Clinical Policy Title: Wilmington Robotic Exoskeleton Upper Extremity Orthosis

Clinical Policy Number: 15.02.06

Effective Date: June 1, 2014
Initial Review Date: Dec. 18, 2013
Most Recent Review Date: Jan. 15, 2014
Next Review Date: Dec. 2014

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina clinical policies are based on guidelines from established industry sources such as Centers for Medicare and Medicaid (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 Select Health of South Carolina 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. Select Health of South Carolina 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. Select Health of South Carolina clinical policies are reflective of evidence based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina clinical policies are not guarantees of payment.

Coverage Policy:
Select Health of South Carolina considers the use of the Wilmington Robotic Exoskeleton Upper Extremity Orthosis to be investigational; and therefore, a finding of medical necessity is not supported.

Limitations: This Policy is limited to the WREX 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. 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 (ROM) 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. A number of validated, performance-based and self-rated measures exist to assess upper limb function across a spectrum of abilities, populations and etiologies. (Connell 2012, Mazzone 2012, Wagner 2012, Lemmens 2012)

Choice of orthosis must also satisfy functionality, comfort, safety and aesthetics. (Herder 2006) A useful orthosis should assist important activity limitations, such as feeding oneself, personal hygiene, and reaching. Ideally, it should have an inconspicuous appearance, good comfort of wearing under different circumstances (clothing) and easy operation (low mental and physical effort), and it must accommodate a fixed armrest.

Available upper extremity orthoses can be subdivided into three main groups: rehabilitation robotic manipulators; powered (electromechanical) orthoses; and non-powered 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 (ADLs). There is a large body of literature regarding the use of robot-assisted therapy to help to improve arm function after stroke. (Merholz 2012, Mundy 2010) A systematic review found that robot-assist therapy improves motor function and decreases time to perform tasks when compared to usual care but not when compared to intensive therapy. (Merholz 2012) A full cost-effectiveness analysis is needed to ascertain the true benefits of robot-assist therapy.

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 ROM (e.g. only horizontal), imperfect balancing quality, or problems related to comfort (i.e. donning and doffing, sliding and perspiration in trough). (Herder 2006)

The Wilmington Robotic Exoskeleton (WREX) (JAECO Orthopedic, Hot Springs, AR) is a passive, body-powered antigravity arm orthosis designed to enhance movement for individuals with neuromuscular disabilities of the upper extremity. (JAECO Orthopedic 2013) It was originally designed to assist children with weakened arms. It has been proposed as a rehabilitation device for people recovering from stroke. Its lightweight exoskeleton approximates normal human anatomy. Linear elastic bands are used both for balance and to assist movement in three dimensions against the effects of gravity providing extensive ROM to aid in movement training and activities of daily living (ADLs). The orthosis can be attached to most common wheelchairs and mobility seating systems using a mounting base. (JAECO Orthopedic 2013) The U.S Food and Drug Administration (FDA) classifies the WREX (product code ILH) as a Class I (general controls) device, which is exempt from the requirement for 510(k) submissions and compliance with GMP regulations. (FDA 2013a, 21CFR890.3475)
Modifications to the WREX include the T-WREX (or “Therapy-Wilmington Robotic Exoskeleton”), now commercialized as Armeo®Spring (Hocoma, Norwell, MA). (Biorobotics Laboratory 2013) Developed by researchers at University of California at Irvine, the original T-WREX was designed for adults with a stroke. It has an integrated grip sensor that allowed detection of 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. Finally, the original T-WREX incorporated new computer games that were easy to learn yet engaging and simulated movements needed for ADLs such as cooking, shopping, bathing and cleaning. The Armeo®Spring (product code IKK) is commercialized as a FDA Class II (general controls and special controls) device. (FDA 2013b, 21CFR890.1925) In development is the Pneu-WREX, a pneumatically actuated version of the T-WREX for arm movement training in virtual environments using an adaptive, "assist-as-needed" controller. (Biorobotics Laboratory 2013)

METHODS

Searches:
We searched PubMed and the databases of:
- UK NHS Centre for Reviews and Dissemination ;
- AHRQ guideline clearinghouse and evidence-based practice centers;
- Centers for Medicare and Medicaid Services.

Searches were conducted on November 8-11, 2013 using the terms “Orthotic Devices”, “Paresis”, “Stroke”, “rehabilitation”, “Upper Extremity”, “exoskeleton”, “robotics” and “Movement Disorders”. 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 pre-determined transparent methods to minimize bias: effectively treating the review as a scientific endeavor, thus are rated highest in evidence grading hierarchies.
- [Guidelines based on systematic reviews](#); and
- [Economic analyses](#): cost-effectiveness, -benefit or -utility studies, which report both costs and outcomes; (but not simple cost studies), sometimes referred to as efficiency studies, also rank near the top of evidence hierarchies.

