Clinical Policy Bulletin: 
Suit Therapy 
Revised April 2014 

Number: 0696

Policy

Aetna considers suit therapy or home use of a suit therapy device (also known as the Adeli Suit, Penguin Suit, Polish Suit, Stabilizing Pressure Input Orthoses, Therapy Suit, Therasuit, and TheraTogs) experimental and investigational for the treatment of members with cerebral palsy or other conditions (e.g., gait rehabilitation following stroke) because there is inadequate evidence of the effectiveness of this therapy in the management of these conditions.

Aetna considers dynamic movement TLSO “brace” (Dynamic Lycra Suit) experimental and investigational for the treatment of members with cerebral palsy or scoliosis because there is inadequate evidence of the effectiveness of this therapy in the management of these conditions.

Aetna considers Dynamic Movement Orthoses experimental and investigational for the treatment of members with cerebral palsy, hemiparesis/hemiplegia, scoliosis, and all other indications because there is inadequate evidence of the effectiveness of this therapy in the management of these conditions.

Also see CPB 0405 - Mechanical Stretching Devices for Contracture and Joint Stiffness.

Background

The Adeli Suit (also known as the Polish Suit, Therapy Suit, and Therasuit) is a modification of a space suit, called the “Penguin” suit used by Russian cosmonauts to counter the effects of long-term weightlessness on the body while in space. The inner workings of the suit have elastic bands and pulleys that created artificial force against which the body could work to help prevent muscle atrophy and osteoporosis.

Although the cause of motor dysfunction between cerebral palsy (CP) patients and astronauts are different, results of a treatment trial with the Penguin suit to
rehabilitate patients with CP appeared promising. The Penguin suit was then modified resulting in an elasticized suit for use in positioning and stretching muscles during physical therapy. Suit therapy for CP is currently available at the Euromed Clinic in Poland and at several other centers in Europe and the United States. The Adeli Suit is used in the Polish facility as part of a comprehensive program of intensive physiotherapy administered 5 to 7 hours per day for 5 to 6 days a week for 4 weeks.

According to the Euromed Rehabilitation Center website: "The Adeli Suit consists of a vest, shorts, knee pads and specially adapted shoes with hooks and elastic cords that help tell the body how it is supposed to move in space. Therapists use the Adeli Suit to hold the body in proper physical alignment. During specialized exercises, the therapists adjust the elastic connectors that topographically mirror flexor and extensor muscles, trunk rotators and the lower limbs. Additional attachments correcting the position of the feet, head and other areas of the body have also been designed. A patient, while wearing the Adeli Suit, goes through various exercises including "how to walk". The Suit works as an elastic frame surrounding the body and does not limit the amplitude of movement but adds an additional weight load on it within designed limits."

There are published anecdotal reports (the majority of which are published in the Russian language) of children gaining in speech, fine motor control, as well as movement with suit therapy, but no randomized controlled clinical trials of suit therapy have been published. The U.S. Food and Drug Administration (FDA) has classified the Adeli Suit and other similar devices as a class 1 limb orthosis (brace). Thus, the Adeli Suit is exempt from the premarket notification procedures of the FDA and the manufacturer is not required to provide evidence of efficacy prior to marketing.

Enough interest has been generated by anecdotal and verbal reports that the United Cerebral Palsy (UCP) Research and Educational Foundation (2004) funded 2 studies on suit therapy. While the results of these studies are not yet available in the peer-reviewed published medical literature, the UCP Research and Educational Foundation website is making the information available due to the current interest in suit therapy.

The first study by Dr. Alexander Frank and associates at the Motion Analysis Laboratory, Assaf Harofeh Medical Center, Zerifin, Israel, reported the results of 24 children who had CP and a functional level of II, III or IV according to the Gross Motor Function Classification System. Patients were randomly assigned to either a standard physical therapy program or to the Adeli Suit. Both groups were treated 5 days per week for 2 hours. Marginal improvement was noted in both groups without any statistical difference in results between the 2 groups.

A second study by Dr. Edward Dabrowski at the Children's Hospital of Michigan reported the results of 57 children, all of whom received 1 hour of physical, occupational, and speech therapy 3 times a week for 8 to 10 weeks followed by a 4-week home program. The experimental group wore the Adeli Suit for the last 4 weeks of their therapy program. Both groups improved and sustained their improvement without any statistical difference in results between the 2 groups.

