



# Medical Coverage Policy

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## Suit Therapy

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### Related Coverage Resources

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#### INSTRUCTIONS FOR USE

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### Overview

This Coverage Policy addresses suit therapy and the home use of a suit therapy device.

### Coverage Policy

**Suit therapy or the home use of a suit therapy device for the treatment of any condition including, but not limited to, cerebral palsy or other neuromuscular conditions is considered experimental, investigational or unproven.**

### General Background

Suit therapy has been proposed as an alternative to conventional physiotherapy to treat the impairments associated with cerebral palsy. This therapy is based on a suit originally designed by the Russian government for use by cosmonauts in space to minimize the effects of weightlessness. The principle is to move body parts against a resistance, thus improving muscle strength. It is theorized that through placement of the elastic cords, selected muscle groups can be exercised as the patient moves limbs, providing a form of controlled exercise against a resistance. It is also claimed that the suit improves coordination. When suit therapy is used it may be part of a comprehensive program of intensive physiotherapy that includes of 5–7 hours a day for four weeks (Cerebral Palsy International Research Foundation [CPIRF], 1999/2004).

Suit therapy first started in clinics in Europe in the early 1990s. Currently, suit therapy is rendered at many physical therapy centers in the United States. After a course of suit therapy at a center, a suit or suit therapy device may be available for purchase in order to continue with home therapy. There are several types of suit therapy including, but not limited to:

- TheraSuit™ (Therasuit LLC, Keego Harbor, MI)
- NeuroSuit (Neurosuit LLC, Hiram, GA)
- TheraTogs™ (TheraTogs Inc, Telluride, CO).

The NeuroSuit consist of a breathable material and includes a hat, vest, shorts, knee pads, elbow pads, and gloves. The TheraSuit includes a cap, vest, shorts, knee pads, arm attachments, and shoe attachments with the pieces connected by elastic bands. TheraTogs include a sleeveless tank top, hipster, extremity cuffs, elasticized straps, extra hook tabs, double-grip hook with loop material, and position marking dots.

While suit therapy has been proposed primarily as a treatment for cerebral palsy, it has also been recommended by manufacturers and providers for treatment of other neuromuscular disorders, including developmental delays, traumatic brain injury, post-stroke, ataxia, athetosis, spasticity, and hypotonia.

Cerebral palsy is a term used to describe a group of chronic disorders that impair the control of movement and that appear in the first few years of life (National Institute of Neurological Disorders and Stroke [NINDS], 2019). The orthopedic difficulties encountered in children with cerebral palsy are frequently a result of high muscle tone, spasticity, and rigidity that prevent normal growth of muscle and cause contractures. Treatment of functional deficits associated with cerebral palsy usually applies a multidisciplinary approach and may include physicians of various specialties, occupational therapists, physical therapists, speech pathologists, social workers, and developmental psychologists. The treatment plan may include physical therapy, surgery, drug therapy, and/or mechanical aids and is tailored to the unique needs and impairments of each patient. The therapy is focused on decreasing the degree of impairment (e.g., muscle spasticity) and increasing participation in activities of daily living. Therapists in the disciplines of physiotherapy, occupational therapy, and speech therapy utilize physical and behavioral approaches aimed at lengthening contracted muscles, improving the strength of weakened muscles, increasing the range of motion at restricted joints, improving movement coordination, and developing compensatory strategies to accomplish tasks.

### **U.S. Food and Drug Administration (FDA)**

The U.S. Food and Drug Administration (FDA) classifies the suit therapy devices (e.g., therapy suit, Adeli therapy suit, TheraSuit, NeuroSuit, TheraTogs) as Class I limb braces or orthosis.

