



LECKEY MyWay+ Gait Trainer

Sample Letter of Medical Necessity



Introduction

(Describe your relationship with the child, their disability, and the product requested.)

As _____'s therapist, I am requesting insurance funding for a Leckey MyWay+ gait trainer. This DME device has been prescribed by ____'s physician and is a medical necessity that would not be used in the absence of disability, illness, or injury. The MyWay+ is unique in providing enhanced wraparound trunk support which connects with a versatile, maneuverable gait trainer. This additional stability optimizes the stepping pattern by improving motor coordination and control and is essential to learning the sequence of upright movements required for independent walking. The upright peer-to-peer position allows for increased emotional well-being and cognitive development making MyWay+ a device to enhance both neurological and musculoskeletal development.

What follows is a breakdown of _____'s clinical needs and the safety requirements of ____ and his/her caregivers.

Diagnosis & Disability

(Describe the ability to sit, stand, walk, and transfer including the amount of assistance needed for each activity, including transfer into the bathtub or shower. Where appropriate, describe other related equipment in use, such as mobility devices, mechanical lifts, etc. May also include clinical evaluation in place of this narrative)

_____ is a _____-year-old boy/girl who has been diagnosed with _____. He/she is unable to stand or walk independently and needs additional trunk support in most activities of daily living (ADL). He/she also has limited head, upper limb, and lower limb control. ____'s medical condition is such that she/he does not experience the movement necessary to stimulate muscle and bone growth. This is detrimental to long-term development and physiological function.

_____ has low/mixed/fluctuating/high muscle tone and requires regular therapy to help stretch his/her joints and strengthen muscles and bones. They already have a wheelchair with postural support, bathing equipment, and a standing frame for stationary weight-bearing. ____ has no means of mobile weight bearing to develop gait or to exercise.

Impact of disability on child's and caregivers' life.

(Include details about the current equipment used, how the child currently walks, and detail anything specific as to why this method may not currently work)

Per review of pertinent research, the benefits of MyWay+ are as follows:

Typically, a child learns to stand at approximately 9-12 months and walk at 12-18 months. This major milestone involves many, many hours of practice (and failure)

of successive and highly coordinated motor patterns. These include lateral weight shift, side stepping, weight transfer, step initiation, single leg stance, contra-lateral leg swing, and push-off.

The benefits of standing upright are well established and include an increase in bone mineral density, decrease in spasticity, improved range of movement, improved bladder and bowel function and increased pressure relief (Glickman, 2010). Moreover, when it comes to walking, a systematic review of the benefits of a gait trainer for children with motor impairments revealed a range of other positive trends: increased walking distance, increased number of steps, improved mobility, improved bowel function, improved bone mineral density and improved motivation and participation (Paleg and Livingstone, 2015).

Children with disabilities are more likely to lead excessively sedentary lives, with the greater the motor impairment the more inactive their everyday life. Verschuren described how for individuals who have extremely high volumes of sedentary behavior, even small increases in the volume of activity may lead to profound health gains (Verschuren et al, 2014).

Unfortunately, these children are also at increased high risk of hip displacement which is associated with pain, spinal deformity, and surgery. A strong correlation has been reported between lack of upright movement and the incidence of hip displacement, with up to 90% of the least active children experiencing hip displacement (Soo et al, 2006).

Independent mobility is a momentous event in childhood, marking the moment when a child moves from complete dependence on adults to a raft of new opportunities and new risks. With this event comes a step increase in the adult-child vocabulary, both spoken by the adult and understood by the child. The new experiences change their relationship from fully nurturing to advising and guiding ("Watch out. It's hot/cold/dangerous!" etc.). Independent mobility also heralds a massive change in perception and judgment. Evidence has demonstrated not just the reciprocal relationship between independent locomotion and cognitive development but that it is the exposure to these new self-generated experiences that guarantees the developing brain receives sufficient stimuli to cause the enormous psychological changes. (Anderson et al, 2013). _____ currently has no means to mobilize independently and must be carried or pushed.

What are the specific clinical benefits of MyWay+ for the child?

(Focus on their gait, what makes it challenging, and how MyWay+ can help.)

_____ needs assistance to improve his/her gait pattern to walk. He/she has trialed several gait trainers but because of muscle weakness and abnormal tone, he/she is unable to manage other frames. The MyWay+ is a gait trainer, available in 3 sizes for ages approximately 1-16 years up to 80 kg/176 lbs. It is designed and manufactured as durable medical equipment and is a registered medical device. The MyWay+ has 6 interchangeable harnesses each with 3 years of growth.