Findings
No systematic reviews or economic analyses of the WREX were identified for this policy. Several individual studies were identified for each of the WREX orthoses covered in this policy. The evidence base is comprised of small feasibility studies of WREX technologies used to assist upper limb function in a select group of children with arthrogryposis or Spinal Muscular Atrophy (SMA), and to assist rehabilitation of the upper limb predominately in adult survivors of stroke. The effectiveness of these technologies to translate restoration of function into practicing everyday tasks, the optimal candidates for WREX devices and the optimal treatment regimens using WREX devices have not been determined.

- **WREX**: 2 case series (Haumont (2011), n=3; Rahman (2006) n=5), one conference abstract (Sample 2002) Low quality evidence suggests the WREX may improve upper-extremity function and quality of life in children with arthrogryposis or SMA. Two unexpected outcomes were increased security with trunk inclination and amelioration of the effects of contractures.

- **T-WREX/ Armeo®Spring**: 1 small randomized control trial (Housman 2009), 3 case series (Iwamuro 2008, n=10; Zariffa 2012, n=12; Colomer 2013, n=23), 3 feasibility studies (Sanchez 2006, Gijbels
2011, Rudhe 2012), 2 conference abstracts (Sanchez 2004, Housman 2007). All but 3 studies (Gijbels 2011, Rudhe 2012, and Zariffa 2012) evaluated these devices among stroke survivors.

One moderate quality study (Housman 2009) assessed the outcomes of 28 chronic stroke survivors with moderate/severe hemiparesis who were randomly assigned to the T-WREX or tabletop exercise treatment, with blinded assessment; preferences were assessed in a single cross-over treatment. All subjects significantly improved upper extremity motor control (Fugl-Meyer score, \( P \leq .05 \)), active reaching ROM (\( P \leq .05 \)), and self-reported quality and amount of arm use (Motor Activity Log, \( P \leq .05 \)). The T-WREX group maintained gains on the Fugl-Meyer scores significantly better than controls at 6 months. Participants also reported a preference for T-WREX training.

Low quality evidence suggests T-WREX/ may be feasible for improving functional reaching tasks. The Armeo®spring may be an effective tool for rehabilitating the upper limb among individuals with stroke, cervical spinal cord injury with some preserved hand function and multiple sclerosis.

- **Pneu-WREX**: 1 RCT (Reinkensmeyer 2012, n=26). Comparing the robot-assisted Pneu-WREX to conventional tabletop therapy, individuals with chronic stroke and moderate-severe deficits benefitted from both forms of training, but there was a trend for greater reduction for the robot-trained group (Fugl-Meyer score, \( P = 0.07 \)) and sensory function (Nottingham Sensory Test, \( P = 0.06 \)). Assisting in 3-dimensional virtual tasks with an assist-as-needed controller may enhance rehabilitation.

**Summary of Clinical Evidence**
No systematic reviews or economic analyses for the Wilmington Robotic Exoskeleton orthoses were identified for this policy.

**Professional Society Guidelines**
No professional society guidelines were identified that specifically addressed the WREX or its modifications. Guidelines from the Dept. of Veterans Affairs and Department of Defense (VA/DoD) and the American Heart Association (AHA) address recommendations for robot-assisted therapy for the upper extremity in stroke survivors. However, neither guideline included studies of the WREX.

VA/DoD recommends robot-assisted movement therapy as an adjunct to conventional therapy in patients with deficits in arm function to improve motor skill at the joints trained. [B] A “B” recommendation indicates at least fair evidence demonstrates that the intervention improves health outcomes and the benefits outweigh harm.

“There is evidence from 1 systematic review and multiple small RCTs that robot-assisted therapy may improve motor control of those UE [upper extremity] areas trained... It is not clear whether robotic therapy improves function at the activity or participation level...This may be a function that most robotic studies have used robots that exercise only the shoulder and elbow rather than the hand. Because few studies have compared robotic therapy to conventional therapy at comparable dose levels, it is unclear whether robotic therapy offers greater benefit to UE motor recovery than conventional therapy. Robotic therapy may be a cost effective way to
achieve a greater amount of UE motor practice than can be provided with direct therapy.”

“There is strong evidence that sensorimotor training with robotic devices improves upper extremity functional outcomes, and motor outcomes of the shoulder and elbow. There is strong evidence that robotic devices do not improve motor outcomes of the wrist and hand.”

