



# CIGNA MEDICAL COVERAGE POLICY

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Subject **Suit Therapy**

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## Hyperlink to Related Coverage Policies

Gait Analysis  
 Neurosurgical Treatment of Spasticity  
 OnabotulinumtoxinA (Botox® A)  
 Physical Therapy

### INSTRUCTIONS FOR USE

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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. Suit therapy is often used as part of a comprehensive program of intensive physiotherapy of 5–7 hours a day for four weeks (Cerebral Palsy International Research Foundation [CPIRF], 1999).

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. The therapy suit is also known as the Adeli® suit (Ayurveda JS Co., Moscow, Russia), the TheraSuit™ (Therasuit LLC, Keego Harbor, MI), the NeuroSuit (Neurosuit LLC, Hiram, GA), the Penguin suit and 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], 2010). 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, Penguin suit, TheraSuit, NeuroSuit, TheraTogs) as Class I limb braces or orthosis.

### **Literature Review**

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."

### **Professional Societies/Organizations**

The Cerebral Palsy International Research Foundation (CPIRF) published two research fact sheets on the Adeli suit. The first was published in March 1999, at which time suit therapy was only provided at facilities in Poland. Due to interest in suit therapy, the November 2004 UCP fact sheet reported on two studies funded by the CPIRF. The first study noted in the UCP research fact sheet involved 24 children. The patients were randomly

assigned either to a standard physical therapy program or to the Adeli suit using the original Russian protocol. Both groups were treated with a two-hour session, five days a week. Evaluation of a number of parameters showed marginal improvement in both groups that persisted over the following year. There was no statistical difference between the children who used the Adeli suit and those who did not (CPIRF, 2004). The second study noted in the fact sheet included 57 children who were randomized to control and treatment groups. All children received one hour each of physical, occupational and speech therapy three times a week for 8–10 weeks, followed by a four-week home program. The experimental group wore the Adeli suit for the last four weeks of their therapy program. It was noted that both groups improved and sustained the improvement but without any statistical difference between the two groups (CPIRF, 2004). The research fact sheet concluded that these studies show that a period of intensive therapy in ambulatory children with cerebral palsy can lead to improvement in a number of disabilities. However, they did not demonstrate that the use of the Adeli suit was helpful, and they reported that any effect is likely to be minor.

### Summary

There is insufficient evidence in the published, peer-reviewed scientific literature to establish the safety and effectiveness of suit therapy for the treatment of functional impairments associated with cerebral palsy or other neuromuscular disorders. 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:** This list of codes may not be all-inclusive.

**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:**

CPT* Codes	Description
97139	Unlisted therapeutic procedure (specify)

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

ICD-9-CM Diagnosis Codes	Description
343.0-343.9	Infantile cerebral palsy
359.0-359.9	Muscular dystrophies and other myopathies
728.2	Muscular wasting and disuse atrophy, not elsewhere classified
728.3	Other specific muscle disorders
728.85	Spasm of muscle
	All other codes

**\*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

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## Policy History

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	5/15/2007	0353	Suit Therapy

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