Clinical Policy Title: Wilmington robotic exoskeleton

Clinical Policy Number: CCP.1076

Effective Date: June 1, 2014
Initial Review Date: December 18, 2013
Most Recent Review Date: February 5, 2019
Next Review Date: February 2020

Related policies:

None.

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ 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 when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state and federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas’ 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’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of the following robotic exoskeleton upper extremity orthoses to be investigational and, therefore, not medically necessary:

- Wilmington robotic exoskeleton (JAECO Orthopedic, Hot Springs, Arkansas).
- Armeo® Spring (Hocoma Inc., Norwell, Massachusetts).
- Pneumatic Wilmington robotic exoskeleton (Biorobotics Laboratory, 2018).
- BONES (Biorobotics Laboratory, 2018).

Limitations:

This policy is limited to the Wilmington robotic exoskeleton device.

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**

Persons 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 robotic manipulators, powered (electromechanical) orthoses, and passive orthoses (Herder, 2006). Robotic manipulators and powered orthoses are used in training and rehabilitation; they are intended for the weakest patients, who in some cases have little to no muscle force. Current robots tend to train the shoulder and elbow, but not the unexercised wrist and hand, thereby limiting activities of daily living (Mehrholz, 2015; Mundy, 2010).

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, 2005). 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).

The Wilmington robotic exoskeleton is a passive, body-powered, antigravity arm orthosis designed to enhance movement for individuals with neuromuscular disabilities of the upper extremity (JAECO Orthopedic, 2018). By using linear elastic bands both for balance and to assist movement in three dimensions against the effects of gravity, the Wilmington robotic exoskeleton provides extensive range of motion to aid in movement training and activities of daily living. Its lightweight exoskeleton approximates normal human anatomy, and it can be attached to most common wheelchairs and mobility seating systems using a mounting base. The U.S. Food and Drug Administration (2018b; 21CFR890.3475) classifies the Wilmington robotic exoskeleton as a Class I (general controls) device (product code ILH), which is exempt from the requirement for 510(k) submissions and compliance with good manufacturing process regulations. Originally designed to assist children with weakened arms, the Wilmington robotic exoskeleton has been proposed as a rehabilitation device for stroke survivors.

Modifications to the Wilmington robotic exoskeleton include the now commercialized Armeo Spring, formerly known as the Therapy Wilmington Robotic Exoskeleton (Biorobotics Laboratory, 2018). It is
classified as a Class II (general controls and special controls) device (product code IKK) (U.S. Food and Drug Administration, 2018a; 21CFR890.1925). Originally designed for adult stroke survivors, it has an integrated grip sensor that detects even trace amounts of hand grasp, allowing people with weakened hands to practice using their hands in a meaningful way in a virtual world, in coordination with their arms. It incorporated new easy-to-learn computer games with simulated movements needed for activities of daily living, such as cooking, shopping, bathing, and cleaning. In development are exoskeletons called Pneumatic Wilmington robotic exoskeleton and BONES for arm movement training in virtual environments, using an adaptive, “assist-as-needed” controller (Biorobotics Laboratory, 2018).

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.

We conducted searches on October 25, 2018. 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:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

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. 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 subjects 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, 2007; 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.

Policy updates:

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. Policy ID changed from CP# 15.02.06 to CCP.1076.

References

Professional society guidelines/other:

Miller EL, Murray L, Richards L, et al. Comprehensive overview of nursing and interdisciplinary rehabilitation


**Peer-reviewed references:**

21 CFR890.1925.


Housman SJ, Scott KM, Reinkensmeyer DJ. A randomized controlled trial of gravity-supported, computer-


Centers for Medicare & Medicaid Services National Coverage Determinations:

No National Coverage Determinations identified as of the writing of this policy. One addressed durable medical equipment that included orthotic devices:

Durable Medical Equipment Reference List (280.1).

Medicare Claims Processing Manual Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS).

Local Coverage Determinations:

No Local Coverage Determinations identified as of the writing of this policy.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

There are no specific codes for robotic-assisted exoskeletons.

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<th>Description</th>
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<td>Myoneural disorders</td>
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<td>G7080, G7081, G7089</td>
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<td>Congenital deformity of finger(s) and hand</td>
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