Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
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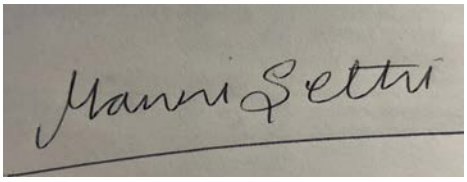
Plan: AmeriHealth Caritas Pennsylvania Community Health Choices	**Submission Date**: 1/1/2024
Policy Number: ccp.1076	**Effective Date:** 6/2014 **Revision Date:** December 1, 2023
Policy Name: Robotic orthoses – upper limb	
Type of Submission – Check all that apply: **New Policy** **x Revised Policy*** **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: 12/2023

Next review date: 4/2025

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

AmeriHealth Caritas Pennsylvania Community HealthChoices has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania Community HealthChoices' 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 AmeriHealth Caritas Pennsylvania Community HealthChoices 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. AmeriHealth Caritas Pennsylvania Community HealthChoices' 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. AmeriHealth Caritas Pennsylvania Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania Community HealthChoices will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania Community HealthChoices' 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 (Herder, 2006). 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 (Herder, 2006). 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 in their movements. Current robots tend to train the shoulder and elbow, but not the unexercised wrist and hand, thereby limiting activities of daily living (Mundy, 2010). However, devices for improving hand dexterity are emerging (Biorobotics Laboratory, 2023).

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, 2023), the Armeo Spring (Hocoma Inc., Norwell, Massachusetts), and the MyoPro® (Myomo, Inc., Cambridge, Massachusetts, 2023).

Findings

We identified no systematic reviews or economic analyses of the Wilmington robotic exoskeleton or professional society guidelines that specifically addressed the Wilmington robotic exoskeleton, or its modifications. We found several individual studies for each of the Wilmington robotic exoskeleton orthoses considered in this policy. The evidence base comprises primarily small feasibility studies of Wilmington robotic exoskeleton technologies used to assist upper limb function in a select group of children with arthrogryposis or spinal muscular atrophy, and rehabilitation of the upper limb predominately in adult stroke survivors. We identified no systematic reviews or

economic analyses of the Wilmington robotic exoskeleton or professional society guidelines that specifically addressed the Wilmington robotic exoskeleton, or its modifications. We found several individual studies for each of the Wilmington robotic exoskeleton orthoses considered in this policy. The evidence base comprises primarily small feasibility studies of Wilmington robotic exoskeleton technologies used to assist upper limb function in a select group of children with arthrogryposis or spinal muscular atrophy, and rehabilitation of the upper limb predominately in adult stroke survivors. The effectiveness of these technologies to translate restoration of function into practicing everyday tasks, the optimal candidates for these devices, and the optimal treatment regimens using these devices, have not been determined.

Low-quality evidence from two case series (eight total patients) suggests the Wilmington robotic exoskeleton may improve upper-extremity function and quality of life in children with arthrogryposis or spinal muscular atrophy (Haumont, 2011; Rahman, 2006). Two unexpected outcomes were increased security with trunk inclination and amelioration of the effects of contractures.

One moderate-quality randomized controlled trial compared the outcomes and preferences of 28 chronic stroke survivors, with moderate/severe hemiparesis assigned to either the Therapy-Wilmington robotic exoskeleton or tabletop exercise treatment, with blinded assessment (Housman, 2009). All participants significantly improved upper extremity motor control (Fugl-Meyer score, $P \leq .05$), active reaching range of motion ($P \leq .05$), and self-reported quality and amount of arm use (Motor Activity Log, $P \leq .05$). The Therapy-Wilmington robotic exoskeleton group maintained gains on the Fugl-Meyer scores, significantly better than controls at six months, and participants also reported a preference for training with it.

Low-quality evidence from three case series, three feasibility studies, and two conference abstracts suggests Armeo Spring may improve functional reaching tasks and be effective for rehabilitating the upper limb among individuals with stroke, cervical spinal cord injury with some preserved hand function, and multiple sclerosis (Colomer, 2013; Gijbels, 2011; Housman, 2009; Iwamuro, 2008; Rudhe, 2012; Sanchez, 2004, 2006; Zariffa, 2012). Both the Pneu-Wilmington robotic exoskeleton and conventional tabletop therapy achieved benefits in 26 individual stroke survivors with moderate to severe deficits, but there was a trend for greater reduction in functional deficit (Fugl-Meyer score, $P = .07$) and sensory function (Nottingham Sensory Test, $P = .06$) in the robot-trained group (Reinkensmeyer, 2012).

Evidence-based guidelines from the Department of Veterans Affairs and Department of Defense (2010) and the American Heart Association (Miller, 2010), address recommendations for upper-extremity, robot-assisted therapy in stroke survivors. However, neither guideline included studies of Wilmington robotic exoskeleton technologies. Both guidelines recommend robot-assisted movement therapy as an adjunct to conventional therapy, to improve motor skill at the trained joints. This is based on at least fair-quality evidence demonstrating that robot-assisted therapy improves upper extremity motor control of the shoulder and elbow, and the benefits outweigh harms.

In 2018, we added updates of a Cochrane review (Mehrholz, 2015) and a guideline by the American Heart Association and American Stroke Association (Winstein, 2016). Their conclusions have not changed, and no policy changes are warranted.

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. The preponderance of the evidence from systematic reviews and meta-analyses examined adults with first-ever, ischemic stroke (Mehrholz, 2018, update of 2015; Suarez-Escobar, 2018), children with stroke (Mirkowski, 2019), adults with spinal cord injury (Singh, 2018), and children with cerebral palsy (Chen, 2016).

