Sensory Belt™

Written By: Cheryl Albright, OTR/L

Do weighted sensory items need a prescription? No

The Miracle Belt, Sensory Belt, & Thera-Belt are noninvasive weighted therapy devices which have been utilized by the following since 2006:

- Behavior Therapists
- Occupational Therapists
- Physical Therapists
- Speech Therapists
- Psychologists
- Physicians
- Parents
- Teachers

Note: *The Miracle Belt, Sensory Belt, & Thera-Belt have been researched and tested child safe under CPSIA Government guidelines. Certificates are provided online at www.miraclebelt.com.*

What if your child's day care or school asks for a prescription?

Medical professionals will most likely not write a prescription for these devices. In the medical world, this is not necessary, as weighted materials are not considered to fall under any of the definitions mentioned below. However, the requestor is most likely asking to decrease liability. Have your therapist and/or any other listed professional write a detailed wearing schedule for the belt. Please make sure the correct sized belt is used with your child/client.

Note: The Thera-Belt is specifically designed for therapists/physicians only.

Federal Drug Administration and Medicare/Medicaid - Prescription Definitions

The Federal Drug Administration and Medicare/Medicaid state that you need a prescription for medications, durable medical equipment (DME), or a medical device.

Durable medical equipment is defined as: medically necessary durable medical equipment (DME) that your doctor prescribes for use in your home. Only your doctor can prescribe medical equipment for you. DME meets these criteria:

- Durable (long-lasting)
- Used for a medical reason
- Not usually useful to someone who isn't sick or injured
- Used in your home
- Has an expected lifetime of at least 3 years

DME that Medicare covers include:

- Air-fluidized beds and other support surfaces (these supplies are only rented)
- Blood sugar monitors
- Blood sugar (glucose) test strips
- Canes (however, white canes for the blind aren't covered)
- Commode chairs
- Continuous passive motion (CPM) machine
- Crutches

- Hospital beds
- Infusion pumps and supplies (when necessary to administer certain drugs)
- Manual wheelchairs and power mobility devices
- Nebulizers and nebulizer medications
- Oxygen equipment and accessories
- Patient lifts
- Sleep apnea and Continuous Positive Airway Pressure (CPAP) devices and accessories
- Suction pumps
- Traction equipment
- Walkers

Medical Device is defined as: Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices. In addition, medical devices include in vitro diagnostic products, such as general purpose lab equipment, reagents, and test kits, which may include monoclonal antibody technology. Certain electronic radiation emitting products with medical application and claims meet the definition of medical device. Examples include diagnostic ultrasound products, x-ray machines and medical lasers. If a product is labeled, promoted or used in a manner that meets the following definition in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act it will be regulated by the Food and Drug Administration (FDA) as a medical device and is subject to premarketing and postmarketing regulatory controls. A device is:

- "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
    - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
    - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
    - intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

This definition provides a clear distinction between a medical device and other FDA regulated products such as drugs. If the primary intended use of the product is achieved through chemical action or by being metabolized by the body, the product is usually a drug. Human drugs are regulated by FDA's Center for Drug Evaluation and Research (CDER). Biological products which include blood and blood products, and blood banking equipment are regulated by FDA's Center for Biologics Evaluation and Research (CBER). FDA's Center for Veterinary Medicine (CVM) regulates products used with animals. If your product is not a medical device but regulated by another Center in the FDA, each component of the FDA has an office to assist with questions about the products they regulate. In cases where it is not clear whether a product is a medical device there are procedures in place to use DICE Staff Directory to assist you in making a determination