### **Literature Review**

Giray et al. (2020) a single-blinded, randomized controlled study to evaluate the effects of vest type dynamic elastomeric fabric orthosis on posture and balance during sitting and gross manual dexterity and to compare the efficacy of daily wearing time of two hours versus six hours. The study included 24 children with cerebral palsy (CP) with GMFCS levels III and IV that were randomized to either of three groups: a control group who received only conventional exercise therapy; dynamic elastomeric fabric orthosis 2 hour group who wore the orthosis for two during therapy and dynamic elastomeric fabric orthosis six group who wore the orthosis for four hours in addition to the two hours of wear along with therapy during hospital inpatient stay for two weeks. Children continued to use dynamic elastomeric fabric orthosis during the post-discharge period. The primary outcome measure was the Sitting Assessment Scale. The secondary outcome measurements were the sitting dimension of Gross Motor Function Measure, Box and Block Test and Parent Satisfaction Survey. Assessments were made before treatment, at post-treatment, at one-month post-treatment, and at three-months post-treatment. Sitting Assessment Scale and Box and Block Test were also assessed when immediately after wearing the orthosis. All groups showed similar improvements except the control group which showed less improvement in Sitting Assessment Scale scores compared to the dynamic elastomeric fabric orthosis groups. Dynamic elastomeric fabric orthosis groups showed greater improvements compared to the control group in the Sitting Assessment Scale but not in the sitting dimension of Gross Motor Function Measure and Box and Block Test at post-treatment, at 1-month post-treatment and at 3-months post-treatment. When the dynamic elastomeric fabric orthosis groups (two versus six hours) were compared, there were no significant differences in any of the

assessments. The Sitting Assessment Scale and Box and Block Test scores also improved immediately after the patients put on the orthosis. The study is limited by the small number of subjects and larger studies are needed to demonstrate order to establish impact of this orthosis type in children with CP at different functional levels and ages.

Karadağ-Saygi conducted a systematic review to evaluate the clinical aspects and effectiveness of suit therapy for patients with cerebral palsy (CP). The review included a total of 29 studies of which ten (34.5%) were Class I, eight Class II-III, and 11 (37.9%) were Class IV. (Class I: RCTs; Class II: Cohort studies and non-RCTs; Class III: Case-control studies; Class IV: Single-case studies and case series). The studies were heterogeneous in design, size, study population, and outcomes measured. The authors noted that the results of the high-quality RCTs showed that wearing the suit along with conventional therapy improved proximal stability, gross motor function, and gait and that the Class II-III and IV studies supported the findings of the Class I studies. The review noted that it was impossible to give precise guidance on the right target group and best effective therapy protocol due to heterogeneity of the included studies. The authors concluded that further studies including large numbers of children with CP at different functional levels and ages in order to establish impact of this orthosis type in children with CP at different functional levels and ages via subgroup analysis; kinematic assessment of evaluated body segment; and assessment of activity and participation in addition to body structure and function must be conducted.

Almeida et al. (2017) conducted a systematic review to evaluate the available evidence on the effects of interventions based on the use of therapeutic suits in the treatment of impairments and functional limitations of children with cerebral palsy. The review included 13 studies: two evaluated the Full Body Suit; two the Dynamic Elastomeric Fabric Orthose; three TheraTogs; and six tested the TheraSuit/AdeliSuit protocols. The review found that the quality of evidence for the Full Body Suit, the Dynamic Elastomeric Fabric Orthose and the TheraSuit/AdeliSuit protocols was very low for body structure and function outcomes, and the evidence for TheraTogs was low quality. Regarding the activity outcomes, the review noted that the Full Body Suit and TheraSuit showed very low quality evidence while the evidence for TheraSuit/AdeliSuit protocols were of low quality. The review concluded that the low quality of evidence suggests caution in recommending the use of these therapeutic suits.

