Clinical Policy Title: Wilmington robotic exoskeleton (WREX) upper extremity orthosis

Clinical Policy Number: 15.02.06

Effective Date: June 1, 2014
Initial Review Date: December 18, 2013
Most Recent Review Date: January 18, 2017
Next Review Date: January 2018

Related policies:
None.

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’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 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’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’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of the Wilmington robotic exoskeleton (WREX) upper extremity orthosis to be investigational and, therefore, not medically necessary.

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 (PT), occupational therapy (OT) 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 (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 as are functionality, comfort, safety and aesthetics (Connell, 2012; Mazzone, 2012; Wagner, 2012; Lemmens, 2012; Herder, 2006).

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 (ADLs)(Merholz, 2012; 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 ROM, imperfect balancing quality or problems related to comfort (i.e., donning and doffing, sliding and perspiration in trough) (Herder, 2006).

The 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). By using linear elastic bands both for balance and to assist movement in three dimensions against the effects of gravity, the WREX provides extensive ROM to aid in movement training and ADLs. 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 (FDA) classifies the WREX as a Class I (general controls) device (product code ILH), which is exempt from the requirement for 510(k) submissions and compliance with GMP regulations (FDA, 2016a; 21CFR890.3475). Originally designed to assist children with weakened arms, the WREX has been proposed as a rehabilitation device for stroke survivors.
Modifications to the WREX include the now commercialized Armeo®Spring (Hocoma Inc., Norwell, MA), formerly known as the Therapy Wilmington Robotic Exoskeleton (T-WREX) (Biorobotics Laboratory, 2013). FDA classifies the Armeo Spring as a Class II (general controls and special controls) device (product code IKK) (FDA, 2016b; 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 ADLs, such as: cooking, shopping, bathing, and cleaning. In development is the Pneumatic Wilmington Robotic Exoskeleton (Pneu-WREX), a pneumatically actuated version for arm movement training in virtual environments, using an adaptive, "assist-as-needed" controller (Biorobotics Laboratory, 2013).

Searches

Keystone First searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on November 14, 2016. Search terms were: “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 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 WREX or professional society guidelines that specifically addressed the WREX, or its modifications. We found several individual studies for each of the WREX orthoses considered in this policy. The evidence base comprises primarily 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 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 WREX devices, and the optimal
treatment regimens using WREX devices, have not been determined.

Low-quality evidence from two case series (eight total patients) suggests the WREX may improve upper-
 extremity function and quality of life in children with arthrogryposis or SMA (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 (RCT) compared the outcomes and preferences of 28
chronic stroke survivors, with moderate/severe hemiparesis assigned to either the T-WREX or tabletop
exercise treatment, with blinded assessment (Housman 2009). All subjects significantly improved upper
extremity motor control (Fugl-Meyer score, P ≤ .05), active reaching ROM (P ≤ .05), and self-reported
quality and amount of arm use (Motor Activity Log, P ≤ .05). The T-WREX group maintained gains on the
Fugl-Meyer scores, significantly better than controls at six months. Participants also reported a
preference for T-WREX training.

Low-quality evidence from three case series, three feasibility studies and two conference abstracts
suggests T-WREX/ Armeo Spring may improve functional reaching tasks and be effective for
rehabilitating the upper limb among individuals with stroke, cervical spinalcord injury with some
preserved hand function, and multiple sclerosis (MS) (Iwamuro, 2008; Zariffa, 2012; Colomer, 2013;
Sanchez, 2006; Gijbels, 2011; Rudhe, 2012; Sanchez, 2004; Housman, 2007). Both the Pneu-WREX 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 =
0.07) and sensory function (Nottingham Sensory Test, P = 0.06) in the robot-trained group
(Reinkensmeyer, 2012).

Evidence-based guidelines from the Department 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 (VA/DoD, 2010; Miller, 2010). However, neither
guideline included studies of WREX 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 update:
None.

References

Professional society guidelines/other:


**Peer-reviewed references:**

21 CFR890.1925.


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.


**CMS National Coverage Determinations (NCDs):**

No NCDs identified for WREX as of the writing of this policy. One NCD addressed durable medical equipment that included orthotic devices:
Local Coverage Determinations (LCDs):

No LCDs 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.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>G800-G809</td>
<td>Cerebral palsy</td>
<td></td>
</tr>
<tr>
<td>G701-2, G731, G733, G7001, G7080, G7081, G7089</td>
<td>Myoneural disorders</td>
<td></td>
</tr>
<tr>
<td>I6991-I69983</td>
<td>Late effects of cerebrovascular disease, hemiplegia/hemiparesis, monoplegia of upper or lower limb, or other paralytic syndrome</td>
<td></td>
</tr>
<tr>
<td>I6990</td>
<td>Unspecified sequelae of unspecified cerebrovascular disease</td>
<td></td>
</tr>
<tr>
<td>M623</td>
<td>Immobility syndrome (paraplegic)</td>
<td></td>
</tr>
<tr>
<td>M6289</td>
<td>Other specified disorders of muscle</td>
<td></td>
</tr>
<tr>
<td>Q678</td>
<td>Other congenital deformities of chest</td>
<td></td>
</tr>
<tr>
<td>Q681</td>
<td>Congenital deformity of finger(s) and hand</td>
<td></td>
</tr>
<tr>
<td>Q743</td>
<td>Arthrogryposis multiplex congenita</td>
<td></td>
</tr>
<tr>
<td>S141xx, S241xx, S341xx</td>
<td>Spinal cord injury</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Level II</th>
<th>Description</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>L3999</td>
<td>Upper limb orthotic, not other specified</td>
<td></td>
</tr>
</tbody>
</table>