INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Standing Systems

Stationary, mobile and active standing systems are proven and medically necessary for the treatment of individuals who are non-ambulatory when ALL of the following criteria are met:

- There is a goal of prevention of one or more of the following medical complications:
  - Decubitus Ulcer: Where there is a need for off-loading of a decubitus ulcer which cannot be accomplished by other means
Osteoporosis: Where improvement or stabilization of bone density cannot be achieved with other treatment or activities

Contracture Development: High potential for progressive contracture formation including but not limited to post-operative release of contractures

Compromised Bowel/Bladder Function: Where there has been demonstration there is incomplete emptying of bladder or constipation refractory to other medical treatment

Pulmonary Complications: Where there has been demonstration of recurrent infections and poor clearance of pulmonary secretions despite the use of other medical treatment

Hip Dislocation: Where hip subluxation/dislocation is worsening and alternate treatments have not been successful;

- The patient is unable to accomplish the above with his/her current medical device/equipment or alternate medical treatment;
- The individual has been evaluated with a trial using the standing device and has shown compliance, tolerance and demonstrated potential for clinical benefit, as determined by an independent reviewer;
- There is a written Plan of Care.

**Powered standing systems, mobile standers, standers attached to a wheelchair, or electric lift mechanisms are unproven and not medically necessary because they are a convenience feature and are not primarily medical in nature.**

**Gait Trainers**

Gait Trainers are proven and medically necessary for the treatment of non-ambulatory individuals when the following criteria are met:

- The individual has the potential for regular or therapeutic ambulation; and
- The individual is able to ambulate and uses the gait trainer as a walker where documentation shows other usual walkers have not been effective.

**Accessories for Standing Systems and Gait Trainers**

All other accessories added to standing systems and gait trainers are unproven and not medically necessary because they are a convenience feature and are not primarily medical in nature. All accessories necessary to use a stander and gait trainer are included in the base code for the device.

**APPLICABLE CODES**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>E0637</td>
<td>Combination sit-to-stand frame/table system, any size including pediatric, with seat lift feature, with or without wheels</td>
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<tr>
<td>E0638</td>
<td>Standing frame/table system, one position (e.g., upright, supine or prone stander), any size including pediatric, with or without wheels</td>
</tr>
<tr>
<td>E0641</td>
<td>Standing frame/table system, multi-position (e.g., 3-way stander), any size including pediatric, with or without wheels</td>
</tr>
<tr>
<td>E0642</td>
<td>Standing frame/table system, mobile (dynamic stander), any size including pediatric</td>
</tr>
<tr>
<td>E2230</td>
<td>Manual wheelchair accessory, manual standing system</td>
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<tr>
<td>E2301</td>
<td>Power wheelchair accessory, power standing system</td>
</tr>
<tr>
<td>E8000</td>
<td>Gait trainer, pediatric size, posterior support, includes all accessories and components</td>
</tr>
<tr>
<td>E8001</td>
<td>Gait trainer, pediatric size, upright support, includes all accessories and components</td>
</tr>
<tr>
<td>E8002</td>
<td>Gait trainer, pediatric size, anterior support, includes all accessories and components</td>
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**Coding Clarification**

Refer to CMS HCPCS Manual for wheelchair and wheelchair accessory codes.
DESCRIPTION OF SERVICES

Standing systems are assistive devices that enable people to achieve and maintain an upright posture. Nonambulatory, physically disabled individuals may use standing systems for a variety of health-related reasons, including: increasing their range of motion; maintaining bone density; maintaining muscle strength and cardiovascular endurance; reducing swelling in the lower limbs; decreasing spasticity (muscle overactivity); preventing pressure sores; and improving bowel and bladder function. (ECRI, 2012)

Standing systems can be categorized by types:
- Passive (static) stander: A passive stander remains in one place, sometimes has casters but cannot be self-propelled; most prone/supine standers are this type.
- Mobile (dynamic) stander: User can self-propel a mobile stander if they have upper body strength to push a manual wheelchair. Some standers are also available with powered mobility ;( also known as multi-positioning standers).
- Active stander: An active stander creates reciprocal movement of the arms legs while standing. Most of these are sit to stand type devices. Long leg braces are also a standing device, but they are not used often today. Systems are available that can be changed by the user from sitting support to standing support; other systems require the assistance of a second person to transfer the disabled person from sitting to standing. The range of devices each disabled person can use depends on the extent of disability.

