



# Guidelines for Medical Necessity Determination for Gait Trainers

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These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information that MassHealth needs to determine medical necessity for gait trainers. A gait trainer is a mechanical device that assists a person in attaining and maintaining an upright position during ambulation. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR [409.000](#) and [450.000](#) and [Subchapter 6 of the Durable Medical Equipment Manual](#) and the [MassHealth DME and Oxygen Payment and Coverage Guidelines Tool](#) for information about coverage, limitations, service conditions, and other prior-authorization (PA) requirements. Providers serving members enrolled in a MassHealth-contracted managed care organization (MCO) or a MassHealth-contracted integrated care organization (ICO) should refer to the MCO's or ICO's medical policies for covered services. These Guidelines describe documentation requirements for purchase of a gait trainer that has been successfully used by a member in an inpatient, outpatient, or school setting.

MassHealth reviews requests for PA on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

## SECTION I. GENERAL INFORMATION

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Gait trainers are durable medical equipment (DME) designed to support a child or adult with lower-extremity and trunk weakness in an upright (or standing) position to allow independent, reciprocal movement of lower extremities (i.e., to allow walking). Gait trainers may provide medical and functional benefits to otherwise chair-bound members. These devices are used to support regular or therapeutic walking or as a walker where other options such as a standard walker have not been effective in achieving ambulation or therapeutic ambulation in a member who is nonambulatory. All gait trainers require Prior Authorization (PA) from MassHealth. MassHealth determines medical necessity on an individual, case-by-case basis, in accordance with 130 CMR 450.204 and 409.000.

Gait trainers may be used by members independently or under the supervision of a caretaker. The member or the caretaker must be trained by a physical therapist (PT) or occupational therapist (OT) and must have written clearance that the member is capable of independently using the gait trainer, or, in the case of a caretaker, that he or she has been trained to monitor for safe, appropriate use of the gait trainer.

## SECTION II. CLINICAL GUIDELINES

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### A. CLINICAL COVERAGE

MassHealth bases its determination of medical necessity for gait trainers on clinical data including, but not limited to, indicators that would affect the relative risks and benefits of the equipment. These criteria include, but are not limited to, the following:

1. The member is able to stand upright in the device and demonstrates adequate head control, lower-extremity and trunk strength (3/5, fair) to be supported in the gait trainer for functional ambulation.
2. The member is not able to ambulate independently due to conditions such as, but not limited to, neuromuscular or congenital disorders, including acquired skeletal abnormalities.
3. The member
  - (a) does not have lower-extremity contractures that would preclude purposeful functional ambulation, and
  - (b) has adequate trunk and lower extremity range of motion (ROM) to support functional mobility
4. The alignment of the member's lower extremity is such that the foot and ankle can tolerate a standing or upright position as well as independent reciprocal movement.
5. The member does not have complete paralysis of the hips and legs.
6. The member has shown clinically meaningful improvement in purposeful mobility, ambulation, function, or physiologic symptoms, or maintained status with the use of the selected gait trainer during a one-month trial period (e.g., used in an inpatient, school or outpatient setting) as measured by a tool that assesses functional ambulation capacity and the member is able to follow a home therapy program incorporating the use of the gait trainer.
7. There is a written home therapy plan (a plan for treatment in the home rather than an institutional setting) developed with emphasis on skill carryover, and goals that target the member's functional use of the requested gait trainer in the home, and there is a caretaker who can appropriately supervise use of the gait trainer.
8. The member is able to perform functional mobility and participate in Instrumental Activities of Daily Living (IADL) and Activities of Daily Living (ADL) using the requested gait trainer.
9. If the request is for replacement of an existing gait trainer, there is sufficient clinical documentation to support that the member has maintained functional ambulation with the use of the gait trainer and alternatives have been trialed and ruled out.

## **B. NONCOVERAGE**

MassHealth does not consider gait trainers to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following.

1. There is no expected improvement in mobility or maintenance of function.
2. The anticipated functional benefits of the gait trainer can be achieved through less-costly alternatives.
3. The member currently has equipment to accomplish the same purpose.
4. The equipment is nonmedical, such as a glider.
5. The base code for gait trainers includes all necessary accessories. Other accessories primarily for convenience are not medically necessary.