The UCP Foundation concluded that "[t]hese 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."

Controlled clinical studies are necessary to determine the beneficial effects of suit therapy, if any, for the treatment of CP, especially which patients would benefit the most and how long any beneficial results would last.

Liptak (2005) reviewed 9 treatment modalities used for children who have CP including the Adeli Suit. The author noted that no conclusive evidence either in support of or against the use of the Adeli suit is available.

Bar-Haim and colleagues (2006) compared the effectiveness of Adeli suit treatment (AST) with neurodevelopmental treatment (NDT) in children with CP. A total of 24 children with CP, levels II to IV according to the Gross Motor Function Classification System (GMFCS), were matched by age and functional status and randomly assigned to the AST or NDT treatment groups. In the AST group (n = 12; 8 males, 4 females; mean age of 8.3 years [SD 2.0]), 6 children had spastic/ataxic diplegia, 1 triplegia and 5 spastic/mixed quadriplegia. In the NDT group (n = 12; 9 males, 3 females; mean age of 8.1 years [SD 2.2]), 5 children had spastic diplegia and 7 had spastic/mixed quadriplegia. 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 2 treatment modes. Post-hoc analysis indicated a greater increase in EIHB after 1 month (p = 0.16) and 10 months (p = 0.004) in AST than in NDT, predominantly in the children with higher motor function (GMFCS Levels II and III). The results suggested that AST might improve mechanical efficiency without a corresponding gain in gross motor skills, especially in children with higher levels of motor function. These investigators also stated that "future studies on the effectiveness 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 to reduce variability ....".

TheraTogs (TheraTogs, Inc., Telluride, CO) are an orthotic undergarment that consist of a 2-piece body suit and a strapping system that is customized for the child. TheraTogs are worn every day and, according to the manufacturer's website, are indicated for children with a variety of disorders, including ataxia, athetosis, low muscle tone, poor postural alignment and joint deviations. There is a lack of evidence of the effectiveness of TheraTogs in the peer-reviewed, published medical literature.

Stabilizing Pressure Input Orthoses (SPIO) are made from a Lycra-like blend material that are intended to provide deep pressure through compression to improve positional limb and body awareness, core muscle and joint stabilization, and increase precision of muscle activation and movement.
Hylton and Allen (1997) stated that the use of flexible compression bracing in persons with neuromotor deficits offers improved possibilities for stability and movement control without severely limiting joint movement options. This treatment modality has been explored with increasing application in children with moderate to severe CP and other neuromotor deficits with good success. Significant functional improvements using Neoprene shoulder/trunk/hip bracing led these researchers to experiment with much lighter compression materials. The stabilizing pressure input orthosis (SPIO) bracing system is custom-fitted to the stability, movement control and sensory deficit needs of a specific individual. The SPIO bracing system supposedly can provide an improved base of support for functional gains in balance, dynamic stability, general and specific movement control with improved postural and muscle readiness. However, there is currently insufficient evidence to support the effectiveness of SPIO.

Autti-Ramo and colleagues (2006) reviewed the evidence on the effectiveness of using upper and lower limb casting or orthoses in children with CP. These researchers used computerized bibliographic databases to search for systematic reviews without any language restrictions. Identification, selection, quality assessment, and data extraction were performed independently by 2 investigators. Of the 40 identified reviews, 23 were selected for closer consideration, and 5 reviews met the inclusion criteria. The quality of existing systematic reviews and original studies included in the review varied widely. The following evidence was found: (i) casting of lower limbs has a short-term effect on passive range of movement; (ii) orthoses that restrict ankle plantar flexion have a favorable effect on an equinus walk, but the long-term clinical significance is unclear; and (iii) evidence on managing upper limb problems with casting or splinting in children with CP is inconclusive. The author concluded that there is a paucity of evidence from primary studies on the use of orthoses in children with CP. They stated that more original, well-designed research is needed. Available evidence does not demonstrate durable benefits from the use of suit therapy for CP (NHSC, 2002; NHS QIS, 2005).

