

Subject: Pediatric Gait Trainers
Guideline #: CG-DME-36
Status: Reviewed

Publish Date: 07/07/2021
Last Review Date: 05/13/2021

Description

This document addresses the indications for a pediatric gait trainer, a device similar to a walker that is intended to provide balance stability and postural control in children who require moderate to maximum support for walking.

Clinical Indications

Medically Necessary:

A pediatric gait trainer with trunk support is considered **medically necessary** for an individual who meets **all** of the following criteria:

- A. Is 18 years of age or younger; **and**
- B. Has a documented acquired injury (for example, spinal cord or traumatic brain injury) **or** a documented chronic physical limitation that affects the ability to ambulate (for example, cerebral palsy, neuromuscular disease, or spina bifida); **and**
- C. Requires moderate to maximum support for ambulation; **and**
- D. Demonstrates the ability to ambulate with the device.

Not Medically Necessary:

A pediatric gait trainer with trunk support is considered **not medically necessary** when the criteria are not met.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

HCPCS

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

ICD-10 Diagnosis

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

All diagnoses

When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met.

Discussion/General Information

A pediatric gait trainer is a medically-related mobility device similar to a standard walker. Pediatric gait trainers are proposed to improve musculoskeletal strength and promote balance stability and postural control for children who require moderate to maximum support for walking. Various movement disorders may affect balance and result in the inability to walk, necessitating the use of a gait trainer. Motor limitations may occur after an event to the brain or spinal column (prior to or after birth), resulting in conditions such as cerebral palsy, spina bifida, or other developmental disabilities. Walking impairment may also occur as a result of an acquired injury, such as a traumatic brain injury or spinal cord injury.

Peredo and colleagues (2010) surveyed caregivers of children and adolescents (n=108) with motor disabilities to investigate the type and reasons for use of specific medical equipment. The most common diagnoses for children using medical equipment were cerebral palsy (45%), intellectual disability (19%), genetic abnormality (13%), spina bifida (13%) and neuromuscular diseases (7%). The average child's age was 7.1 years ($\pm$ 5.0 years). Gait trainers were reported as used by 10 of 52 children (19%) with cerebral palsy and 1 of 14 children (7%) with a genetic abnormality, with daily use by 5 of 11 children (46%).

Paleg and Livingstone (2015) performed a systematic review of the literature measuring outcomes related to gait trainer use. The authors used the 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. A total of 17 trials involving 182 children were reviewed. Evidence from 1 small randomized controlled trial suggested a non-significant trend toward increased walking distance while another level II study reported increased number of steps with use of a gait trainer. Two level III studies (non-randomized two-group studies) reported a statistically significant impact on mobility level or bowel function and an association between increased intervention time and bone mineral density. Other publications described a positive impact on gait trainer use on a range of activity outcomes, with some studies reporting an impact on user "affect, motivation and participation with others." The authors concluded that the evidence in the peer-reviewed literature supporting improved outcomes for children using gait trainers was "primarily descriptive" and "insufficient to draw firm conclusions."

Pediatric gait trainers are available from various medical equipment manufacturers in multiple sizes and models. One such device is the Rifton Pacer Gait Trainer (Community Products, LLC dba Rifton Equipment, Rifton, NY), a type of walker proposed for use by infants 9 months of age and older. The basic unit is described as a lightweight aluminum frame with a stable U-shaped base with four large-diameter caster wheels. The casters have separate control features for brake, swivel lock, variable drag, and one-way ratchet control, to use in any combination to control movement. The frame with prompts can be used in an anterior or posterior position. The frame telescopes for height adjustment to accommodate growth and is available in three sizes from 44.5 cm to 119.5 cm (user elbow heights).

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Pediatric Gait Trainers

Other models of pediatric gait trainers include, but are not limited to:

- the Walkabout Gait Trainer (Meylan-Smith A/S, Denmark), a posterior support, weight-relieving gait trainer, which gives dynamic support throughout the rise and fall of the pelvis during ambulation and is hands-free and open in the front;
- the KidWalk® Gait Mobility System (Prime Engineering, Fresno, CA), an open front, hands free gait trainer with a swivel seat and support systems that track the child's up and down and side-to-side motion to assist in achieving a natural walking pattern; and,
- the Therapeutic Ambulatory Orthotic System (TAOS) (Sky Medical, Inc., Sunrise, FL), an orthotic and walker-based device whose components work together to provide a child with cerebral palsy an “upright, hands-free environment.”

The U.S. Food and Drug Administration (FDA, 2014) categorizes gait trainers as Class I “device chair, adjustable, mechanical” devices under the product code: INN and exempt from premarket approval (PMA) notification and the 510(k) clearance process.

