



Health Net

National Medical Policy

Subject: Suit Therapy for Cerebral Palsy

Policy Number: NMP378

Effective Date*: October 2007

Updated: October 2009, March 2011, January 2012

This National Medical Policy is subject to the terms in the IMPORTANT NOTICE at the end of this document

The Centers for Medicare & Medicaid Services (CMS)

For Medicare Advantage members please refer to the following for coverage guidelines first:

Use	Source	Reference/Website Link
	National Coverage Determination (NCD)	
	National Coverage Manual Citation	
	Local Coverage Determination (LCD)	
	Article (Local)	
	Other	
X	None	Use Health Net Policy

Instructions

- Medicare NCDs and National Coverage Manuals apply to ALL Medicare members in ALL regions.
- Medicare LCDs and Articles apply to members in specific regions. To access your specific region, select the link provided under "Reference/Website" and follow the search instructions. Enter the topic and your specific state to find the coverage determinations for your region
- If more than one source is checked, you need to access all sources as, on occasion, an LCD or article contains additional coverage information than contained in the NCD or National Coverage Manual.
- If there is no NCD, National Coverage Manual or region specific LCD/Article, follow the Health Net Hierarchy of Medical Resources for guidance.

Current Policy Statement (Update January 2012 – A Medline search failed to reveal any studies that would cause Health Net, Inc. to change its current position)

Health Net, Inc. considers suit therapy for the treatment of cerebral palsy or any other neuromuscular condition investigational due to lack of evidence in the

published peer review literature validating its safety and effectiveness in the management of these conditions.

Codes Related To This Policy

ICD-9 Codes

343.0-343.9 Infantile Cerebral Palsy

CPT Codes

97139 Unlisted therapeutic procedure (specify)

HCPCS Codes

N/A

Scientific Rationale – Update January 2011

Bailes et al (2011) examined the effects of suit wear during an intensive therapy program on motor function among children with cerebral palsy. Twenty 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 (4 and 9 weeks). Parent satisfaction was also assessed. No significant differences were found between groups. Significant within-group differences were 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 Self-care, and PEDI Functional Skills Mobility. No adverse events were reported. The authors concluded children wearing the TheraSuit during an intensive therapy program did not demonstrate improved motor function compared with those wearing a control suit during the same program.

Scientific Rationale

Cerebral palsy (CP) refers to a disorder of aberrant control of movement and posture, appearing early in life secondary to a CNS lesion or dysfunction that is not the result of a recognized progressive or degenerative brain disease. The brain abnormality may occur during fetal development, during the birth process or during the first few months after birth. Although CP is not a progressive disease, the effects have been known to change over time. The majority of children with CP present with symptoms as infants or toddlers, and the diagnosis of CP is generally made before 2 years of age. In some children the symptom onset may be delayed. According to the American Academy of Neurology, CP is a common problem and approximately 10,000 babies born in the United States develop CP. CP occurs more commonly in children who are born very prematurely or at term.

The diagnosis of CP depends upon a combination of findings including motor delay, neurologic signs, persistence of primitive reflexes, and abnormal postural reactions. Classification of CP syndromes is based upon the type and distribution of motor abnormalities (e.g. spastic, dyskinetic and ataxic.) There may be substantial overlap among the clinical features. There is no cure for CP, however, treatment can often improve a child's capabilities. There is no standard therapy that works for all patients. Management may include physical and occupational therapy, speech therapy, medication to control seizures and relax muscle spasms, medication to alleviate pain; surgery to correct anatomical abnormalities or release tight muscles;

braces and other orthotic devices; wheelchairs and rolling walkers; and communication aids.