Martins et al. (2016) reported on a systematic review and meta-analysis that examined the efficacy of suit therapy on functioning in children and adolescents with cerebral palsy (CP). The review included four randomized controlled trials (n=110). Two RCTs compared Adeli suit treatment (AST) with neurodevelopmental treatment (NDT); one study compared modified suit therapy with conventional therapy; and, the other compared TheraSuit with a treatment classified as other therapy approach. Small, pooled effect sizes were found for gross motor function at post-treatment ( $g=0.46$ , 95% confidence interval [CI] 0.10-0.82) and follow-up ( $g=0.47$ , 95% CI 0.03-0.90). The review noted limitations that included the small number of studies, the variability between them, and the low sample sizes. The authors noted that there is a need for better evidence to examine and prove the effects of short intensive treatment such as suit therapy on gross motor function in children and adolescents with CP.

Bailes et al. (2011) conducted a randomized controlled trial to examine the effects of suit wear during an intensive therapy program on motor function among 20 children with cerebral palsy. The children were randomized to an experimental (TheraSuit) or a control (control suit) group and participated in an intensive therapy program. The Pediatric Evaluation of Disability Inventory (PEDI) and Gross Motor Function Measure (GMFM)-66 were administered before and after treatment (four and nine weeks) with parent satisfaction also assessed. There were no significant differences found between the groups. There were significant within-group differences found for the control group on the GMFM-66 and for the experimental group on the GMFM-66, PEDI Functional Skills Self-care, PEDI Caregiver Assistance Selfcare, and PEDI Functional Skills Mobility. There were no adverse events reported.

Bar-Haim et al. (2006) conducted a randomized study of 24 children that compared the efficacy of Adeli suit treatment (AST) with neurodevelopmental treatment (NDT) in children with cerebral palsy. In the AST group (n=12) six children had spastic/ataxic diplegia, one triplegia and five had spastic/mixed quadriplegia. In the NDT group (n=12) five children had spastic diplegia and seven had spastic/mixed quadriplegia. Treatment was for two hours daily, five days per week over four weeks for a total of 20 sessions. Outcome measurements included the

Gross Motor Function Measure (GMFM-66) and the mechanical efficiency index (EIHB). These were measured during stair-climbing, at baseline, immediately after one month of treatment, and 10 months after baseline. There was an increase in both the GMFM-66 and EIHB noted at one month for both intensive physiotherapy courses. This increase appeared to be greater than expected from natural maturation of children with cerebral palsy at this age. It was noted that the improvements in motor skills and their retention nine months after treatment were not significantly different between the two treatment modes. A post hoc analysis indicated a greater increase in EIHB after one month and 10 months in the AST group than that in the NDT group. This was noted to be more predominant in the children with higher motor function. The authors conclude that “The results suggest that AST might improve mechanical efficiency without a corresponding gain in gross motor skills, especially in children with higher levels of motor function.” The authors note that, “Future studies on the efficacy of AST should measure changes in metabolic efficiency and fitness level, as well as motor skills. It is also important to determine changes induced by the suit itself, by having two groups perform the same physical training, with and without the suit. Future studies should increase the number of participants and homogenize the participants with CP [cerebral palsy] to reduce variability.”

**Use Outside of the US:** No relevant information

**Centers for Medicare & Medicaid Services (CMS)**

- National Coverage Determinations (NCDs): No NCDs found.
- Local Coverage Determinations (LCDs): no LCDs found

**Coding/Billing Information**

**Note:** 1) This list of codes may not be all-inclusive.  
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Experimental/investigational/unproven when used to report suit therapy or a suit therapy device for the treatment of any condition, including but not limited to cerebral palsy or other neuromuscular conditions:**

CPT® Codes	Description
97139	Unlisted therapeutic procedure (specify)
97799	Unlisted physical medicine/rehabilitation service or procedure

HCPCS Codes	Description
E1399	Durable medical equipment, miscellaneous
L1499	Spinal orthosis, not otherwise specified
L2999	Lower extremity orthosis, not otherwise specified
L3999	Upper limb orthosis, not otherwise specified

**\*Current Procedural Terminology (CPT®) ©2019 American Medical Association: Chicago, IL.**

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