Pediatric Gait Trainers and Standing Systems (for Tennessee Only)

Policy Number: CS159TN.K
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➲ Instructions for Use

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Related Policy

- Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements (for Tennessee Only)

Application

This Medical Policy applies to Medicaid and CoverKids in the state of Tennessee.

Coverage Rationale

Pediatric Gait Trainers

Gait Trainers for Functional Ambulation are proven and medically necessary when the following criteria are met:
- The individual is 18 years of age or younger; **and**
- The individual has the potential for Functional Ambulation; **and**
- The individual uses the Gait Trainer when documentation shows assistive devices have not been effective

Gait Trainers for therapeutic ambulation are proven and medically necessary for treating non-ambulatory individuals when the following criteria are met:
- The individual is 18 years of age or younger; **and**
- The individual is capable of utilizing and tolerating the equipment safely; **and**
- The individual requires moderate to maximum support for ambulation (i.e., handheld ambulation assist devices are not feasible); **and**
- The individual has an acquired injury (e.g., spinal cord or traumatic brain injury) or a chronic physical limitation that affects the ability to ambulate (e.g., cerebral palsy, neuromuscular disease, or spina bifida); **and**
- The individual has a physician directed written treatment plan (including frequency and duration)

Standing Systems

TennCare Medicaid

Stationary, mobile, and active Standing Systems are proven and medically necessary for treating non-ambulatory individuals 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 of 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;

  and
- The individual is unable to accomplish the above goals with his/her current medical device/equipment or alternate medical treatment; **and**
- The individual has been evaluated in physical therapy with a trial using the standing device and has shown compliance, tolerance and demonstrated potential for clinical benefit, as determined by the evaluator; **and**
- There is a written plan of care

For power Standing Systems, refer to the [TennCare Medicaid, Chapter 1200-13-13-.01 Definitions].

Tennessee CoverKids

For coverage limitations and exclusions, refer to the [CoverKids, Chapter 1200-13-21-.06: Exclusions].

Definitions

Refer to the definitions within the federal, state, or contractual guidelines that supersede the definitions below.

Functional Ambulation: The ability to walk, with or without the aid of appropriate assistive devices (such as prostheses, orthoses, canes, or walkers), safely and sufficiently to carry out mobility-related activities of daily living (Lam et al., 2008).

Gait Trainer: A Gait Trainer (sometimes referred to as a rollator) is a term used to describe certain devices that are used to support a member during ambulation.

Standing System: A standing frame, also known as a standing aid or stander, is specifically designed for wheelchair users. These devices allow the individual to achieve a standing position and then support the person in the standing position.

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 federal, state, or contractual requirements 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 Guidelines may apply.

HCPCS Code	Description
E0637	Combination sit-to-stand frame/table system, any size including pediatric, with seat lift feature, with or without wheels
E0638	Standing frame/table system, one position (e.g., upright, supine or prone stander), any size including pediatric, with or without wheels
E0641	Standing frame/table system, multi-position (e.g., 3-way stander), any size including pediatric, with or without wheels
E0642	Standing frame/table system, mobile (dynamic stander), any size including pediatric
E8000	Gait trainer, pediatric size, posterior support, includes all accessories and components
E8001	Gait trainer, pediatric size, upright support, includes all accessories and components
E8002	Gait trainer, pediatric size, anterior support, includes all accessories and components

Description of Services

Gait Trainers are supportive walking devices that take the weight of the body through a solid or fabric 'seat,' stabilize the trunk, and support the pelvis (Paleg and Livingstone, 2016).

Supported standing devices such as standers or tilt-tables allow the user to attain and maintain a standing or partial-standing position and commonly stabilize hips, knees and ankles through posterior heel, anterior knee and posterior hip supports and/or straps (Paleg and Livingstone, 2015).