In a case report, Bailes et al (2010) investigated the effects of intensive suit therapy on gait, functional skills, care-giver assistance, and gross motor ability in children with CP. Two children with spastic diplegia classified at level III on the GMFCS participated. Outcomes were assessed using dimensions D and E of the GMFCS, the Pediatric Evaluation of Disability Inventory (PEDI), and instrumented gait analysis. Each child participated in the Therasuit Method, 4 hours a day, 5 days a week for 3 weeks. Very small improvements in function were noted in dimension D of the GMFCS and PEDI Self-care Domain with decreased function in other areas. Improved walking speed, cadence, symmetry, joint motion, and posture were found with gait analysis. The authors concluded that further investigation is needed of the suit itself, and intensive therapy programs in children with CP.

Bailes et al (2011) examined the effects of suit wear during an intensive therapy program on motor function among children with CP. A total of 20 children were randomized to an experimental (TheraSuit) or a control (control suit) group and participated in an intensive therapy program. The PEDI and 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 that 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.

Maguire et al (2012) presented the protocol of a study designed to investigate the long-term effects on the recovery of gait, balance and social participation of gait rehabilitation with TheraTogs compared to gait rehabilitation with a cane following first time acute stroke. This study will be a multi-center, single-blind, randomized trial with 120 patients after first stroke. When subjects have reached Functional Ambulation Category 3 they will be randomly allocated into TheraTogs or cane group. TheraTogs will be applied to support hip extensor and abductor musculature according to a standardized procedure. Cane-walking held at the level of the radial styloid of the sound wrist. Subjects will walk throughout the day with only the assigned walking aid. Standard therapy treatments and usual care will remain unchanged and documented. The intervention will continue for 5 weeks or until patients have reached Functional Ambulation category 5. Outcome measures will be assessed the day before begin of intervention, the day after completion, 3 months, 6 months and 2 years. Primary outcome is Timed "up and go" test; secondary outcomes are peak surface electromyography of gluteus maximus and gluteus medius, activation patterns of hemiplegic leg musculature, temporo-spatial gait parameters, hemiplegic hip kinematics in the frontal and sagittal planes, dynamic balance, daily activity measured by accelerometry, Stroke Impact Scale. Significance levels will be 5 % with 95 % confidence intervals. Intention-to-treat analyses will be performed. Descriptive statistics will be presented. The authors concluded that this study could have significant implications for the clinical practice of gait rehabilitation after stroke, particularly the effect and appropriate use of walking aids. The results could be important for the development of clinical guidelines and for the socio-economic costs of post-stroke care.

In a case-study, Matthews and Crawford (2006) noted that treatment of scoliosis has been under discussion in relation to surgical intervention since the Boston brace was presented by Hall in 1976. The effects of rigid bracing on thoracic skeletal integrity and the possible deformation of ribs due to the high localized pressure due to prolonged wear have been high-lighted. The lack of compliance has encouraged clinicians to examine other options for non-surgical treatment. The Spinecor and Triac bracing systems have been developed as a result of this research; however, both of these orthoses had been designed with idiopathic scoliosis in mind. Little research has been done into the effects of bracing on the neuropathic curve. The use of dynamic Lycra garments in the treatment of neurological scoliosis offers the advantage of deformity correction without the bulk and discomfort of rigid braces. Recent clinical experience has shown that the Lycra suits have a positive effect in the treatment of scoliosis. The authors discussed the treatment of a child presenting with a spinal tumor and although not truly of neurological presentation indicates that the garment can be used for the different scoliotic presentations.
In a phase 1 exploratory study, Matthews et al (2009) aimed to establish proof of concept of the effects of dynamic elastomeric fabric orthoses (DEFOs) on the gait of children with spastic diplegic CP. Replicated single case experiments employing an ABA methodology were carried out on 8 subjects (median age of 5.5 years, range of 3 to 13 years; 4 girls and 4 boys) utilizing quantitative/qualitative data collection. Outcome measures were: 10-meter walking test (10MWT); physiological cost index (PCI); visual analog scale (VAS) scoring of perceived gait changes; functional mobility changes using Patient Specific Functional Scale (PSFS); subject/carer perceptions recorded in daily diaries. Results identified following analysis of quantitative data indicated a treatment effect from the orthoses, which could be corroborated by participant's subjective impressions and comments. Statistically significant (p < 0.05) intervention-related improvements in gait velocity and gait consistency were identified in 5/8 and 4/8 subjects, respectively. Power calculations support the feasibility of a larger controlled study to further investigate this orthotic intervention. This study indicated that DEFO leggings can confer beneficial effects on the gait of some children with spastic diplegia resulting from CP. They noted that these findings have implications for orthotic intervention with this subject group.

