Cigna Medical Coverage Policy

Effective Date **4/15/2014**
Next Review Date **4/15/2015**
Coverage Policy Number **0353**

Subject **Suit Therapy**

Table of Contents

Hyperlink to Related Coverage Policies

Occupational Therapy
Physical Therapy

INSTRUCTIONS FOR USE
*The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supersedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2014 Cigna*

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)

- 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], 2011). 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
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."

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.

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:

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 orthotic, not otherwise specified
L2999	Lower extremity orthoses, not otherwise specified
L3999	Upper limb orthosis, not otherwise specified

References

1. Adeli Project [information on the Adeli approach]. Ayurveda JS Co. Accessed March 5, 2014. Available at URL address: http://adeli.gr/adeli-suit_en.php

2. Adeli Suit [product information]. Euromed. Accessed March 5, 2014. Available at URL address: http://www.locomotordysfunction.com/

3. Anttila H, Autti-Rämö I, Suoranta J, Mäkelä M, Malmivaara A. Effectiveness of physical therapy interventions for children with cerebral palsy: a systematic review. BMC Pediatr. 2008 Apr 24;8:14.

4. Bailes AF, Greve K, Schmitt LC. Changes in two children with cerebral palsy after intensive suit therapy: a case report. Pediatr Phys Ther. 2010 Spring;22(1):76-85.

5. Bailes AF, Greve K, Burch CK, Reder R, Lin L, Huth MM. The effect of suit wear during an intensive therapy program in children with cerebral palsy. Pediatr Phys Ther. 2011 Summer;23(2):136-42.

6. Bar-Haim S, Harries N, Belokopytov M, Frank A, Copeliovitch L, Kaplanski J, Lahat E. Comparison of efficacy of Adeli suit and neurodevelopmental treatments in children with cerebral palsy. Dev Med Child Neurol. 2006 May;48(5):325-30.

7. Cerebral Palsy International Research Foundation (CPIRF). The Adeli Suit [research fact sheet: diagnosis/treatment]. March 1999. Accessed March 5, 2014. Available at URL address: http://cpirf.org/category/fact-sheets/diagnosis-and-treatment/

8. Cerebral Palsy International Research Foundation (CPIRF). The Adeli Suit Update [research fact sheet]. 2004 Nov. Accessed March 5, 2014. Available at URL address: http://cpirf.org/category/fact-sheets/diagnosis-and-treatment/

9. Cerebral Palsy International Research Foundation (CPIRF). Dolphin Assisted Treatment, Hyperbaric Oxygen Therapy and the Adeli Suit. January 2010 Fact Sheet. Accessed March 5, 2014. Available at URL address: http://cpirf.org/category/fact-sheets/diagnosis-and-treatment/

10. Cooley WC; American Academy of Pediatrics Committee on Children With Disabilities. Providing a primary care medical home for children and youth with cerebral palsy. Pediatrics. 2004 Oct;114(4):1106-13.

11. Flanagan A, Krzak J, Peer M, Johnson P, Urban M. Evaluation of short-term intensive orthotic garment use in children who have cerebral palsy. Pediatr Phys Ther. 2009 Summer;21(2):201-4.

12. Goldstein M. The treatment of cerebral palsy: what we know, what we don't know. J Pediatr. 2004 Aug;145(2 Suppl):S42-6.

13. Hurvitz EA, Leonard C, Ayyangar R, Nelson VS. Complementary and alternative medicine use in families of children with cerebral palsy. Dev Med Child Neurol. 2003 Jun;45(6):364-70.

14. Kliegman RM, Stanton BF, St. Geme III JW, Schor NF, Behrman RE, editors. Nelson textbook of pediatrics, 19th ed. Philadelphia, PA: W.B. Saunders Company; 2011.

15. Liptak GS. Complementary and alternative therapies for cerebral palsy. Ment Retard Dev Disabil Res Rev. 2005;11(2):156-63.

16. Michaud LJ; American Academy of Pediatrics Committee on Children With Disabilities. Prescribing therapy services for children with motor disabilities. Pediatrics. 2004 Jun;113(6):1836-8. (Statement of reaffirmation for this policy published on September 1, 2007; July 1, 2011). Accessed March 5, 2014. Available at URL address: http://pediatrics.aappublications.org/content/113/6/1836.abstract?sid=e6a2c4bf-5d3f-4ced-86bf-2ef3852bbd84

17. NINDS cerebral palsy information page. Cerebral Palsy: Hope Through Research. National Institute of Neurological Disorders and Stroke (NINDS). Bethesda, MD: NINDS, National Institutes of Health (NIH). Last updated August 23, 2012. Accessed March 12, 2013. Available at URL address: http://www.ninds.nih.gov/disorders/cerebral_palsy/detail_cerebral_palsy.htm

18. NOMC [North Oakland Medical Centers] Euro-Pēds program: SUIT therapy. Accessed March 5, 2014. Available at URL address: http://www.europeds.org/

19. Oppenheim WL. Complementary and alternative methods in cerebral palsy. Dev Med Child Neurol. 2009 Oct;51 Suppl 4:122-9.

20. Richards A, Morcos S, Rethlefsen S, Ryan D. The use of TheraTogs versus twister cables in the treatment of in-toeing during gait in a child with spina bifida. Pediatr Phys Ther. 2012 Winter;24(4):321-6.

21. Rosenbaum P. Cerebral palsy: what parents and doctors want to know. BMJ. 2003 May 3;326(7396):970-4.

22. Suit therapy for cerebral palsy [information about the TheraSuit Method™ and the TheraSuit™]. Therasuit LLC. Accessed March 5, 2014. Available at URL address: http://www.suittherapy.com/

23. TheraTogs [product information]. TheraTogs, Inc. Accessed March 5, 2014. Available at URL address: http://www.theratogs.com/

24. United Cerebral Palsy (UCP). The Treatment of Cerebral Palsy [research status report]. Washington, DC: United Cerebral Palsy (UCP) Research & Educational Foundation; 2003 Jun.

25. U.S. Food and Drug Administration (FDA). Code of federal regulations; title 21, vol. 8; subchapter H (medical devices); part 890 (physical medicine devices); subpart D (physical medicine prosthetic devices); sec. 890.3475]. Limb orthosis. Revised as of April 1, 2008. Accessed March 5, 2014. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=890.3475

26. Weisleder P. Unethical prescriptions: alternative therapies for children with cerebral palsy. Clin Pediatr (Phila). 2010 Jan;49(1):7-11.