The AHA guideline for stroke care recommended that robot-assisted therapy for the upper extremity in the outpatient and chronic care settings is useful and effective based on Class I, Level of Evidence A for Stroke Care. (Miller 2010) The evidence was derived from multiple populations in multiple RCTs or meta-analyses that showed a significant treatment effect where the benefits outweighed the risks (Benefit > Risk). The AHA recommended in favor of robot-assisted therapy for the upper extremity treatment or procedure being useful/effective in the inpatient setting based on Class IIa, Level of Evidence A for stroke care. The evidence was derived from multiple populations in multiple RCTs or meta-analyses with some conflicting evidence that showed an overall significant treatment effect where the benefits outweighed the risks (Benefit > Risk), but additional evidence with focused objectives are still needed. (Miller 2010)

<table>
<thead>
<tr>
<th>CMS NCD for Durable Medical Equipment Reference List (280.1)</th>
<th>No specific mention of robotically assisted, mechanically powered or non-powered upper extremity orthoses.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The Medicare Claims Processing Manual, Chapter 20, “Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS).”</td>
<td>• Whether the item has been approved for marketing by the Food and Drug Administration (FDA) and is otherwise generally considered to be safe and effective for the purpose intended; and</td>
</tr>
<tr>
<td>• Whether the item is reasonable and necessary for the individual patient.</td>
<td>• Whether the item is reasonable and necessary for the individual patient.</td>
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</table>

The term DME is defined as equipment which:

- Can withstand repeated use; i.e., could normally be rented and used by successive patients;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of illness or injury; and,
- Is appropriate for use in a patient's home.

**PM&R policy (L27513)**

**Orthotic management and training (CPT code 97760)**

- Orthotic management includes assessment of the patient and determination of the most appropriate orthotic; design and fabrication of the orthotic; fitting and training required to properly use the orthotic device.
- The patient or caregiver must be capable of being trained to use the particular device prescribed in an appropriate manner. In some cases the patient may not be able to perform this function, but a responsible individual can be trained about the use of the device.
- The medical record should document the distinct treatments rendered when orthotic training for a lower extremity is done during the same visit as gait training (CPT code 97116) or self-care/home management training (CPT code 97535).

**Prosthetic training, upper and/or lower extremity(s), each 15 minutes (CPT code 97761)**
This procedure may be considered reasonable and necessary, if there is an indication for education in the application of the prosthetic and the functional use of the prosthesis is present and documented.
- The medical record should document the distinct goals and service rendered when prosthetic training for a lower extremity is done during the same visit as gait training (97116), orthotics fitting and training (97760) or self-care/home management training (97535).
- Periodic revisits beyond the third month may require supportive documentation of medical necessity if requested.
- In some cases, prosthetic training may require more than 30 minutes on a given date and when this occurs the medical record must document the medical necessity of the additional time.

**Orthotic/Prosthetic Checkout established patient, each 15 minutes (CPT code 97762)**
- These assessments may be medically necessary for “established patients who have already received the orthotic or prosthetic device (permanent or temporary).
- These assessments may be medically necessary when patients experience loss of function directly related to the orthotic or prosthetic device (e.g., pain, skin breakdown, or falls).
- These assessments may be reasonable and necessary for determining “the patients response to wearing the device, determining whether the patient is donning/doffing the device correctly, determining the patient need for padding, under wrap, or socks and determining the patient’s tolerance to any dynamic forces being applied.”
- Requires direct one-on-one patient contact.

**Note:** The following items are included in the Durable Medical Equipment Medicare Administrative Contractors (DMAC) reimbursement for a prosthesis/ORTHOSIS within 90 days of delivery of the prosthesis/ORTHOSIS and, therefore, are not separately billable to Medicare:

a. Evaluation of the residual limb and/or gait.
b. Fitting of the prosthesis/ORTHOSIS.
c. Cost of base component parts and labor contained in HCPCS base codes.
d. Repairs due to normal wear or tear.
e. Adjustments of the prosthesis/ORTHOSIS or the prosthetic component/orthotic component made when fitting the prosthesis/ORTHOSIS or component when the adjustments are not necessitated by changes in the residual limb or the patient’s functional abilities.

**Glossary of terms:**
**Activity limitation:** restriction in the execution of a task or action by an individual.

**Arthrogryposis** (or Arthrogryposis multiplex congenita): a congenital condition characterized by reduced mobility of multiple joints due to contractures causing fixation of the joints in extension or flexion.

**Assistive technology:** any object or system either acquired commercially, modified, or customized that is used to maintain or improve functional capabilities of individuals with disabilities.

**Contracture:** a permanent shortening (as of muscle, tendon, or scar tissue) producing deformity or distortion.

**Exoskeleton:** a term used to describe certain external, structural assistive devices that are applied externally to a part of the human body to provide motor assistance and functional compensation to a disabled person. The joints of an exoskeleton match those of the human body allowing physical contact with the operator and enabling a direct transfer of mechanical power and information signals.
Impairment: is a problem in body function or structure, e.g. a significant deviation or loss of muscle strength.

Orthosis: an orthopedic appliance or apparatus used to support, align, prevent, or correct deformities or to improve function of movable parts of the body.