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## SECTION III. SUBMITTING CLINICAL DOCUMENTATION

Requests for PA for gait trainers must be submitted by a MassHealth provider of DME and must be accompanied by clinical documentation by a licensed physician, nurse practitioner, physician's assistant, or physical or occupational therapist who actively cares for members with disabilities. Documentation must support the medical necessity for this equipment. All requests for PA must be submitted to MassHealth by the provider of DME in accordance with 130 CMR 409.418.

A. Documentation of medical necessity must include all of the following:

1. A prescription and letter of medical necessity that meet the criteria described in 130 CMR 409.416(A). The prescription and letter of medical necessity must be signed by a licensed physician, nurse practitioner, or physician's assistant that actively cares for members with disabilities. The date of the prescription must be in accordance with 130 CMR 409.418(B). MassHealth accepts written prescriptions and letters of medical necessity in the formats described under 130 CMR 409.416(B).
2. An assessment of the member's current functional mobility, including, but not limited to, diagnosis, age, ROM, strength, muscle tone, functional status, cognitive status, sensation, gait pattern, and balance. Such assessment must be conducted by a physical therapist (PT) or occupational therapist (OT), and must include evidence that the recommended equipment can be accommodated and safely used in the member's home.
3. Results of trial period for all equipment and in each setting documentation of similar equipment that the member has tried but was deemed unsuccessful in leading to clinically meaningful improvement or maintenance of current motor skills or the member was unable to follow a home program including which gait trainers were considered and why they were ruled out as well as which gait trainers were tried and why they were unsuccessful by the PT or OT who conducted the assessment.
4. Documentation that the member has shown improvement in purposeful mobility, ambulation, function, or physiologic symptoms, or maintained status with the use of the selected gait trainer (e.g., as used in an inpatient, school or outpatient setting).
5. Documentation that demonstrates that the member can safely use the device and does not have postural and extremity deformities/contractures or significant strength deficits that would inhibit purposeful, functional, independent gait ability.
6. Documentation that the member does not have existing bone mineral density loss and osteoporosis, postural hypotension, at risk of sacral shearing, and adaptive or custom seating.
7. Documentation from the PT or OT that the member is capable of independently using the gait trainer and that the member's caretaker has been trained to monitor safe and appropriate use of the gait trainer.
8. The most recent comprehensive history and physical exam by a licensed physician, nurse practitioner, or physician's assistant, including summary of medical condition, age at diagnosis, prognosis, and co-morbid conditions.
9. A written home therapy plan outlining the planned use of the requested gait trainer and documentation supporting that the member is able to follow the home therapy program incorporating the use of the gait trainer.

10. Documentation that the member does not otherwise have sufficient access to equipment in an alternative setting (e.g., other available gait training at outpatient facilities).
  11. Demonstrates functional goals with the use of the requested gait trainer including, but not limited to restoring, establishing or maintaining ambulation, improve mobility, and the ability to ambulate safely and efficiently in as physiologic a manner possible. A video of the member demonstrating purposeful, functional use of the requested gait trainer may be required to determine medical necessity.
- B. Clinical documentation and prior authorization requests for gait trainers must be submitted by a MassHealth provider of DME services. Use the MassHealth Prescription and Medical Necessity Review Form for DME <http://www.mass.gov/eohhs/gov/departments/masshealth/masshealth-provider-forms.html>. Providers are strongly encouraged to submit PA requests and all information pertinent to the request electronically using the [Provider Online Service Center \(POSC\)](#) or by completing a MassHealth [Prior Authorization Request](#) form and attaching the documentation. Questions about POSC access should be directed to MassHealth Customer Service at 1-800-841-2900.

## SELECT REFERENCES

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These Guidelines are based on review of the medical literature and current practice in gait trainers. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products or services. Some language used in this communication may be unfamiliar to other readers; in this case, contact your health-care provider for guidance or explanation.

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## ADDENDUM:

### *Code      Definition*

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.