Clinical Policy Title: Dynamic movement orthoses (suit therapy)

Clinical Policy Number: 14.02.05

Effective Date: October 1, 2015
Initial Review Date: June 17, 2015
Most Recent Review Date: July 3, 2018
Next Review Date: July 2019

Policy contains:
- Dynamic movement orthoses.
- Suit therapy.
- Motor-related problems.
- Cerebral palsy.

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Select Health of South Carolina when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Select Health of South Carolina’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of dynamic movement orthoses (suit therapy) to be investigational and, therefore, not medically necessary.

Limitations:

None.

Alternative covered services:

None.

Background

Dynamic movement orthosis, also known as suit therapy, has been used in patients with various motor dysfunctions, especially cerebral palsy, who typically have problems with gait and other aspects of movement. An estimated 764,000 Americans have the condition, of whom 500,000 are children under 18 (MyChild, 2018). Intensive physical therapy is sometimes given to children suffering from certain motor-
related disorders, with cerebral palsy being the most common. Treatment tends to be short term, i.e., several weeks, featuring a daily regimen lasting several hours per day.

Therapeutic suits were first created in the late 1960s in Russia for use by astronauts (Semenova, 1997). An adaptation of this suit used in medicine cerebral palsy was developed by the Pediatric Institute of the Russian Academy of the Medical Sciences in the early 1990s. The suit, which consists of a vest, kneepads, shoes, and sometimes a headpiece, stabilizes the torso to allow coordinated movement of the limbs. Stimulation of the brain retrained it to recognize and initiate proper movement of the muscles.

While motor functions of many body parts can be improved by orthoses, this policy focuses on lower limbs. There are a variety of suits available for such treatment. They include stabilizing pressure input orthosis, the Adeli suit, the Penguin suit, the Polish suit, the Therapy suit, the Therasuit, and TheraTogs. Garments can include vests, shirts, pants, shorts, unitards, abdominal wraps, arm and leg wraps, and compression gloves. The garments are designed to essentially “inform” the patient’s body how to correctly move, by changing positions of certain body parts and adding additional weight. The U.S. Food and Drug Administration (2017) has approved dynamic movement orthoses/suit therapy products typically as class 1 orthoses, which means the manufacturer is not required to inform efficacy.

Searches

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on May 9, 2018. Search terms were: “Adeli suit,” “Penguin suit,” “Polish suit,” “stabilizing pressure input orthoses,” “suit therapy,” “Thera suit,” “TheraTogs” and “Therapy suit.”

We included:

- Systematic reviews, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- Guidelines based on systematic reviews.
- Economic analyses, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings
One early dynamic movement orthoses model was the Adeli-92 device, evaluated in Russia, showing positive results in improvement in walking and self-care ability in children with cerebral palsy (Semenova, 1997; Shvarkov, 1997). Another was an ankle-foot orthosis for children ages 2 – 5 years with spastic diplegia and dynamic equinus, successfully used in Texas Scottish Rite Hospital in Dallas, Texas (Wilson, 1997) and Kluge Children’s Rehabilitation Center in Charlottesville, Virginia (Carlson, 1997).

A search of the medical literature found six randomized controlled trials on suit therapy published subsequent to the initial studies in Israel and Michigan. The trials included a relatively small number of participants (13 to 57) and reported conflicting results of efficacy, e.g., improvement in gait and other motor functions, compared to baseline and controls.

One randomized controlled trial showed improvement in gait using TheraTogs, a type of suit therapy, and orthoses in children with cerebral palsy (Abd El Kafy, 2014). Another showed that TheraTogs and hip abductor taping significantly improved gait speed and hip abductor activity in patients with stroke (Maguire, 2010). Alagesan (2010) found significantly greater improvement in gross motor function among children with cerebral palsy using modified suit therapy. Another supported suit therapy to improve functional outcomes, gait analysis, posture, walking speed, and mechanical efficiency (Pitchay, 2012).

On the other hand, Bailes (2011) found no significant difference in gross motor function measure change between cerebral palsy children wearing Thera suits and controls. Bar-Haim (2006) found no significant differences in gross motor function measure improvement between cerebral palsy children wearing Adeli suits versus controls, but found significantly greater improvements in mechanical efficiency index. A randomized controlled trial of 28 children with spastic cerebral palsy, who were able to walk, found no benefit and poor tolerance of the ankle-foot orthoses over a 12-month period (Maas, 2014).

