Pediatric Gait Trainers, Standing Systems, and Walkers

Policy Number: DME 041.1 T2
Effective Date: May 1, 2021

Instructions for Use

Table of Contents Page

Related Policy

- Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements

Coverage Rationale

See Benefit Considerations

Indications for Coverage

Walkers

Walkers are proven and Medically Necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2021, Apr. 2021 Release, Medicare: Durable Medical Equipment, Walkers.

Click here to view the InterQual® criteria.

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 pediatric gait trainer when documentation shows assistive devices have not been effective.

Gait Trainers for therapeutic ambulation are proven and Medically Necessary for treating of non-ambulatory individuals when the following criteria are met:

- The individual is 18 years of age or younger; and
- The patient 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

Stationary, mobile and active standing systems are proven and Medically Necessary for treating 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; and/or
  - Hip Dislocation: Where hip subluxation/dislocation is worsening and alternate treatments have not been successful; and
- The patient 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.

Powered standing systems, standers attached to a wheelchair, or electric lift mechanisms are not Medically Necessary because they are a convenience feature.

Definitions

The following definitions may not apply to all plans. Refer to the member specific benefit plan document for applicable 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.

Gait Trainers: A gait trainer (or sometimes referred to as a rollator) is a term used to describe certain devices that are used to support a member during ambulation. Refer to the Applicable Codes section for coding instruction.

Medically Necessary: Health Care Services that are all of the following as determined by us or our designee.

- In accordance with Generally Accepted Standards of Medical Practice.
- Clinically appropriate, in terms of type, frequency, extent, service site and duration, and considered effective for your Sickness, Injury, Mental Illness, substance-related and addictive disorders, disease or its symptoms.
- Not mainly for your convenience or that of your doctor or other health care provider.
- Not more costly than an alternative drug, service(s), service site or supply that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your Sickness, Injury, disease or symptoms.

Reasonable Useful Lifetime: RUL is the expected minimum lifespan for the item. It starts on the initial date of service and runs for the defined length of time. The default RUL for durable medical equipment is set at 5 years. RUL is also applied to other non-DME items such as orthoses and prostheses. RUL is not applied to supply items.

Standing Systems: 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.

Prior Authorization Requirements

Prior authorization is required in all sites of service for:

- The purchase of any DME item that is greater than $500.00.
- All custom molded or custom made (fabricated) items; this includes custom molded/custom made or custom fabricated orthotics and custom molded helmets.
- Any DME being rented, repaired and/or replaced; this includes coverage for the repair or replacement of custom molded/custom made or custom fabricated and custom molded helmets for children when growth or change in the member's medical condition make replacement Medically Necessary.

Note: If an authorization is not required, referral guidelines apply in order for a member to receive in-network coverage. A prescription form or provider's medical necessity form may be accepted as a referral for Durable Medical Equipment.

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 may apply.

Oxford Health Plans has adopted the requirements and intent of the National Correct Coding Initiative. The Centers for Medicare & Medicaid Services (CMS) has contracted with Palmetto to manage Pricing, Data and Coding (PDAC) for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). This notice is to confirm Oxford Health Plans has established the PDAC as a source for correct coding and coding clarification.

HCPCS Code	Description
A4636	Replacement, handgrip, cane, crutch, or walker, each
A4637	Replacement, tip, cane, crutch, walker, each
E0130	Walker, rigid (pickup), adjustable or fixed height
E0135	Walker, folding (pickup), adjustable or fixed height
E0140	Walker, with trunk support, adjustable or fixed height, any type
E0141	Walker, rigid, wheeled, adjustable or fixed height
E0143	Walker, folding, wheeled, adjustable or fixed height
E0144	Walker, enclosed, 4 sided framed, rigid or folding, wheeled with posterior seat
E0147	Walker, heavy duty, multiple braking system, variable wheel resistance
E0148	Walker, heavy-duty, without wheels, rigid or folding, any type, each
E0149	Walker, heavy-duty, wheeled, rigid or folding, any type
E0154	Platform attachment, walker, each
E0155	Wheel attachment, rigid pick-up walker, per pair
E0156	Seat attachment, walker
E0157	Crutch attachment, walker, each
E0158	Leg extensions for walker, per set of four
E0159	Brake attachment for wheeled walker, replacement, each
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

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

Description of Services

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)

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)

Benefit Considerations

Convenience features are excluded from coverage. Refer to the Administrative Policy titled Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements.