Suit therapy (e.g. TheraSuit, Adeli Suits, Polish Suits, NeuroSuit, Penguin Suits, or Therapy Suits) is proposed as an alternative therapy in the management of cerebral palsy as well as other neuromuscular disorders. The research and development for Suit Therapy began in Russia's space program. The Russian cosmonauts wore a space suit developed to maintain muscle tone in a weightless environment. Later, the suit was modified for use with patients with cerebral palsy. The suit includes a vest, shorts, kneepads, and shoes. The pieces are laced together with bungee-type cords. The cords are adjustable to apply varying degrees of tension to the child's different muscle groups. The bungee cords are positioned to keep the body properly aligned, and to forcibly encourage movement within a normal range of motion. The proposed benefits of suit therapy include: proper alignment of the body; improvement of muscle tone; nervous system retraining to help facilitate more regular body movement; improvement of body awareness; utilizes, but supports weak muscles until they are developed; improves gross motor skills and balance and strengthens the body. Suit therapy is often used as part of a comprehensive physical therapy program.

Suit therapy has been proposed primarily as a treatment for CP, however, the manufacturer of the TheraSuit (Therasuit LLC), also recommends the treatment for other neuromuscular disorders, including developmental delays, traumatic brain injury, post-stroke, ataxia, athetosis, spasticity, and hypotonia. Per the manufacturer, the TheraSuit is contraindicated in patients with hip subluxation greater than 50% or severe scoliosis and used with precautions in patients with heart conditions, uncontrolled seizure activities, hip subluxation, hydrocephalus (VP shunt), diabetes, kidney problems and hypertension.

The United Cerebral Palsy (UCP) Research and Education Foundation has 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 UCP Research and Educational Foundation. These two studies have not yet been published or referenced in the medical literature.

In the first study, Dr. Alexander Frank and his associates in Israel reported on 24 children with cerebral palsy between the ages of 6 and 12 years of age and various levels of disability. Each were matched for age and other variables and randomly assigned to either a standard physical therapy program or to the Adeli Suit using the original Russian Protocol. Both groups were treated 5 days per week for two hours. Evaluation with 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.

The second study was conducted by Dr. Edward Dabrowski at the Children's Hospital of Michigan. In this study, 57 children who were randomized to control and treatment groups. All children received an hour of physical, occupational, and speech therapy three times a week for 8-10 weeks followed by a 4-week home program. The experimental group wore the Adeli Suit for the last 4 weeks of their therapy regimen. Both groups improved and sustained their improvement without any

statistical difference in results between the 2 groups. The UPC 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 use of the Adeli Suit was helpful. Any effect is likely to be minor.

Bar-Haim et al. (2006) compared the efficacy of Adeli suit treatment (AST) with neurodevelopmental treatment (NDT) in children with cerebral palsy (CP). Twenty-four children with CP and various levels of disability were matched by age and functional status and randomly assigned to the AST or NDT treatment groups. Both groups were treated for 4 weeks (2 hours daily, 5 days per week, 20 sessions). To compare treatments, the Gross Motor Function Measure (GMFM-66) and the mechanical efficiency index (EIHB) during stair-climbing were measured at baseline, immediately after 1 month of treatment, and 10 months after baseline. The small but significant time effects for GMFM-66 and EIHB that were noted after 1 month of both intensive physiotherapy courses were greater than expected from natural maturation of children with CP at this age. Improvements in motor skills and their retention 9 months after treatment were not significantly different between the two treatment modes. Post hoc analysis indicated a greater increase in EIHB after 1 month and 10 months in AST than that in NDT, predominantly in the children with higher motor function. The author concluded that 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.

In a review reported by Liptak (2005), nine treatment modalities used for children who have cerebral palsy (CP), including hyperbaric oxygen, the Adeli Suit, patterning, electrical stimulation, conductive education, equine-assisted therapy, craniosacral therapy, Feldenkrais therapy, and acupuncture were evaluated. The author noted that no conclusive evidence either in support of or against the use of the Adeli suit is available.

At this time, there is insufficient evidence in the published, peer-reviewed scientific literature to establish the safety and effectiveness of suit therapy for the treatment and management of cerebral palsy or any other neuromuscular disorders.