A narrative review of neurodevelopmental therapy concluded that Adeli suit programs have not demonstrated superiority over alternative treatments (Damiano, 2009). One published meta-analysis found that suit therapy significantly improved gross motor function after treatment and follow up (Martins, 2016). It also noted that there are small numbers of studies (just four of 46 studies qualified for this review), often with small sample sizes, on the efficacy of suit therapy, and more trials are needed on all dimensions of functioning.

Additional observational studies analyzed changes in motor functions for children with cerebral palsy. Two of these reviewed the TheraSuit (Christy, 2012) and TheraTog garments (Flanagan, 2009); the former found improvement in gross motor function measure, but not in walking amount or intensity, while the latter found improved gait. Matthews (2009) identified greater gait velocity in five of eight subjects and consistency with cerebral palsy in four of eight subjects that used dynamic elastomeric fabric orthoses.

**Policy updates:**

New references have been added, several of which were included in the Summary of clinical evidence section.

In 2017, we found no new information to add. Therefore, no policy changes are warranted.
In 2018, we added one systematic review (Almeida, 2017) and no changes to the policy.

### Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td><strong>Almeida (2017)</strong></td>
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</table>
| Effects of interventions with therapeutic suits (clothing) on impairments and functional limitations of children with cerebral palsy (CP): a systematic review | Key points:  
  - Systematic review of 13 studies of therapeutic suits: Full Body Suit (two studies); Dynamic Elastomeric Fabric Orthose (two studies); TheraTogs (three studies); and Thera Suit/Adeli Suit protocols (six studies).  
  - Overall quality: very low or low based on the Grading of Recommendations Assessment, Development, and Evaluation protocol.  
  - Inconclusive results for improving body structure, function, and activity outcomes based on poor quality data. |
| **Martins (2016)**     |                                   |
| Suit therapy efficacy on children and adolescents with cerebral palsy | Key points:  
  - Meta-analysis included four trials.  
  - Significant increase in gross motor function at post-treatment and follow up.  
  - Small number of studies and small sample sizes. |
| **Abd El-Kafy (2014)** |                                   |
| Improvement in gait, cadence, stride length from dynamic movement orthoses | Key points:  
  - Fifty-seven subjects with CP given 12 weeks of therapy.  
  - Subjects grouped into those with orthotic management, TheraTogs only, and TheraTogs and ankle foot orthoses.  
  - TheraTogs and ankle foot orthoses had greatest improvement in gait. |
| **Maas (2014)**        |                                   |
| Maintenance of ankle-foot dorsiflexion range of motion using ankle-foot orthoses | Key points:  
  - Twenty-eight subjects ages 4 – 16, divided into experimental and control groups.  
  - No difference between groups in change of ankle-foot dorsiflexion range of motion, or in secondary outcomes.  
  - Average wearing time limited to 3.2 hours a night due to discomfort. |
| **Pitchay (2012)**     |                                   |
| Literature review of effectiveness of suit therapy on children with CP | Key points:  
  - Eight studies (only two were randomized controlled trials).  
  - All but one study found suit therapy improved functional outcomes, gait analysis, posture, walking speed, and mechanical efficiency. |
| **Bailes (2011)**      |                                   |
| Measuring gross motor function measure change in patients wearing Thera suit | Key points:  
  - Twenty subjects with CP given nine weeks' therapy or in control group.  
  - No significant differences in gross motor function measure change found between groups. |
| **Alagesan (2010)**    |                                   |
| Measuring improvements in gross motor function | Key points:  
  - Thirty subjects with CP given three weeks therapy.  
  - Modified suit therapy and physiotherapy groups had significant improvements. |
<table>
<thead>
<tr>
<th>Citation</th>
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<tr>
<td>using modified suit therapy and physiotherapy:</td>
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<tr>
<td>Maguire (2010)</td>
<td>Key points:</td>
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<tr>
<td>Measuring changes in hemiplegic hip abductor activity and gait speed</td>
<td>• Thirteen subjects with stroke given six gait cycle therapy.</td>
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<tr>
<td></td>
<td>• Hip abductor taping, TheraTogs, cane in non-hemiplegic hand.</td>
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<td>• Hip abductor taping and TheraTogs showed significantly better progress.</td>
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**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**CMS National Coverage Determinations:**
No NCDs identified as of the writing of this policy.

**Local Coverage Determinations:**

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill in accordance with those manuals.

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