The evidence from these systematic reviews either in general or specific to individual robotic systems lacks important details of the study population, intervention, and outcomes necessary to inform a determination of

medical necessity. There is evidence that robotic-led rehabilitation improves 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 classical therapist-led training performed on the same quantity of movements has been determined. Therefore, we cannot conclude with certainty that motor therapy provided by robots would be superior to conventional motor therapy under the same training conditions (intensity, amount, and frequency of therapy).

The Mehrholz (2018) Cochrane review provides the most comprehensive and rigorous review of 45 trials (n = 1,619 participants) of electromechanical and robot-assisted upper limb rehabilitation. They rated the quality of evidence as high. The results suggest that electromechanical and robot-assisted arm training devices are safe and acceptable to most participants and modestly improved 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. Three additional trials not included in the Cochrane review—one multisite randomized controlled trial (Rodgers, 2019), one comparative study of two robot-assisted therapies (Hung, 2019), and one small case series (McCabe, 2019)—also enrolled participants after first stroke and reached similar conclusions.

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, but to date, the evidence consists of prototype development with little examination of commercially available devices as complements to conventional post-stroke therapy (Suarez-Escobar, 2018). Results of two preliminary individual studies illustrate the potential of portable myoelectric elbow-wrist-hand orthoses to perform multi-joint functional movements and improve self-reported function and perceptions of overall recovery in participants with stroke (Peters, 2017; Willigenburg, 2017).

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).

The Department of Veterans Affairs and Department of Defense updated their guideline (2019) on the management of stroke rehabilitation. They continue to offer a weak recommendation for robot-assisted movement therapy as an adjunct to conventional therapy in patients with deficits in upper limb function to improve motor skill, but also acknowledge that the low-quality evidence supporting their recommendation was fraught with bias and inconsistency.

In December 2020, we added a randomized controlled trial (Straudi, 2020) that compared the effectiveness of unilateral, proximal arm, robot-assisted therapy plus hand functional electrical stimulation (30 sessions at five sessions per week) to time-matched intensive conventional therapy for restoring arm function in 40 participants with subacute stroke (time since stroke less than eight weeks) and upper limb impairment. Outcomes were measured at baseline, after three weeks, at the end of treatment, and at 6-month follow-up. There were no between-group differences in the improvement of arm motor recovery measured with the Fugl-Meyer Motor Assessment or in secondary measures of motor function, arm spasticity, or activities of daily living. The results confirm previous findings and warrant no policy changes.

In 2021, we added four randomized controlled trials (Cho, 2021; Lee, 2021; Park, 2021; Singh, 2021) and one systematic review and meta-analysis (Moggio, 2021) examining the effectiveness of robot-assisted therapy

targeting distal sites of the wrist, hand, and fingers in stroke survivors. The evidence suggests 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.

We added three systematic reviews comparing robot-assisted arm training to other protocols in stroke survivors (Chen, 2020; Ferreira, 2021; Wu, 2021), one systematic review synthesizing stroke rehabilitation guidelines (Morrone, 2021), and one economic evaluation comparing stroke rehabilitation protocols in the United Kingdom (Fernandez-Garcia, 2021). The new evidence comprises randomized or quasi-randomized controlled trials general of moderate to high quality and reported mixed results that fail to support a clear superiority of robot-assisted rehabilitation over standard rehabilitation protocols for the upper limb following stroke:

- Compared to therapist-mediated training, robot-assisted arm training was slightly superior in motor impairment recovery and noninferior in improving arm capacity, activities of daily living, and social participation (Chen, 2020, 35 studies, n = 2,241).
- For improving individual community participation, low-quality evidence suggests robot-assisted therapy was slightly superior to minimal intervention in the short term but was not superior to other interventions in either the short or medium term. (Ferreira, 2021, 12 studies, n = 845).
- For improving motor impairment, results of dose-matched comparative studies suggest robot-assisted therapy was superior to conventional rehabilitation but with a small effect size ((Hedges g = 0.25; 95% confidence interval 0.11 to 0.38). End effector type devices (Hedges g = 0.22; 95% confidence interval 0.09 to 0.36) but not exoskeleton devices were superior to conventional rehabilitation. The between-group difference (robot-assisted therapy versus convention rehabilitation) was significant only for patients with late subacute or chronic stroke (Hedges g = 0.33; 95% confidence interval 0.16 to 0.50) (Wu, 2021, 41 studies, n = 1,916).
- Fernandez-Garcia (2021) conducted an economic evaluation from the United Kingdom perspective using data from the Robot-Assisted Training for the Upper Limb after Stroke randomized controlled trial (Rodgers, 2019; trial registration number ISRCTN69371850). Mean quality-adjusted life years were highest for the study participants who underwent an enhanced upper limb therapy protocol (0.23), but no difference was observed between the robot-assisted training (0.21) and usual care groups (0.21) (*P* = .995). Robot-assisted training was unlikely to be cost-effective, compared to the usual care and enhance care options, as delivered in the trial protocol.
- Current guidelines highlight the deficiencies in individual studies, which generally recommend robotic therapy to improve upper limb motor function and strength but fail to identify either the characteristics of patients who could benefit or the optimal protocol (Morrone, 2021, eight guidelines).

In 2022, we added a meta-analysis of 46 studies comparing robotic-assisted therapy with non-robotic therapy in post-stroke patients found robotic-assisted therapy had superior outcomes in Fugl-Meyer upper extremity assessment and activity function. However, differences were observed only at end of treatment, not at follow-up; only with training time over 15 hours; and only for patients whose impairment was not severe (Zhang, 2022).

We also added a network meta-analysis of 15 meta-analyses of rehabilitation of upper limb motor function for stroke patients showed robotic therapy to be superior to other treatment modalities for severe-moderate impairments in the subacute phase, but not during the subacute phase (Everard, 2022).

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

References

On September 20, 2023, 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.