The MyWay+ harness is unique in offering wrap-around trunk support from shoulder to groin. The corset fit ensures a close coupling between the harness and child to suit. This increases trunk stability and provides proprioceptive feedback, significantly reducing abnormal muscle tone, providing symmetry, and controlling dystonic movements. For _____, this will mean that as he/she learns controlled, purposeful movements, he/she will not be overwhelmed by unhelpful, uncontrolled movements thus increasing his/her confidence and chance of succeeding.

The MyWay+ side-stepping ability offers a unique feature when compared to other gait trainers. Children with additional needs often have weaker muscles, especially around their hips. This can impact their gait, function, and hip joint development. The new side-step function of the MyWay+ locks the casters in a sideways position, providing the opportunity to target and strengthen hip abductor muscles while they are fully supported in the frame. Cruising and side-stepping are part of typical development and improves hip strength and this feature allows therapists to be hands-free and provide targeted therapy to support the child.

With many gait trainers, children have great difficulty propelling the device and quickly lose motivation. The MyWay+ uses a combination of features to optimize the position of each child to promote stepping, including variable prone angle, fine height adjustment, anti-rollback, and lightweight maneuverable frame, all of which can be adjusted in situ.

Caregivers can find it difficult to position children into gait training devices. This can lead to poor positioning or reluctance to use the equipment, particularly as they grow. Those who can get into the equipment are frequently very tired at the end of a therapy session making it difficult for caregivers to return them to their wheelchair. The MyWay+ harness is compatible with a mechanical lift strap, making it easy to transfer the child from the floor, standing frame, or wheelchair into the MyWay+ and vice versa using a mechanical lift.

Many other gait training devices require a child to use their hands to support themselves and/or guide the device making it difficult to interact with toys and develop fine motor skills. With an open front, hands-free design, the MyWay+ enables the child to get close to stimulating sensory environments such as sand tables, or to learn ADL such as hand and face washing at a sink. The hands-free design enables _____ to strengthen and increase the coordination in his/her upper limbs as he/she practices the diagonal-spiral movement patterns of gait (right arm/left leg and vice versa).

Children with disabilities are at increased risk of fractures (Stevenson *et al*, 2006). The MyWay+ promotes active weight bearing through the lower limbs to improve bone density and reduce the potential for fractures. Walking programs can be enhanced by following the accompanying Walking Skills Program which offers stimulating activities that gently increase in duration, skill, and complexity.





The MyWay+ will empower ___ to move independently. As a lightweight and portable product, MyWay+ can also be used in suitable outdoor settings and therapy clinics. It can be easily folded for transport to enable him/her to explore other more stimulating environments. This self-generated movement will improve his/her visual proprioception (spatial awareness, depth perception), cause her/him to develop new attention strategies, improve his/her understanding of other intentions, improve his/her working memory, cause him/her to have a greater tolerance of delays in goal attainment and improve his/her spatial search (Kermoian and Campos, 1988).




What are the key components and accessory requirements?

(Delete components and accessories that you are not requesting.)

To meet _____'s needs for a gait trainer I am requesting funding for a size _____ LECKEY MyWay+ walking frame with the features and accessories set out below.

This will have approximately X years left of growth.

Item	Description of Medical Necessity
Harness 	The unique MyWay+ harness provides the core trunk stability required to develop head and limb control and in turn, enable an optimum stepping pattern. The size __ harness will suit ___'s weight and height with suitable room for growth.
Standard Saddle  Narrow Saddle 	This may be required to help support the user before attaching the harness to the frame. However, once positioned, the user may not require the saddle. This can be removed, and the user takes their weight with additional support from the harness and groin straps.
Saddle Drop 	If the user tends to keep their thighs and knees close together, the drop can be attached to the saddle to help keep their legs in a more neutral position.

<p>Adult Handles</p> 	<p>These are a useful adjunct to MyWay+ to enable caregivers to safely push and steer the device.</p>
<p>Hoist Straps</p> 	<p>The MyWay harness is compatible with a dependent lift. The straps enable the child to be lifted from a plinth, floor, or chair to MyWay+ and vice versa.</p> <p>There is no need to use a different mechanical lift sling to do this, saving time and supporting the child in getting maximum use and enjoyment out of their MyWay+.</p>
<p>MyWay Pedal</p> 	<p>The MyWay Pedal is a unique accessory that clips onto the size 2 or 3 MyWay+ frame to enable children to move the device using an elliptical pedaling motion. The MyWay Pedal has integrated Bluetooth technology which measures speed, duration, and frequency.</p>

How does the Pedal accessory uniquely benefit the child?

(Discuss impairment and how pedaling gives specific unique benefits to the child. Delete this section if not requesting a Pedal accessory.)

The MyWay+ Pedal is a unique elliptical pedaling device that attaches to the MyWay+ to work lower limb muscles in the range that would be used during gait. The following is a list of common clinical issues and how these are addressed with the MyWay+ Pedal.