Clinical Evidence

Pediatric Gait Trainers

A 2020 Cochrane systematic review assessed the effects of mechanically assisted walking training compared to control for walking, participation, and quality of life in children with cerebral palsy. Mechanically assisted walking training consists of using a treadmill (with or without body weight support and the assistance of one or more therapists), an end-effector system (such as a gait trainer, with or without body weight support, or a robotic training device). The review included 17 studies of randomized controlled trials (RCTs) or Quasi-RCTs (n = 451) in outpatient settings. Three of the studies focused on gait trainer with and without body weight support. The intervention consisted of 2-5 sessions a week for a period of 4-12 weeks with ranges of intensity of 15-40 minutes. The authors concluded mechanically assisted walking with or without body weight support may result in small improvements in walking speed and gross motor function compared to both no walking and same amount of overground walking. Mechanically assisted walking training may be a useful means for children to undertake high-intensity, repetitive, task-specific training. (Gharib et al. (2011) cited below, was included in this systematic review).

Paleg and Livingstone (2015a) conducted a systematic review regarding use of gait trainers at home or school with children who are unable to walk independently or with hand-held walkers. Included studies involved at least one child with a mobility limitation and measured an outcome related to gait trainer use. Seventeen studies involving 182 children were included. Evidence from one small randomized controlled trial suggested a non-significant trend toward increased walking distance while another evidence level II study (concurrent multiple baseline design) reported increased number of steps. Two level III studies (non-randomized) reported statistically significant impact on mobility level with one finding significant impact on bowel function and an association between increased intervention time and bone mineral density. Remaining descriptive level evidence provided support for positive impact on a range of activity outcomes, with some studies reporting impact on affect, motivation and participation with others. The authors concluded that evidence supporting outcomes for children using gait trainers is primarily descriptive and, while mainly positive, is insufficient to draw firm conclusions.

Gharib et al. (2011) conducted a RCT to assess the effects of additional gait trainer assisted walking exercises on walking performance in children with hemiparetic cerebral palsy. Thirty children with spastic hemiparetic cerebral palsy were included in the study. Children were randomly assigned into two equal groups; experimental and control. Participants in both groups received a traditional physical therapy exercise program. Those in the experimental group received additional gait trainer based walking exercises which aimed to improve walking performance. Treatment was provided three times per week for three successive months. Children received baseline and post-treatment assessments to evaluate gait parameters including average step length, walking speed, time on each foot and ambulation index. The ambulation index was 75.53 ±7.36 (11.93 ±2.89 change score) for the experimental group and 66.06 ±5.48 (2.13 ±4.43 change score) for the control group. Time of support for the affected side was 42.4 ±3.37 (7 ±2.20 change score) for the experimental group and 38.06 ±4.63 (3.33 ±6.25 change score) for the control group. Also, there was a significant improvement in step length and walking speed in both groups. The authors concluded that gait trainer walking exercises combined with traditional physical therapy increase the chance of improving gait performance in children with spastic hemiparetic cerebral palsy.

Standing Systems

Freeman et al. (2019) conducted a multi-center RCT assessing the clinical program of home-based, self-managed standing frames in people with progressive multiple sclerosis. The study included 140 participants randomly assigned to either the standing frame group (n = 71) or the usual care group (n = 69). The intervention consisted of two home-based physiotherapy sessions for set-up, six follow-up telephone calls and participants were asked to stand for 30 minutes, three times per week over 20 weeks or longer. Assessments were completed at baseline, 20 weeks, and 36 weeks. The use of the standing frame resulted in a significant increase in amended motor club assessment (AMCA) scores compared with that for usual care alone, with a fully adjusted between-group difference in AMCA scores at 36 weeks of 4·7 points (95% CI 1·9–7·5; p = 0·0014). The authors concluded the standing frame program significantly increased motor function in people with severe progressive multiple sclerosis, although not to the degree that was inferred as clinically consequential.

They assert that the standing frame is one of the first physiotherapy interventions to be effective in this population. The program is suggested as a feasible intervention that could be routinely implemented in clinical practice.

