Suit Therapy

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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.

Overview

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

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], 2016). 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 (United Cerebral Palsy [UCP], 2003).

**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**

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.”

Liptak (2005) conducted a review of nine complementary and alternative therapies for cerebral palsy. Regarding
the use of the Adeli suit, the review noted that “no published evidence from a controlled trial is available in
English to support or reject the use of the suit. Thus, no conclusive evidence either in support of or against the
use of the Adeli suit is available.”

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:
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<td>Lower extremity orthosis, not otherwise specified</td>
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<td>L3999</td>
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References


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