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Pediatric Gait Trainers and ^[MS1] Standing Systems (for Louisiana Only)

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[➔ Instructions for Use](#)

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

Standing Frames

State Specific Criteria

The criteria to be considered for a ~~Standing Frame~~ Standing Frame include, but are not limited to the following. The beneficiary must:

- Be at a high risk for lower extremity contractures that cannot be improved with other interventions (stretching, medications, serial casting, splinting, and modalities);
- Be able to tolerate a standing or upright position on the foot and ankle;
- Be non-ambulatory or is unable to stand due to conditions such as, but not limited to, neuromuscular or congenital disorders, including acquired skeletal abnormalities;
- Have tried more cost effective alternatives and still requires a stander;
- Not have a walker or gait trainer and it is not anticipated they will require one;
- Have demonstrated improved mobility, function and physiologic symptoms or has maintained status with the use of the requested stander and is able to follow a home standing program with the use of the requested stander; and
- Use the equipment for personal use only (the equipment will not be used at school)

Non-coverage of the standing frame includes, but is not limited to the following:

- The beneficiary has complete paralysis of the lower extremities;
- When there is no expected improvement in mobility or maintenance of function;

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- The anticipated functional benefits of standing can be achieved through less-costly alternatives;
- Mobile (dynamic) stander – either self-propelled standers or standers with powered mobility;
- Active stander – allows movement of the arms and legs in a standing position;
- In beneficiaries with syncope, orthostatic hypotension, postural tachycardia syndrome, osteogenesis imperfecta, osteoporosis and other brittle bone diseases, and hip subluxation;
- In beneficiary’s that have hip and knee flexion contractures of more than 20 degrees; and
- **A stander will not be purchased** for [IG2] a beneficiary who has a gait trainer or ambulatory device.

Pediatric Gait Trainers

Non State-Specific Criteria

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)

Definitions

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 Frame:** A standing frame (also known as a stander, standing aid, standing device) is an assistive technology that can be used by a person who relies on a wheelchair for mobility. A standing frame provides alternative positioning to sitting in a wheelchair by supporting the person in the standing position. (Louisiana Department of Health, Durable Medical Equipment Provider Manual)~~

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

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HCPCS Code	Description
*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

Codes labeled with an asterisk (*) are not on the State of Louisiana Medicaid Fee Schedule and therefore may not be covered by the State of Louisiana Medicaid Program.

Description of Services

A gait trainer unweights an individual using a rigid or flexible seat, stabilizes or supports the trunk and pelvis with lateral and posterior components, and assists with ambulation are supportive walking devices that take the weight of the body through a solid or fabric 'seat', stabilize the trunk, and support the pelvis **ambulation** (Paley and Livingstone, 2016**2015a**).

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 (Paley and Livingstone, 2015).

A supported standing system or device secures an individual in a standing position. The device also facilitates movement from a horizontal position to standing position (e.g. a tilt table), or from a sitting position to a standing position (e.g. a standing frame). The device may be mechanical (non-powered) or electric (powered). A standing system is either a separate device, which requires an individual to transfer into it (e.g., a tilt table or standing frame), or integrated the individual's mobility device (e.g. a power standing system on a power wheelchair.) Static supported standing devices are not intended to move while the individual is in the supported standing position (e.g. tilt table or standing frame). Dynamic supported standing devices may be moved by the individual or caregiver in the supported standing position using non-powered (e.g., standing manual wheelchair) or powered (e.g., power wheelchair with a standing system) means (Masselink, et al. 2024).

Clinical Evidence

Pediatric Gait Trainers

Qian et al. (2023) conducted a systematic review and network meta-analysis (NMA) to evaluate the relative effectiveness of gait training interventions for individuals with cerebral palsy. The systematic review included 20 randomized controlled trials (RCTs) and a total of 516 individuals. Age ranged from 6 to 25 years. Body weight supported treadmill training (BWSTT), robot-assisted gait training (RAGT), treadmill training (TT), external cues treadmill training (ECTT), over ground gait training (OGT), and conventional physical therapy (CON) were compared. CON included treatments like static stretching of lower limb muscles and resistance training, but did not include any form of over ground gait training. The results of the NMA revealed that both ECTT and BWSTT showed better gait velocity than OGT. BWSTT showed better gait velocity than RAGT, TT, and CON. Surface under the cumulative ranking curve (SUCRA) indicated BWSTT optimally improved the gait velocity. Assessment of Gross Motor Function Measures (GMFM) showed no statistical difference between each comparison for standing (GMFM-D). However, RAGT was significantly more effective than CON for walking, running and jumping (GMFM-E). SUCRA results also indicated RAGT optimally improved GMFM-D/E. The authors concluded that this study of individuals with cerebral palsy suggested BWSTT was optimal for increasing gait velocity. However, RAGT was optimal for optimizing GMFM. Limitations of the study include the small number of GMFM studies, lack of description between RAGT and ECTT, and some studies did not define CON. Additionally, due to missing

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information from some studies, total duration of gait training, duration and frequency of sessions, and intensity was not considered. RCTs with larger sample sizes, multiple centers, and higher quality were recommended to validate the conclusions of the systemic review.

A 2020 Cochrane systematic review **by Chiu et al. (2020)** 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 **use of a** 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 RCT** 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 **(BMD)**. 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 an 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 also 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. (This study is included in the systematic review by Qian et al. 2023 and Chiu et al., 2020.)**

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)

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Policy History/Revision Information

Date	Summary of Changes
<u>TBD</u>	<p><u>Definitions</u></p> <ul style="list-style-type: none"> <u>Removed definition of:</u> <ul style="list-style-type: none"> <u>Gait Trainer</u> <u>Standing System</u> <p><u>Applicable Codes</u></p> <ul style="list-style-type: none"> <u>Added notation to indicate HCPCS code E0642 is not on the State of Louisiana Medicaid Fee Schedule and therefore may not be covered by the State of Louisiana Medicaid Program</u> <p><u>Supporting Information</u></p> <ul style="list-style-type: none"> <u>Updated <i>Description of Services, Clinical Evidence, and References</i> sections to reflect the most current information</u> <u>Archived previous policy version CS159LA.C</u>

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

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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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