CLINICAL EVIDENCE

A recent systematic review was completed which evaluated effective dosing for pediatric standing programs (Paleg, Smith, & Glickman, 2013). After a thorough review of the available literature the authors concluded that standing a minimum of five days per week is necessary. During each standing session, a minimum of 60 minutes is needed to affect bone density and hip stability. Range of motion improvements in the lower extremities require a minimum of 45 minutes, while spasticity reduction may occur with as little as 30 minutes per session of standing. Limitations of this current review included very minimal pediatric dosing literature, lack of higher levels of evidence from which to extract potential dosing recommendations for any population, and authors’ subjectivity in the choices for search and classification parameters, interpretation of the literature, and for the specific clinical recommendations/author comments. Given these limitations, clearly more research, ranging from higher-level research studies to well-described case reports, is necessary to define important outcomes, describe clinical reasoning, and determine the effect of standing programs on the participation of children.

A randomized controlled trial by Bagley et al. (2005), evaluated the effectiveness of the Oswestry Standing Frame in severely disabled stroke patients. The intervention group (n=71) and control group (n=69) both received usual stroke care, but the intervention group also received at least 14 consecutive days' treatment using the standing frame. At 6 weeks, 12 weeks, and 6 months follow-up, there was no statistically significant difference between the groups in any of the clinical outcome measures or resource savings.

A randomized controlled trial by Caulton et al. (2004) was performed to determine if participation in 50% longer periods of standing would increase vertebral and proximal tibial bone mineral density of 26 non-ambulant children with cerebral palsy. The participants were matched into pairs and children within the pairs were randomly allocated to intervention (a 50% increase in regular standing duration) or control (no increase in regular standing duration). The mean vertebral pre-trabecular bone mineral density in the intervention group demonstrated a 6% mean increase in vertebral bone density. No change was observed in the mean proximal tibial bone density. The investigators concluded that prolonged standing may reduce the risk of vertebral fractures but may not reduce the risk lower limb fractures.

Eng et al. (2001) undertook a study to document the patterns of use of prolonged standing and their perceived effects in subjects with spinal cord injuries (SCI). The subjects were 152 adults with SCIs (103 male, 49 female; mean age=34 years, SD=8, range=18-55) who returned mailed survey questionnaires. This study identified a number of body systems and functions that may need to be investigated if clinical trials of prolonged standing in people with SCI are undertaken.

Ben et al. (2005) conducted an assessor-blinded within-subject randomized controlled trial of a 12-week standing program (tilt-table standing for 30 minutes, 3 times a week for 12 weeks) in 20 patients with lower limb paralysis following spinal cord injury. This standing program had a small effect on ankle mobility and little or no effect on femur bone mineral density.

Jacobs et al. (2003) studied 15 patients with paraplegia who completed physiologic testing of frame-supported passive standing and active functional electrical stimulation assisted standing. The investigators concluded that standing with functional electrical stimulation provided more exercise conditioning than passive standing.
Dunn et al. (1998) conducted a follow-up assessment of 77 paraplegics and 22 quadriplegics who returned their manufacturer’s warranty card for standing devices. Improvements in quality of life were reported by all users and less than 10% reported adverse side effects. Reductions in leg spasticity and a decreased incidence of pressure ulcers were also reported.

A case series by Gudjonsdottir and Stemmons (2002), of 4 children evaluated how 2 types of prone standers affected bone mineral density. During an eight-week standing program, 2 children stood in a conventional stander, and 2 stood in a motorized (dynamic) stander that provided intermittent weight bearing. Measurements of bone mineral density before and after the program revealed increases in bone mineral density in both children who used the dynamic stander and 1 child who used the static stander. The authors indicated that there is potential value in additional research on prone standers.

Frequency and duration of standing were examined in relation to outcomes in a survey of respondents with spinal cord injuries who used standing devices. Respondents (n=99) who stood 30 minutes or more per day had significantly improved quality of life with fewer bed sores and bladder infections and improved bowel regularity compared with those who stood for less time. (Walter et al., 1999)

Manley, et al. (1985) evaluated the vertical wheeler, a device that provides mobility while standing, in a case series of 15 children with cerebral palsy. The wheeler was reported to be safe, easy, and fun to use by children, but the tool used to evaluate patient understanding, ease of use of the device, posture, mobility and behavioral improvement was not described.

In an article by Pin (2007), he stated that physiotherapists commonly use static weight-bearing exercises in children with cerebral palsy. These exercises are believed to stimulate antigravity muscle strength, prevent hip dislocation, improve bone mineral density, improve self-esteem, improve feeding, assist bowel and urinary functions, reduce spasticity, and improve hand function. The effectiveness of these exercises has not been thoroughly investigated. Pin’s systematic review is intended to examine the research evidence of the effectiveness of static weight-bearing exercises in children with cerebral palsy. Ten studies met the inclusion criteria for this review. The review concludes that the evidence supporting the effectiveness of static weight-bearing exercises in children with cerebral palsy, except the findings of increased bone density and temporary reduction in spasticity, remains limited because of an inadequate number of studies undertaken, inadequate rigor of the research designs and the small number of subjects involved. Clinicians should carefully consider all available evidence before making a decision regarding the potential effectiveness of static weight-bearing for the targeted outcomes.