Review History

October 2007	Medical Advisory Council, initial approval
October 2009	Update – no revisions
March 2011	Update. Added Medicare Table. No revisions
January 2012	Update – no revisions

Patient Education Websites

English

1. National Institute of Neurological Disorders and Stroke. Cerebral Palsy Information Page. Available at:
http://www.ninds.nih.gov/disorders/cerebral_palsy/cerebral_palsy.htm
2. Nemours Foundation. Cerebral palsy. Available at:
http://kidshealth.org/parent/medical/brain/cerebral_palsy.html

Spanish

1. National Institute of Neurological Disorders and Stroke. La Parálisis Cerebral: Esperanza en la Investigación. Acceso en: <http://www.ninds.nih.gov/disorders/spanish/paraliscerebral.htm>
2. Nemours Foundation. Cuando su hijo tiene parálisis cerebral. Acceso en: http://kidshealth.org/parent/en_espanol/medicos/cerebral_palsy_esp.html

This policy is based on the following evidence-based guideline:

1. Ashwal S, Russman BS, Blasco PA, et al. Practice Parameter: Diagnostic assessment of the child with cerebral palsy: Report of the Quality Standards Subcommittee of the American Academy of Neurology and the Practice Committee of the Child Neurology Society. *Neurology* 2004;62;851-863. Available at: <http://www.neurology.org/cgi/reprint/62/6/851.pdf>

References Update - January 2012

Bailes AF, Greve K, Burch CK, et al. The effect of suit wear during an intensive therapy program in children with cerebral palsy. *Pediatr Phys Ther.* 2011 Summer;23(2):136-42

References Update – March 2011

1. Bailes AF, Greve K, Schmitt LC. Changes in two children with cerebral palsy after intensive suit therapy: A case report. *Pediatr Phys Ther.* 2010;22(1):76-85.
2. Flanagan A, Krzak J, Peer M, et al. Evaluation of short-term intensive orthotic garment use in children who have cerebral palsy. *Pediatr Phys Ther.* 2009;21(2):201-204.
3. Weisleder P. Unethical prescriptions: alternative therapies for children with cerebral palsy. *Clin Pediatr (Phila).* 2010 Jan;49(1):7-11. Epub 2009 Jul 23.

References Initial

1. Bar-Haim S, Harries N, Belokopytov M, et al. Comparison of efficacy of Adeli suit and neurodevelopmental treatments in children with cerebral palsy. *Dev Med Child Neurol.* 2006 May; 48(5): 325-30.
2. Semenova KA, Antonova LV. The influence of the LK-92 "Adeli" treatment loading suit on electro-neuro-myographic characteristics in patients with infantile cerebral paralysis. *Zh Nevrol Psikhiatr Im S S Korsakova.* 1998;98(9):22-5.
3. Semenova KA. Basis for a method of dynamic proprioceptive correction in the restorative treatment of patients with residual-stage infantile cerebral palsy. *Neurosci Behav Physiol.* 1997 Nov-Dec;27(6):639-43.
4. Sologubov EG, Iavorskii AB, Kobrin VI. The significance of visual analyzer in controlling the standing posture in individuals with the spastic form of child cerebral paralysis while wearing "Adel" suit. *Aviakosm Ekolog Med.* 1996;30(6):8-13.
5. Liptak GS. Complementary and alternative therapies for cerebral palsy. *Ment Retard Dev Disabil Res Rev.* 2005;11(2):156-63.
6. National Institute of Neurological Disorders and Stroke. Cerebral palsy: Hope Through Research. Last updated July 13, 2007. Available at: http://www.ninds.nih.gov/disorders/cerebral_palsy/detail_cerebral_palsy.htm
7. United Cerebral Palsy (UCP) Research & Education Foundation. The Adeli Suit Update – March 1999. Available at: <http://www.ucpresearch.org/factsheets/adeli-suit-update-3-1999.php>

8. United Cerebral Palsy (UCP) Research & Education Foundation. The Adeli Suit Update – November 2004. Available at: <http://www.ucpresearch.org/fact-sheets/adeli-suit-update-11-2004.php>
9. The TheraSuit Method. Available at: <http://www.suittherapy.com/therasuit%20info.htm>
10. Adeli Suit. Euromed. Available at: <http://www.euromed.pl/en/index.php>

Important Notice

General Purpose.