Range of motion: The full movement potential of a joint, usually its range of flexion and extension.

Rehabilitation: health care services that help maintain, restore or improve skills and functioning for daily living that have been lost or impaired because of illness, injury or disability. These services include physical therapy, occupational therapy, speech language pathology and psychiatric rehabilitation services in a variety of inpatient and/or outpatient settings.

Related Policies: Select Health of South Carolina Utilization Management Program Description

REFERENCES

Professional Society Guidelines


Peer-Reviewed References


Isokinetic testing and evaluation system, 21 CFR890.1925 (2013).


Mundy L, Hiller JE. *Robot-assisted therapy for long-term upper limb impairment after stroke*. Adelaide: Adelaide Health Technology Assessment (AHTA) on behalf of National Horizon Scanning Unit (HealthPACT and MSAC); 2010.


**Clinical Trials**

Search strategy: WREX OR "Wilmington robot" | Open Studies | Interventional Studies OR Robot | Open Studies | Interventional Studies | stroke. Retrieved one relevant result.


**Centers for Medicare and Medicaid Services (CMS) National Coverage Determination**

No NCDs identified for Wilmington Robotic Exoskeleton. One NCD addressed durable medical equipment that included orthotic devices:


**Local Coverage Determinations**


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 in accordance with those manuals.

There are no specific codes for robotic-assisted exoskeletons.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>97760</td>
<td>Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(s), lower extremity(s) and/or trunk, each 15 minutes</td>
<td>Not covered</td>
</tr>
<tr>
<td>97761</td>
<td>Prosthetic training, upper and/or lower extremity(s), each 15 minutes</td>
<td>Not covered</td>
</tr>
<tr>
<td>97762</td>
<td>Checkout for orthotic/prosthetic use, established patient, each 15 minutes</td>
<td>Not covered</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>ICD-9 Code</th>
<th>Description</th>
<th>Comment</th>
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</thead>
<tbody>
<tr>
<td>343.0 - 343.9</td>
<td>Cerebral palsy</td>
<td>Not covered</td>
</tr>
<tr>
<td>358.00 - 358.9</td>
<td>Myoneural disorders</td>
<td>Not covered</td>
</tr>
<tr>
<td>438.20 - 438.53</td>
<td>Late effects of cerebrovascular disease, hemiplegia/hemiparesis, monoplegia of upper or lower limb, or other paralytic syndrome</td>
<td>Not covered</td>
</tr>
<tr>
<td>438.89</td>
<td>Other and unspecified late effects of cerebrovascular disease</td>
<td>Not covered</td>
</tr>
<tr>
<td>438.84</td>
<td>Ataxia</td>
<td>Not covered</td>
</tr>
<tr>
<td>728.3</td>
<td>Other specific muscle disorders</td>
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</tr>
<tr>
<td>754.89</td>
<td>Arthrogryposis multiplex congenita</td>
<td>Not covered</td>
</tr>
<tr>
<td>952.04, 952.09, 952.14, 952.19, 952.9</td>
<td>Spinal cord injury [incomplete spinal cord lesion]</td>
<td>Not covered</td>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>G800-G809</td>
<td>Cerebral palsy</td>
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<tr>
<td>G701-2, G731, G733, G7001, G7080, G7081, G7089</td>
<td>Myoneural disorders</td>
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<td>I6991-I69983</td>
<td>Late effects of cerebrovascular disease, hemiplegia/hemiparesis, monoplegia of upper or lower limb, or other paralytic syndrome</td>
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<td>Code</td>
<td>Description</td>
<td>Comment</td>
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<tr>
<td>I6990</td>
<td>Unspecified sequelae of unspecified cerebrovascular disease</td>
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</tr>
<tr>
<td>I69993</td>
<td>Ataxia</td>
<td>Not covered</td>
</tr>
<tr>
<td>M623</td>
<td>Immobility syndrome (paraplegic)</td>
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</tr>
<tr>
<td>M6289</td>
<td>Other specified disorders of muscle</td>
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</tr>
<tr>
<td>Q678</td>
<td>Other congenital deformities of chest</td>
<td>Not covered</td>
</tr>
<tr>
<td>Q681</td>
<td>Congenital deformity of finger(s) and hand</td>
<td>Not covered</td>
</tr>
<tr>
<td>Q743</td>
<td>Arthrogryposis multiplex congenita</td>
<td>Not covered</td>
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<tr>
<td>S141xx, S241xx, S341xx</td>
<td>Spinal cord injury</td>
<td>Not covered</td>
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<table>
<thead>
<tr>
<th>HCPCS Level II</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>3999</td>
<td>Upper limb orthosis NOS</td>
<td>Not covered</td>
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<tr>
<td>L3650 - L4398</td>
<td>Orthotic Devices -- Upper Limb</td>
<td>Not covered</td>
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