Reports in rehabilitation literature suggest that early standing enhances hip alignment, bone mineralization, urinary function, respiratory functioning, and psychosocial functioning. However, appropriately designed research studies investigating the use of standers have not been conducted and, despite the theoretical foundation regarding both the developmental and preventive benefits of early standing, these presumed benefits have not been studied and demonstrated in available research literature. If quality of life issues are to be considered, they must be clearly defined and investigated in appropriately designed research studies to demonstrate both the psychosocial and physiological benefits for the use of standing systems in the management of individuals with neurological dysfunction.

Professional Societies

**American Academy of Physical Medicine and Rehabilitation (AAPMR)**

The AAPMR supports an updated 2013 position statement by the Rehabilitation Engineering & Assistive Technology Society of North America (RESNA). It is RESNA’s position that wheelchair standing devices are often medically necessary, as they enable certain individuals to:

- Improve functional reach to enable participation in Activities of Daily Living (ADLs) (i.e., grooming, cooking, reaching medication)
- Enhance independence and productivity
- Maintain vital organ capacity
- Reduce the occurrence of urinary tract infections
- Maintain bone mineral density
- Improve circulation
- Improve passive range of motion and reduce risk of contractures
- Reduce abnormal muscle tone and spasticity
- Reduce the occurrence of pressure sores
- Reduce the occurrence of skeletal deformities, and
- Enhance numerous psychosocial and quality of life benefits

Standers are contradicted in patients with:

- Existing contractures
Standing Systems and Gait Trainers

- Skeletal deformities
- Person has not been standing for a significant amount of time
- Existing bone mineral density loss and osteoporosis
- Postural hypotension
- Persons at risk of sacral shearing
- Persons with adaptive or custom seating

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Standing systems may be classified in product categories ION (exerciser, non-measuring), INW (table, mechanical) and IPL (stand-up wheelchair). Devices classified under product codes ION and INW are Class I, 510(k) exempt devices. Although manufacturers may voluntarily submit product information via the 510(k) process, it is not a requirement. All manufacturers are, however, required to submit a "Device Listing" form.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not cover standing systems (also referred to as a standing frame/table system or multi-position system) as these are considered convenience items and are not primarily medical in nature. Refer to the National Coverage Determination (NCD) for Durable Medical Equipment Reference List (280.1). Medicare may cover multi-positional patient support systems (HCPCs Code E0636) when specific criteria are met. See the Local Coverage Determinations (LCDs) for Patient Lifts.

Medicare does not have an NCD for gait trainers. LCDs do not exist at this time. (Accessed August 4, 2016)

REFERENCES


**POLICY HISTORY/REVISION INFORMATION**

<table>
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<tr>
<th>Date</th>
<th>Action/Description</th>
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| 11/01/2016 | • Reformatted and reorganized policy; transferred content to new template<br>• Revised coverage rationale:<br>**Standing Systems**<br>  o Updated coverage criteria for proven/medically necessary services:<br>     ▪ Removed criterion requiring the individual using equipment has the capacity for at least partial independence in one or more of the following activities of daily living in his/her home:<br>       - Eating<br>       - Personal hygiene<br>       - Toileting<br>       - Dressing<br>       - Transfer<br>     ▪ Added criterion requiring a written Plan of Care<br>  o Replaced language indicating "powered standing systems or electric lift mechanisms are unproven and not medically necessary because they are a convenience feature and are not primarily medical in nature" with "powered standing systems, mobile standers, standers attached to a wheelchair, or electric lift mechanisms are unproven and not medically necessary because they are a convenience feature and are not primarily medical in nature"
|            | **Gait Trainers**<br>  o Replaced language indicating "gait trainers are proven and medically necessary for the treatment of non-ambulatory individuals when the individual has the potential for ambulation" with "gait trainers are proven and medically necessary for the treatment of non-ambulatory individuals when the individual has the potential for regular or therapeutic ambulation"
|            | **Accessories for Standing Systems and Gait Trainers**<br>  o Revised language to indicate:<br>     ▪ All accessories necessary to use a stander and gait trainer are included in the base code for the device<br>     ▪ All other accessories added to standing systems and gait trainers are unproven and not medically necessary because they are convenience feature and are not primarily medical in nature<br>  • Updated list of applicable HCPCS codes; removed E0636<br>  • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information<br>  • Archived previous policy version 2015T02100