Farrarello et al. (2015) conducted a RCT evaluating standing frames as an adjunct rehabilitation intervention in individuals with severe disability due to stroke. After baseline assessment, 75 participants with severe disability due to stroke, all receiving conventional physical therapy (PT), were randomly assigned to adjunctive 20 (n = 24) or 40 (n = 31) minutes of supported standing practice (SSP) or PT only (n = 20). Motor function, autonomy, and mobility were assessed before and after training, and three months later. Most outcome measures improved from baseline through the end of treatment, and at follow-up, in all groups. The extent of change was comparable across the three groups. The authors concluded that SSP did not provide any sizeable adjunctive benefit, above and beyond PT, in this patient population.

In a systematic review, Paleg and Livingstone (2015b) evaluated the evidence for all outcomes potentially impacted by a supported standing program in adults with chronic neurological conditions. The primary goal was effectiveness, and the secondary goal was to identify evidence-based dosage recommendations for home-based programs. A standing intervention was defined as being positioned above 60° (from horizontal) for at least 10 min for a minimum of five sessions within a 2-week period. Thirty-six articles met the inclusion criteria (studies published in English, peer-reviewed journals, with clear information on standing dosage). The results of the review showed that moderate to high quality evidence supports the positive impact of standing on range of motion (ROM) and activity for adults with neurological conditions. The strongest evidence, resulting from level II moderate or high quality studies, supports impact on ROM for adults with stroke and spinal cord injury. Strong evidence from a high quality randomized study, and other lower quality studies, also support the benefit of supported standing on activity outcomes such as standing symmetry and ability to maintain a stable standing position for the sub-acute and chronic stroke population. Strong evidence also supports the addition of task-specific training to tilt-table standing for improvement in gait, functional activity and muscle strength in the sub-acute stroke population. Evidence for other outcomes is weak or very weak. Dosage data suggests that use of a standing device should occur for 30 min 5 times a week for positive impact on most outcomes such as self-care and standing balance, ROM, cardio-respiratory, strength, spasticity, pain, skin and bladder and bowel function while 60 min 4–6 times a week may be required for positive impact on bone mineral density (BMD) and mental function.

In a systematic review, Glickman et al. (2010) investigated the available evidence underlying supported standing use for individuals of all ages, with a neuromuscular diagnosis, based on the Center for Evidence-Based Medicine (CEBM) Levels of Evidence framework. Of 112 unique studies, 39 met the inclusion criteria, 29 with adult and 10 with pediatric participants. In each group of studies were user and therapist survey responses in addition to results of clinical interventions. The data were moderately strong for the use of supported standing for BMD increase, showed some support for decreasing hypertonicity (including spasticity) and improving ROM, and were inconclusive for other benefits of using supported standers for children and adults with neuromuscular disorders. The addition of whole body vibration (WBV) to supported standing activities appeared a promising trend but empirical data were inconclusive. The survey data from physical therapists (PTs) and participant users attributed numerous improved outcomes to supported standing: ROM, bowel/bladder, psychological, hypertonicity and pressure relief/bedsores. BMD was not a reported benefit according to the user group. The authors recommend empirical mechanistic evidence to guide clinical supported standing programs across practice settings and with various-aged participants, particularly when considering a life-span approach to practice.

In a one-group quasi-experimental study, Gibson et al. (2009) studied whether static weight-bearing in a standing frame affected hamstring length and ease of activities of daily living (ADLs) in non-ambulant children with CP. Five children were recruited (age range 6-9 years, mean age 7 years 2 months, SD 1 year 4 months). Participants stood in a standing frame for 1 hour, 5 days per week, for 6 weeks, followed by 6 weeks of not using a standing frame; each phase was repeated. Popliteal angle measurements were made at baseline and weekly throughout the study period. High compliance with the standing regime was achieved (85% of intended sessions completed). Repeated-measures analysis of variance and t-tests showed hamstrings significantly lengthened during standing phases (mean improvement 18.1 degrees, SD 5.5, $p < 0.01$ for first standing phase; mean improvement 12.1 degrees, SD 7.7, $p = 0.03$ for second standing phase). A trend for hamstrings to shorten during nonstanding phases was observed (mean change -14.0 degrees, SD 4.2, $p = 0.02$ for first nonstanding phase; mean change -7.3 degrees, SD 6.5, $p = 0.20$ for second nonstanding phase). Preliminary evidence that 6 weeks of standing frame use leads to significant improvements in hamstring length in non-ambulant children with CP, and may increase ease of performance of ADLs was found.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Gait trainers are classified as Class I devices in product category INN and are exempt from 510(k) marketing requirements.