In a pilot study, Jeon et al (2012) evaluated the feasibility of intensive training using a spring-assisted hand orthosis on upper extremity in individuals with chronic hemiparetic stroke. A total of 5 participants for the experimental group and 5 for the control group were recruited from a local rehabilitation hospital. Subjects in the experimental group participated in 4 weeks of training using a SaeboFlex orthosis for 1 hour per day, 5 times per week. Each subject in the control group wore the same orthosis for 1 hour per day without participating in upper extremity training. Outcome measures included the Fugl-Meyer Assessment, Box and Block Test, and Action Research Arm Test; kinematic parameters were collected using a 3-D motion analysis system. The Fugl-Meyer assessment and the Box and Block Test score were increased significantly in the experimental group after the intervention. The resultant velocity of the wrist joint for the reach-to-grasp task decreased significantly, and the resultant velocity of the shoulder joint while performing a reach-to-grasp task at acromion height decreased significantly in the experimental group. The authors concluded that spring-assisted dynamic hand orthosis training is feasible in recovering the movement of the hemiparetic upper extremity.

In a pilot study, Barry et al (2012) compared the effect of therapy using a wrist-hand orthosis (WHO) versus manual-assisted therapy (MAT) for individuals with chronic, moderate-to-severe hemiparesis. The relationship between the repetitions during therapy and functional change was also examined. A total of 19 participants were randomly assigned to either the WHO group (n = 10) or the MAT group (n = 9). The WHO group performed therapy while wearing a dynamic WHO (SaeboFlex), the MAT group performed therapy with manual assistance of a therapist. Both groups participated in 1 hour of therapy per week for 6 weeks and were prescribed exercises to perform at home 4 days per week. Pre- and post-training assessments included grip strength, the Action Research Arm Test (ARAT), Box and Blocks (B&B) test, and Stroke Impact Scale (SIS). There were no significant between-group differences for any of the measures. Within-group differences showed that the WHO group had a significant improvement in the
ARAT score (mean = 2.2; p = 0.04). The MAT group had a significant improvement on the percent recovery on the SIS (mean = 9.3 %; p = 0.03) and approached a significant improvement on the ARAT (mean = 1.4; p = 0.08). When analyzing all participants together, the relationship between the number of exercise repetitions and functional improvement was moderate for the ARAT and the B&B test (r = 0.55, p = 0.02, and r = 0.30, p = 0.10, respectively). The authors concluded that small improvements in function and perception of recovery were observed in both groups, with no definite advantage of the WHO.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes not covered for indications listed in the CPB:

There is no specific CPT code for suit therapy or Dynamic Movement Orthoses:

ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>342.00</td>
<td>Hemiplegia and hemiparesis</td>
</tr>
<tr>
<td>342.92</td>
<td></td>
</tr>
<tr>
<td>343.0 - 343.9</td>
<td>Infantile cerebral palsy</td>
</tr>
<tr>
<td>358.0 - 359.9</td>
<td>Myoneural disorders, muscular dystrophies and other myopathies</td>
</tr>
<tr>
<td>438.0 - 438.9</td>
<td>Late effects of cerebrovascular disease</td>
</tr>
<tr>
<td>718.40 - 718.49</td>
<td>Contracture of joint</td>
</tr>
<tr>
<td>728.2</td>
<td>Muscular wasting and disuse atrophy, not elsewhere classified</td>
</tr>
<tr>
<td>728.85</td>
<td>Spasm of muscle</td>
</tr>
<tr>
<td>728.89</td>
<td>Other disorders of muscle, ligament, and fascia</td>
</tr>
<tr>
<td>733.00 - 733.09</td>
<td>Osteoporosis</td>
</tr>
<tr>
<td>737.30 - 737.4</td>
<td>Kyphoscoliosis and scoliosis</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:


