require the submission or review of data related to safety or efficacy in order to be marketed in the United States.

Definitions

Action Research Arm Test (ARAT): A clinical measurement tool used to assess the functional performance of an upper extremity of individuals with impaired movement, including coordination, dexterity and functioning.

Enhanced upper limb therapy (EULT): A type or physical therapy used to exercise the arm, wrist and hand involving repetitive functional task practice directed towards achieving specific task-oriented goals, such as putting on a shirt.

Fugl-Meyer Assessment of Motor Assessment After Stroke (FMA): A clinical performance-based impairment index and evaluation tool designed to measure recovery in post-stroke hemiplegic patients. It is designed to assess motor functioning, balance, sensation and joint function.

Functional Independence Measure (FIM): A clinical evaluation tool used to measure of disability for a variety of populations and is not specific to any diagnosis. Assesses independence for self-care, sphincter control, transfers, locomotion, communication, and social cognition.

Wolf Motor Function Test (WMFT): A clinical quantitative measurement tool used to asses upper extremity motor ability through timed and functional tasks.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

HCPCS

E0739	Rehabilitation system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors

ICD-10 Diagnosis

	All diagnoses

References

Peer Reviewed Publications:

1. Cherry CO, Chumbler NR, Richards K, et al. Expanding stroke telerehabilitation services to rural veterans: a qualitative study on patient experiences using the robotic stroke therapy delivery and monitoring system program. Disabil Rehabil Assist Technol. 2017; 12(1):21-27.
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3. He YZ, Huang ZM, Deng HY, et al. Feasibility, safety, and efficacy of task-oriented mirrored robotic training on upper-limb functions and activities of daily living in subacute poststroke patients: a pilot study. Eur J Phys Rehabil Med. 2023; 59(6):660-668.
4. Hesse S, Werner C, Pohl M, et al. Mechanical arm trainer for the treatment of the severely affected arm after a stroke: a single-blinded randomized trial in two centers. Am J Phys Med Rehabil. 2008; 87(10):779-788.
5. Housley SN, Garlow AR, Ducote K, et al. Increasing access to cost effective home-based rehabilitation for rural veteran stroke survivors. Austin J Cerebrovasc Dis Stroke. 2016; 3(2):1-11.
6. Krebs HI, Mernoff S, Fasoli SE, et al. A comparison of functional and impairment-based robotic training in severe to moderate chronic stroke: a pilot study. NeuroRehabilitation. 2008; 23(1):81-87.
7. Kutner NG, Zhang R, Butler AJ, et al. Quality-of-life change associated with robotic-assisted therapy to improve hand motor function in patients with subacute stroke: a randomized clinical trial. Phys Ther. 2010; 90(4):493-504.

8. Lo AC, Guarino PD, Richards LG, et al. Robot-assisted therapy for long-term upper-limb impairment after stroke. N Engl J Med. 2010; 362(19):1772-1783.
9. Park S, Fraser M, Weber LM, et al. User-driven functional movement training with a wearable hand robot after stroke. IEEE Trans Neural Syst Rehabil Eng. 2020; 28(10):2265-2275.
10. Wolf SL, Sahu K, Bay RC, et al. The HAAPI (Home Arm Assistance Progression Initiative) trial: a novel robotics delivery approach in stroke rehabilitation. Neurorehabil Neural Repair. 2015; 29(10):958-968.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Rodgers H, Bosomworth H, Krebs HI, et al. Robot-assisted training compared with an enhanced upper limb therapy programme and with usual care for upper limb functional limitation after stroke: the RATULS three-group RCT. Health Technol Assess. 2020; 24(54):1-232.
2. U.S Department of Veterans Affairs/U.S. Department of Defense. Management of Stroke Rehabilitation. 2024. Available at https://www.healthquality.va.gov/guidelines/rehab/stroke/index.asp. Accessed on November 12, 2024.
3. Winstein CJ, Stein J, Arena R, et al.; American Heart Association Stroke Council, Council on Cardiovascular and Stroke Nursing, Council on Clinical Cardiology, and Council on Quality of Care and Outcomes Research. Guidelines for adult stroke rehabilitation and recovery: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2016; 47(6):e98-e169.

Websites for Additional Information

1. American Stroke Association. About Stroke. 2024. Available at: https://www.stroke.org/en/about-stroke. Accessed on November 12, 2024.
2. Centers for Disease Control. About stroke. May 15, 2024. Available at: https://www.cdc.gov/stroke/about/index.html#aboutCDC. Accessed on November 12, 3024.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
New	11/14/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.
