Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First	**Submission Date**: 1/2/2025
Policy Number: ccp.1076	**Effective Date:** 6/2014 **Revision Date:** December 1, 2024
Policy Name: Robotic orthoses – upper limb	

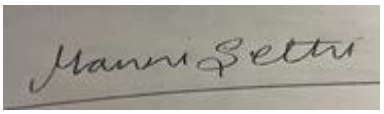
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Statewide PDL**

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Robotic orthoses – upper limb

Clinical Policy ID: CCP.1076

Recent review date: 12/2024

Next review date: 4/2026

Policy contains: Exoskeleton/orthosis; rehabilitation; robot; upper extremity.

Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First- CHIP, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First- CHIP's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.

Coverage policy

The robotic orthosis (exoskeleton) as an adjunct to upper limb rehabilitation is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Rehabilitation services for improving or preserving upper limb function including, but not limited to, physical therapy, occupational therapy, and home exercise therapy (V57.x).
- Durable medical equipment for the upper limb including, but not limited to, static and dynamic orthotic devices for the upper limb (e.g., extension/flexion devices and mobile arm support) as deemed medically necessary.

Background

People with neuromuscular disabilities often have trouble using their upper limbs and must rely on assistance from others and/or assistive technology to perform routine functions. An orthosis (or orthotic device) for aiding upper limb movement enables use of the limb in a larger range of motion than can be accomplished independently (Herder, 2006). Choice of orthosis will depend on a number of objective and subjective factors. Assessment of upper limb impairment and activity using standardized measurement is essential, as are

functionality, comfort, safety, and aesthetics (Connell, 2012; Herder, 2006; Lemmens, 2012; Mazzone, 2012; Wagner, 2012).

Three main groups of upper extremity orthoses are rehabilitation robots, powered (electromechanical) orthoses, and passive orthoses. Passive (non-powered or body powered) orthoses are based on static balancing, typically using springs. They require some muscle force for accelerating and decelerating, and for overcoming friction and balancing errors. Users with some residual function generally preferred a non-powered device, because it allows use of existing natural control, tends to be less conspicuous, and uses less energy consumption, especially for persons using respiration augmentation. However, most currently available passive orthoses cannot be adjusted by the user and have limited range of motion, imperfect balancing quality, or problems related to comfort (i.e., donning and doffing, sliding, and perspiration in trough) (Herder, 2006).

Rehabilitation robots and powered orthoses are intended for the weakest patients, who in some cases have little to no muscle force (Herder, 2006). They serve as means of increasing training intensity (e.g., number of repetitions) and may allow the patient to train without a therapist. These devices amplify weak muscle signals from nerve signals on the skin surface to activate arm and/or hand movement, as the user intends. A powered orthosis helps to correct, rehabilitate, or support the limb, whereas a rehabilitation robot works in parallel with the body to assist the user's movements. Current robots tend to train the shoulder and elbow, but devices for improving hand dexterity are emerging that may improve self-reported function and perceptions of overall recovery in stroke survivors (Peters, 2017; Willigenburg, 2017).

Rehabilitation robots are either end-effector types or exoskeletons depending on the way the limb is supported and moved (Zhang, 2018). An end-effector type uses a device connected to the end of a robotic arm (e.g., a gripper where the hand would be) that interacts with the environment as a substitute for limb movement. An example is the MIME (Stanford University). End-effector robots can be easily adapted and used by several patients with different pathologies. They provide information about end effector performance that allows the therapist to objectively assess and customize therapy, but they cannot provide kinematic information about the joints of the upper limb (Bertomeu-Motos, 2018).

The robotic exoskeleton is a wearable device consisting of a protective and supportive shell with integrated sensor and control information that allows the patient total control of the arm joints to perform limb movements aided by the robot (Zhang, 2018). However, exoskeletons are difficult to adapt and attach to the patient's arm, as they require meticulous attention to detail to avoid misalignment between the robot and arm and potential injury. Several robotic exoskeletons have been developed for the upper limb. Examples are (Zhang, 2018): RUPERT (University of Arizona); the CADEN-77 (University of Washington); the Wilmington robotic exoskeleton (JAECO Orthopedic, 2024); the Armeo Spring (Hocoma Inc., Norwell, Massachusetts); and the MyoPro® (Myomo, Inc., Cambridge, Massachusetts, 2024).

Findings

Guidelines

The Department of Veterans Affairs and Department of Defense (2024) updated their guideline on the management of stroke rehabilitation. There is insufficient evidence to recommend for or against robot-assisted therapy to improve upper extremity motor outcomes based on systematic review evidence showing that the short-term improvements in upper limb movements, as measured by Fugl-Meyer Assessment, only slightly outweighed the potential harms, which were considered minimal and related to discomfort from the harnesses and skin integrity issues.

