Robotic orthoses – upper limb

Clinical Policy ID: CCP.1076

Recent review date: 12/2025

Next review date: 4/2027

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

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 Individuals, 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 Individual 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 Individuals 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 Individual 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 Individual'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

The evidence base regarding robotic orthoses for upper limb rehabilitation includes updated clinical guidelines, systematic reviews, and large-scale meta-analyses. Current clinical guidelines generally recommend against routine adoption or suggest limiting usage to research settings due to a lack of proven superiority over standard care. Systematic reviews indicate that while robotic therapy is safe, it fails to yield significant, sustained improvements in activities of daily living performance compared with conventional rehabilitation. Furthermore, meta-analyses consistently demonstrate that although statistical improvements in motor scores are often observed, these gains do not meet the established thresholds for clinical meaningfulness.

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.

Updated clinical guidelines from the United Kingdom, published in 2023, provide recommendations regarding the use of robotic technology in stroke recovery. The National Institute for Health and Care Excellence (NICE) explicitly recommends against offering robot-assisted arm training as part of an upper limb rehabilitation program (National Institute for Health and Care Excellence, 2023). Similarly, the Intercollegiate Stroke Working Party advises that while robot-assisted movement therapy may be considered as an adjunct to usual therapy for improving motor recovery, this should preferably be undertaken within the context of a clinical trial (Intercollegiate Stroke Working Party, 2023).

A review comparing these United Kingdom guidelines with those of the European Stroke Organisation highlights a divergence in international recommendations. While the European body strongly recommends electromechanical and robot-assisted arm training to improve upper limb function and muscle strength, the United Kingdom guidelines do not support routine adoption, citing evidence from the RATULS trial that indicated robotic therapy was not cost-effective and did not yield superior functional outcomes compared to usual care (O’Flaherty, 2024).

Systematic reviews

Evidence regarding the comparative effectiveness of robotic devices versus standard care and their impact on activities of daily living remains unfavorable or mixed. One multisite trial carried out in the United Kingdom (n = 770) found that robot-assisted training did not improve upper limb function success, measured by the Action Research Arm Test at three months, compared with usual care or an enhanced therapy protocol for participants with moderate or severe impairment (Rodgers, 2019). Newer systematic reviews indicate that robotic rehabilitation does not result in significant differences in the performance of activities of daily living compared to conventional rehabilitation either immediately post-treatment or at follow-up (Boardsworth, 2025). While one review noted a small, statistically significant positive effect on upper limb capacity immediately following intervention, these gains were not maintained at follow-up assessments (Boardsworth, 2025). Other randomized or quasi-randomized controlled trials reported mixed results regarding the superiority of robotic protocols (Chen, 2020; Ferreira, 2021; Wu, 2021).

The comparative effectiveness of robotic therapy may depend on device characteristics, treatment dose, and participant selection. Subgroup analyses suggest that devices that allow for partial assistance, where the user actively contributes to movement, may yield better results than those providing full assistance. Furthermore, targeting the distal upper limb may be more effective than proximal training (Boardsworth, 2025). Additionally, portable rehabilitation robots have demonstrated effectiveness in improving upper limb function compared to non-robotic therapy in a smaller subset of trials (n = 295), suggesting feasibility for portable designs (Tseng, 2024). Regarding timing, the effectiveness of the intervention may be influenced by the recovery phase and duration of treatment (Everard, 2022; Zhang, 2022).

Reviews of specific anatomic locations and non-stroke populations provide limited support for these interventions. For hand and finger function specifically, randomized controlled trials found some improvement in motor function with a robotic adjunct, but conclusions are limited by small sample sizes, variations in devices, and inconsistent protocols (Cho, 2021; Lee, 2021; Moggio, 2022; Park, 2021; Singh, 2021). In participants with cervical spinal cord injury, a systematic review of one randomized clinical trial and several case series suggests robot-assisted interventions are safe and feasible and may reduce the active assistance provided by therapists, but the optimal device and training protocol remain undefined (Singh, 2018). Finally, in children with cerebral palsy, limited results from case studies and small observational studies suggest a moderate improvement in reaching duration, smoothness, or decreased muscle tone (Chen, 2016).

Meta analysis

Recent large-scale evidence reviews have focused heavily on distinguishing between statistical significance and clinical relevance regarding robotic therapy for stroke rehabilitation. An umbrella review of 16 meta-analyses (n = 19,280) and a re-analysis of randomized controlled trials found that while robot-assisted therapy produced statistically significant improvements in motor recovery compared to conventional therapy, the magnitude of these improvements failed to meet the established thresholds for the minimal clinically important difference in both subacute and chronic stroke populations (Park, 2025). This finding is corroborated by a separate meta-analysis (n = 3,452) which concluded that although robotic training showed statistically significant effects on dexterity, strength, and arm function, none of these domains achieved clinical relevance when compared to control groups (Verola, 2025).

Further analysis questions the generalization of motor gains to functional capacity. A large review of 90 trials (n = 4,311) determined that the small significant effects observed at the level of motor impairment did not generalize to clinically meaningful effects regarding upper limb capacity (De Iaco, 2024). A Cochrane review of 45 trials (n = 1,619) rated as high quality similarly found that electromechanical and robot-assisted arm training devices were safe and acceptable to most participants and modestly improved arm function and muscle strength. However, it remained unclear if these slight improvements were clinically meaningful to most participants, and due to heterogeneity in trial designs, the optimal therapeutic intensity could not be determined (Mehrholz, 2018).

In 2025, we streamlined the findings section and updated the policy with new literature, including umbrella reviews, systematic reviews, and meta-analyses, as well as updated clinical guidelines (Boardsworth, 2025; De Iaco, 2024; Intercollegiate Stroke Working Party, 2023; National Institute for Health and Care Excellence, 2023; O'Flaherty, 2024; Park, 2025; Tseng, 2024; Verola, 2025).

References

On November 13, 2025, 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.

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

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

12/2020: Policy references updated.

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12/2022: Policy references updated.

12/2023: Policy references updated.

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