

Cigna Medical Coverage Policy

Subject: Suit Therapy

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Coverage Policy

Cigna does not cover 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, because it 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:

- Adeli® suit (Ayurveda JS Co., Moscow, Russia)
- TheraSuit™ (Therasuit LLC, Keego Harbor, MI)
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, NeuroSuit, TheraSuit, TheraTogs) as Class I limb braces or orthosis.

Literature Review
Martins et al. 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 (suit control) 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

Summary
There is insufficient evidence in the published, peer-reviewed scientific literature to establish the safety and effectiveness of suit therapy or the home use of a suit therapy device for the treatment of functional impairments associated with cerebral palsy, other neuromuscular disorders, or other medical conditions. Well-designed clinical trials are needed to demonstrate that this treatment is as effective as conventional physiotherapy in the treatment of cerebral palsy or other neuromuscular disorders, that it improves patients’ functional abilities and activities of daily living, and that it decreases impairment.

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.

Experimental/investigational/unproven/not covered 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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<th>CPT® Codes</th>
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References