Evidence reviews

Systematic reviews and meta-analyses examined the use of robotic exoskeletons for upper limb rehabilitation in predominately in adult stroke survivors, and to a lesser extent, adults with spinal cord injury and children with stroke or cerebral palsy. The evidence lacks important details of the study population, intervention, and outcomes necessary to inform a determination of medical necessity with regard to the optimal candidates for these devices and the optimal treatment regimens using these devices. Robotic-led rehabilitation may improve upper limb motor scores and strength in the short-term for people with upper limb disability, but neither the translation of this improvement to performance of activities of daily living nor the superiority of robotic-led therapy to dose-matched, classical therapist-led training has been determined.

A Cochrane review provides the most comprehensive and rigorous review of 45 trials (n = 1,619 participants) of electromechanical and robot-assisted upper limb rehabilitation in stroke rehabilitation. The review rated the quality of evidence as high. Electromechanical and robot-assisted arm training devices are safe and acceptable to most participants and modestly improve activities of daily living, arm function, and arm muscle strength after stroke. It was unclear if these slight improvements were clinically meaningful to most patients with stroke, and because of the heterogeneity of trial designs, therapy variables, and participant characteristics, the optimal therapeutic intensity could not be determined (Mehrholz, 2018).

One multisite trial carried out in the United Kingdom randomly assigned 257 participants to robot-assisted training, 259 to an enhanced upper limb therapy protocol, and 254 to usual care. The primary outcome measure was upper limb function success measured by the Action Research Arm Test at three months. Robot-assisted training and an enhanced upper limb therapy protocol did not improve upper limb function after stroke compared with usual care for patients with moderate or severe upper limb functional limitation after first stroke (Rodgers, 2019).

Evidence from newer systematic reviews compared robot-assisted arm training to other protocols in stroke survivors. Randomized or quasi-randomized controlled trials of moderate to high quality reported mixed results that fail to support a clear superiority of robot-assisted rehabilitation over standard rehabilitation protocols for the upper limb following stroke (Chen, 2020; Ferreira, 2021; Wu, 2021). The comparative effectiveness of robotic therapy may depend on treatment dose and duration, severity of impairment, and recovery phase (Everard, 2022; Zhang, 2022).

Rehabilitation of hand and finger function in stroke has significant implications for the ability to perform activities of daily living, independence, and quality of life (Suarez-Escobar, 2018). Evidence from randomized controlled trials found some improvement in motor function with a robotic adjunct, but small study sizes and variations in devices studied, stroke chronicities, treatment protocols, and measured outcomes limit these conclusions. Most devices remain in early stages of development or are not currently available in the United States (Cho, 2021; Lee, 2021; Moggio, 2022; Park, 2021; Singh, 2021).

In cervical spinal cord injury, a systematic review (Singh, 2018) of one randomized clinical trial, six case series, and five case studies of low quality examined five exoskeletons and three end-effector systems. The results suggest robot-assisted interventions are safe, feasible, and may reduce active assistance provided by therapists, but the optimal device, training protocol, and outcome measure(s) require further study.

In children with cerebral palsy, a systematic review (Chen, 2016) of seven case studies and two other small observational studies examined three different robotic systems. These limited results suggest a moderate improvement of robotic therapy in reaching duration, smoothness, or decreased muscle tone, and in standardized clinical assessment (e.g., Fugl-Meyer).

In 2018, we updated the literature with no policy changes.

In 2019, we added no new information. The policy ID was changed from CP# 15.02.06 to CCP.1076.

In 2020, we expanded the scope of the policy to include all robotic exoskeletons for upper limb rehabilitation. No policy changes are warranted.

In December 2020, we updated the references and made no policy changes.

In 2021, we updated the references with no policy changes warranted.

In 2022, we updated the references and made no policy changes.

In 2023, we found no new large reviews to add to the policy.

In 2024, we reorganized the findings, deleted older references, and updated one guideline. No policy changes are warranted.

References

On September 26, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “orthotic device,” “paresis,” “stroke,” “rehabilitation,” “upper extremity,” “exoskeleton,” “robotics,” “movement disorder,” “exoskeleton device” (MeSH), “robotics” (MeSH), and “upper extremity” (MeSH). We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

12/2013: initial review date and clinical policy effective date: 6/2014

11/2016: Policy references updated.

12/2017: Policy references updated. Title changed.

12/2018: Policy references updated.

12/2019: Policy references updated. Policy ID changed.

1/2020: Policy references updated. Policy scope expanded.

12/2020: Policy references updated.

12/2021: Policy references updated.

12/2022: Policy references updated.

12/2023: Policy references updated.

12/2024: Policy references updated.