Clinical Evidence

Standing Systems

In a systematic review, Paleg and Livingstone (2015a) 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.

Gait Trainers

Paleg and Livingstone (2015b) 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. Articles were appraised using American Academy of Cerebral Palsy and Developmental Medicine criteria for group and single-subject designs and quality ratings completed for studies rated levels I-III. The PRISMA statement was followed with inclusion criteria set a priority. Seventeen studies involving 182 children were included. Evidence from one small randomized controlled trial suggests a non-significant trend toward increased walking distance while the other evidence level II study (concurrent multiple baseline design) reports increased number of steps. Two level III studies (non-randomized two-group studies) report 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 provides 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.

In a systematic review, Swinnen et al. (2014) evaluated whether balance was determined as an outcome measurement of gait trainers in stroke patients. Nine studies were included (7 true experimental and 2 pre-experimental studies; methodological quality score, 56%-81%). In total, 229 subacute or chronic stroke patients (70.5% male) were involved in RAGT (3 to 5 times per week, 3 to 10 weeks, 12 to 25 sessions). In 5 studies, the gait trainer was used; in 2, the Lokomat was used; in 1 study, a single-joint wearable knee orthosis was used; and in 1 study, the AutoAmbulator was used. Eight studies compared RAGT with other gait rehabilitation methods. Significant improvements (no to large effect sizes, Cohen's d = 0.01 to 3.01) in balance scores measured with the Berg Balance Scale, the Tinetti test, postural sway tests, and the Timed Up and Go test were found after RAGT. No significant differences in balance between the intervention and control groups were reported. The authors concluded that RAGT can lead to improvements in balance in stroke patients; however, it is not clear whether the improvements are greater compared with those associated with other gait rehabilitation methods. Additional research (e.g., randomized controlled trials with larger, specific populations) is necessary to draw stronger conclusions.

Gharib et al. (2011) conducted a randomized controlled trial to assess the effects of additional gait trainer assisted walking exercises on walking performance in children with hemiparetic cerebral palsy. Thirty spastic hemiparetic cerebral palsied children of both sexes (10-13 years - 19 girls and 11 boys) were included in the study. Children were randomly assigned into two equal groups; experimental and control groups. 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 in the experimental group showed a significant improvement as compared with those in the control group. 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 (t = 3.99 and P = 0.0001). 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 (t = 2.92 and P = 0.007). 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.

Professional society guidelines for use of standing systems or gait trainers were not identified.

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.

Standing systems may be classified in product categories ION (exerciser, non-measuring), INW (table, mechanical) and IPL (stand-up wheelchair). These devices are classified as Class I, 510(k). Refer to the following for additional information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed March 9, 2020)

Although manufacturers may voluntarily submit product information via the 510(k) process, it is not a requirement.

Centers For Medicare And Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) for standing systems (stationary, mobile and active). However, Medicare does reference "standing tables" as not covered in the NCD for Durable Medical Equipment Reference List (280.1). Local Coverage Determinations (LCDs) do not exist at this time.

Medicare does not have an NCD for gait trainers. LCDs do not exist at this time.
(Accessed March 9, 2020)

References

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Coverage Determination Guidelines Committee. [*CDG.038.001*]

Centers for Medicare and Medicaid Services (CMS). Medicare National Coverage Determinations Manual (Pub. 100-3), Chapter 1, Part 4 (Sections 200 – 310.1), § 280.

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National Coverage Determination (NCD) for Durable Medical Equipment. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?&NCDId=190&ncdver=1&NCDSect=280.1&bc=BEAAAAAAAQAAAA==&.

Noridian Healthcare Solutions:

- https://med.noridianmedicare.com/web/jddme/article-detail/-/view/2230703/reasonable-useful-lifetime-and-duplicate-items-billing-reminder
- https://med.noridianmedicare.com/documents/2230703/7218263/Walkers+LCD+and+PA/5c4c220b-ed8c-47fe-ad48-b30b15de5f0c

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Swinnen E, Beckwée D, Meeusen R, et al. Does robot-assisted gait rehabilitation improve balance in stroke patients? A systematic review. Top Stroke Rehabil. 2014 Mar-Apr;21(2):87-100.

Policy History/Revision Information

Date	Summary of Changes
05/01/2021	• New Clinical Policy

Instructions for Use

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

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical Policies 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.