Health Net's National Medical Policies (the "Policies") are developed to assist Health Net in administering plan benefits and determining whether a particular procedure, drug, service or supply is medically necessary. The Policies are based upon a review of the available clinical information including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the drug or device, evidence-based guidelines of governmental bodies, and evidence-based guidelines and positions of select national health professional organizations. Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract, including medical necessity requirements. Health Net may use the Policies to determine whether under the facts and circumstances of a particular case, the proposed procedure, drug, service or supply is medically necessary. The conclusion that a procedure, drug, service or supply is medically necessary does not constitute coverage. The member's contract defines which procedure, drug, service or supply is covered, excluded, limited, or subject to dollar caps. The policy provides for clearly written, reasonable and current criteria that have been approved by Health Net's National Medical Advisory Council (MAC). The clinical criteria and medical policies provide guidelines for determining the medical necessity criteria for specific procedures, equipment, and services. In order to be eligible, all services must be medically necessary and otherwise defined in the member's benefits contract as described in this "Important Notice" disclaimer. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to practice medicine.

Policy Effective Date and Defined Terms.

The date of posting is not the effective date of the Policy. The Policy is effective as of the date determined by Health Net. All policies are subject to applicable legal and regulatory mandates and requirements for prior notification. If there is a discrepancy between the policy effective date and legal mandates and regulatory requirements, the requirements of law and regulation shall govern. * In some states, new or revised policies require prior notice or posting on the website before a policy is deemed effective. For information regarding the effective dates of Policies, contact your provider representative. The Policies do not include definitions. All terms are defined by Health Net. For information regarding the definitions of terms used in the Policies, contact your provider representative.

Policy Amendment without Notice.

Health Net reserves the right to amend the Policies without notice to providers or Members. In some states, new or revised policies require prior notice or website posting before an amendment is deemed effective.

No Medical Advice.

The Policies do not constitute medical advice. Health Net does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

No Authorization or Guarantee of Coverage.

The Policies do not constitute authorization or guarantee of coverage of particular procedure, drug, service or supply. Members and providers should refer to the Member contract to determine if exclusions, limitations, and dollar caps apply to a particular procedure, drug, service or supply.

Policy Limitation: Member's Contract Controls Coverage Determinations.

The determination of coverage for a particular procedure, drug, service or supply is not based upon the Policies, but rather is subject to the facts of the individual clinical case, terms and conditions of the member's contract, and requirements of applicable laws and regulations. The contract language contains specific terms and conditions, including pre-existing conditions, limitations, exclusions, benefit maximums, eligibility, and other relevant terms and conditions of coverage. In the event the Member's contract (also known as the benefit contract, coverage document, or evidence of coverage) conflicts with the Policies, the Member's contract shall govern. Coverage decisions are the result of the terms and conditions of the

Member's benefit contract. The Policies do not replace or amend the Member's contract. If there is a discrepancy between the Policies and the Member's contract, the Member's contract shall govern.

Policy Limitation: Legal and Regulatory Mandates and Requirements.

The determinations of coverage for a particular procedure, drug, service or supply is subject to applicable legal and regulatory mandates and requirements. If there is a discrepancy between the Policies and legal mandates and regulatory requirements, the requirements of law and regulation shall govern.

Policy Limitations: Medicare and Medicaid.

Policies specifically developed to assist Health Net in administering Medicare or Medicaid plan benefits and determining coverage for a particular procedure, drug, service or supply for Medicare or Medicaid members shall not be construed to apply to any other Health Net plans and members. The Policies shall not be interpreted to limit the benefits afforded Medicare and Medicaid members by law and regulation.