Definitions

Cerebral palsy (CP): A group of disorders that can involve brain and nervous system functions, such as movement, learning, hearing, seeing, and thinking, the result of an event to the immature, developing brain, most often before birth. Signs and symptoms appear during infancy or preschool years. In general, cerebral palsy causes impaired movement associated with exaggerated reflexes, floppiness or rigidity of the limbs and trunk, abnormal posture, involuntary movements, unsteadiness of walking, or some combination of these. Some individuals may have difficulty with swallowing, eye muscle imbalance, and/or reduced range of motion at various joints of their bodies due to muscle stiffness. Some individuals are able to walk while others aren't able to walk. Others show normal to near normal intellectual function, while others may have intellectual disabilities due to underlying developmental brain abnormalities. Epilepsy, blindness or deafness also may be present.

Gross Motor Function Classification System (GMFCS): A five level classification system (Levels I-V) for cerebral palsy based on self-initiated movement with particular emphasis on sitting (truncal control) and walking. Distinctions between levels of motor function are based on functional limitations, the need for assistive technology, including mobility devices (such as walkers, crutches, and canes) and wheeled mobility, and to much lesser extent quality of movement. Children in Level II do not require assistive mobility devices after age 4, while children in Level III will need assistive mobility devices to walk (Palisano, 1997).

Spina bifida: Part of a group of birth defects called neural tube defects that include spinal cord malformation presenting in varying degrees of severity and impairment. Functional deficits include, but are not limited to, lower limb paralysis, sensory loss, and cognitive dysfunction.

Traumatic brain injury (TBI): Occurs when an external mechanical force causes brain dysfunction, often associated with a diminished or altered state of consciousness, and potentially leads to permanent or temporary impairment of cognitive, physical, and psychosocial functions. TBI usually results from a violent blow or jolt to the head or body, but can also be caused by an object penetrating the skull.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

References

Peer Reviewed Publications:

1. Henderson S, Skelton H, Rosenbaum P. Assistive devices for children with functional impairments: impact on child and caregiver function. *Dev Med Child Neurol*. 2008; 50(2):89-98.
2. Johnson KL, Dudgeon B, Kuehn C, Walker W. Assistive technology use among adolescents and young adults with spina bifida. *Am J Public Health*. 2007; 97(2):330-336.
3. Ostensjo S, Carlberg EB, Vollestad NK. The use and impact of assistive devices and other environmental modifications on everyday activities and care in young children with cerebral palsy. *Disabil Rehabil*. 2005; 27(14):849-861.
4. Paleg G, Livingstone R. Outcomes of gait trainer use in home and school settings for children with motor impairments: a systematic review. *Clin Rehabil*. 2015; 29(11):1077-1091.
5. Peredo DE, Davis BE, Norvell DC, Kelly PC. Medical equipment use in children with disabilities: a descriptive survey. *J Pediatr Rehabil Med*. 2010; 3(4):259-267.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Michaud LJ. American Academy of Pediatrics Committee on Children With Disabilities. Prescribing therapy services for children with motor disabilities. *Pediatrics*. 2004; 113(6):1836-1838.
2. Palisano R, Rosenbaum P, Walter S, et al. Development and reliability of a system to classify gross motor function in children with cerebral palsy. *Dev Med Child Neurol*. 1997; 39(4):214-223.

Websites for Additional Information

1. American Academy of Physical Medicine and Rehabilitation (AAPMR). Available at: <http://www.aapmr.org/Pages/default.aspx>. Accessed on March 23, 2021.
2. U.S. National Library of Medicine. National Institutes of Health. MedlinePlus. Cerebral palsy. Updated March 30, 2020. Available at: <http://www.nlm.nih.gov/medlineplus/cerebralpalsy.html>. Accessed on March 23, 2021.

Index

KidWalk Gait Mobility System
 Rifton Pacer Gait Trainer
 Therapeutic Ambulatory Orthotic System (TAOS)
 Walkabout Gait Trainer

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
--------	------	--------

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Pediatric Gait Trainers

Reviewed	05/13/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Websites section. Reformatted Coding section.
Reviewed	05/14/2020	MPTAC review. Updated Discussion and Websites sections.
Reviewed	06/06/2019	MPTAC review. Updated Websites section.
Reviewed	07/26/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Discussion/General Information, Websites for Additional Information, and Index sections.
Revised	08/03/2017	MPTAC review. Updated formatting in Clinical Indications section. Removed abbreviations from Clinical Indications. Updated Websites for Additional Information section.
Reviewed	08/04/2016	MPTAC review. Updated References and Websites for Additional Information sections. Removed ICD-9 codes from Coding section.
Revised	08/06/2015	MPTAC review. Removed “independently” from the medically necessary statement, criteria 2. and 4. Minor clarification to the not medically necessary statement. Updated Discussion and References sections.
New	08/14/2014	MPTAC review. Initial document development.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue’s standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue’s Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.