- Children with disabilities often lack strength in the anti-gravity (quadriceps and hamstring) muscles of the lower limbs causing them to exhibit a flexed 'crouch' gait. The MyWay+ Pedal accessory works these muscles at the end of their range where conditioning is required.
- Children with disabilities lead sedentary lives and lack general fitness (Verschuren, 2014). The MyWay+ Pedal provides aerobic activity to improve cardio-respiratory fitness.
- Children often display joint instability around the hip, knees, and ankles. The MyWay+ Pedal implements muscle co-contraction around lower limb joints.
- Children can have difficulty isolating and controlling specific muscle groups -selective control. The MyWay+ Pedal breaks difficult patterns enforcing opposite movements between the left and right legs through pedaling, the left and right arm through steering, and between the arms and legs through pedaling while steering.
- Children with high levels of motor impairment are at risk of muscle shortening (Noordmark, 2009). The MyWay+ Pedal supports active hamstring lengthening during downward pedaling action.
- Misalignment and asymmetry are addressed through aligned mobile weight bearing with pelvis over knees over ankles.
- Finally, the MyWay+ Pedal has integrated Bluetooth technology which tracks and records common gait parameters such as speed, duration, and frequency. It enables personalized walking programs to be set up to record outcome measures, capture progress, compare performance at set intervals, provide evidence of activity and inclusion, inform the family, and motivate the child.

What are the safety factors relevant to adults and caregivers?

A gait training device must combine the safety needs of the child with their drive for independence. The MyWay+ has multi-directional casters and has 3 safety features: they can have additional resistance to limit speed in confined environments, they can be direction locked to only go in a straight line, they can have anti-rollback block rearward movement and brakes can be applied. The device also has adult handles to guide the child if they become tired.

The MyWay+ harness reduces the need for care staff to physically strain while positioning _____ into or out of the device as it is compatible with a mechanical lift using the hoist strap. The largest size of the harness supports up to 176 lbs. The open frame design enables an adult to guide movement without having to bear any of ____'s weight. These factors will greatly reduce the chance of future personal injury costs resulting in time away from assisting _____.

What alternatives are available but not suitable?

(Give at least one example of another product that has been trialed or is similar but does not have as many features or benefits.)

Other gait trainers, with their anterior supports, encourage a flexed, minimally weight-bearing posture where there is no opportunity to develop or improve gait patterns. The child can also not see what's in front of them or their feet which causes fear and limits gait initiation. When positioned posteriorly, the _____ is only suitable for less complex children. There is also less trunk support in either position so less support for those with weak core or high and fluctuating tone. The _____ design does not allow for a headrest. This is essential for ____ as he/she becomes tired easily, but the MyWay+ has an optional headrest. There are no ankle supports to control scissoring gait on the _____. This is a must-have for ____ due to his/her gait.

Tricycles provide a similar pedaling motion to the MyWay+ Pedal, however they work muscles in their shortened flexed position. The MyWay+ pedal works the muscles where they need to be strengthened at the end of their range. Tricycles also enforce a circular motion whereas the MyWay Pedal provides a stretched elliptical movement which is more representative of functional gait.

Repeated exercise consolidates motor tasks into muscle memory patterns which can be embedded and strengthened through repetition. This is evidenced by a recent case study on a child who used the MyWay+ Pedal 3 times/week for 30 minutes over 6 weeks. At the end of 6 weeks, the child's therapist timed how long he could stand with his hands held. This improved from 20s to 48s. Classroom staff reported that he is "able to stand up much straighter and needs less help in and out of his wheelchair than before" and for the first time, he managed to descend stairs by stepping instead of transferring on his bottom. (Sunrise Medical, 2023, October 09)

Summary/Conclusion

Upright mobility confers an extensive range of neurological and musculoskeletal benefits. From improved spatial awareness and decision-making to increased joint stability, range of movement, bone mineral density, and cardio-respiratory fitness. The MyWay+ Gait trainer will enable _____ to avail of these benefits. The unique frame-harness design will reduce abnormal tone and support him/her in an upright engaged position, ready for active movement. The multi-functional casters, lightweight frame, prone, gross, and fine height adjustment combine to help the initiation, grading, and control of movement, while the open frame design allows for both therapist facilitation and interaction with peers and family. A range of accessories such as ankle guides, saddle, and headrest will address more challenging traits while the unique MyWay+ Pedal uses elliptical movement to strengthen and stretch the anti-gravity lower limb muscles which are crucial for upright active weight bearing.

The MyWay+ is the best gait trainer to meet ____'s medical needs and as such I do not hesitate to recommend that it should be funded.

Activities that can be achieved with the MyWay+ and MyWay Pedal.

(If you have pictures of the child in a demo, they can be attached with descriptions.)



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