Standing systems may be classified in product categories ION (exerciser, non-measuring), INW (table, mechanical) and IPL (stand-up wheelchair). Devices in product categories ION and INW are Class I devices and are exempt from 510(k) marketing requirements. For additional information on product category IPL, refer to the following website: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed January 18, 2024)

References

Chiu HC, Ada L, Bania TA. Mechanically assisted walking training for walking, participation, and quality of life in children with cerebral palsy. Cochrane Database Syst Rev. 2020 Nov 18;11(11):CD013114.

Ferrarello F, Deluca G, Pizzi A, et al. Passive standing as an adjunct rehabilitation intervention after stroke: a randomized controlled trial. Arch Physiother. 2015 Jul 8;5:2.

Freeman J, Hendrie W, Jarrett L, et al. Assessment of a home-based standing frame programme in people with progressive multiple sclerosis (SUMS): a pragmatic, multi-centre, randomised, controlled trial and cost-effectiveness analysis. Lancet Neurol. 2019 Aug;18(8):736-747.

Gharib NM, El-Maksoud GM, Rezk-Allah SS. Efficacy of gait trainer as an adjunct to traditional physical therapy on walking performance in hemiparetic cerebral palsied children: a randomized controlled trial. Clin Rehabil. 2011 Oct;25(10):924-34.

Gibson SK, Sprod JA, Maher CA. The use of standing frames for contracture management for nonmobile children with cerebral palsy. Int J Rehabil Res. 2009 Dec;32(4):316-23.

Glickman LB, Geigle PR, Paleg GS. A systematic review of supported standing programs. J Pediatr Rehabil Med. 2010;3(3):197-213.

Lam T, Noonan VK, Eng JJ; SCIRE Research Team. A systematic review of functional ambulation outcome measures in spinal cord injury. Spinal Cord. 2008;46(4):246-254.

Marvin, K. Functional Ambulation Categories (FAC). Stroke Engine. https://strokengine.ca/en/assessments/fac/. Accessed January 18, 2024.

Paleg G, Livingstone R. Evidence-informed clinical perspectives on selecting gait trainer features for children with cerebral palsy. Int J Ther Rehabil. 2016 Aug;23(8).

Paleg G, Livingstone R. Outcomes of gait trainer use in home and school settings for children with motor impairments: a systematic review. Clin Rehabil. 2015a Nov;29(11):1077-91.

Paleg G, Livingstone R. Systematic review and clinical recommendations for dosage of supported home-based standing programs for adults with stroke, spinal cord injury and other neurological conditions. BMC Musculoskelet Disord. 2015b Nov 17;16:358.

Paleg GS, Smith BA, Glickman LB. Systematic review and evidence-based clinical recommendations for dosing of pediatric supported standing programs. Pediatr Phys Ther. 2013 Fall;25(3):232-47.

TennCare Medicaid, Chapter 1200-13-13-.01 Definitions. https://publications.tnsosfiles.com/rules/1200/1200-13/1200-13-13.20220517.pdf. Accessed February 20, 2024.

Tennessee CoverKids, Chapter 1200-13-21-06 Exclusions. https://publications.tnsosfiles.com/rules/1200/1200-13/1200-13-21.20210411.pdf. Accessed February 20, 2024.

Policy History/Revision Information

Date	Summary of Changes
07/01/2024	**Supporting Information** • Updated *Clinical Evidence* section to reflect the most current information • Archived previous policy version CS159TN.J

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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