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 21, 2015
Next Review Date: June 2016

Related policies: None

ABOUT THIS POLICY: Arbor Health Plan has developed clinical policies to assist with making coverage determinations. Arbor Health Plan’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 Arbor Health Plan 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. Arbor Health Plan’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. Arbor Health Plan’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Arbor Health Plan will update its clinical policies as necessary. Arbor Health Plan’s clinical policies are not guarantees of payment.

Coverage policy

Arbor Health Plan considers the use of dynamic movement orthoses (suit therapy) to be investigational and not clinically proven, and therefore, not covered.

Limitations:

None

Alternative covered services:

None

Background

Dynamic movement orthoses (DMO), also known as suit therapy, is a treatment administered to patients with motor dysfunctions. Most frequently, suit therapy is used for children with cerebral palsy (CP) who typically have problems with gait and other aspects of movement. While motor functions of many body parts can be improved by orthoses, this review will focus on lower limbs.
There are a variety of suits available for such treatment. They include stabilizing pressure input orthosis (SPIO), the Adeli suit, the Penguin suit, the Polish suit, the Therapy suit, the Thera suit 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.

Intensive physiotherapy is sometimes given to children suffering from certain motor-related disorders, with CP being the most common of these. Treatment tends to be short-term, i.e., several weeks, featuring a daily regimen of several hours per day.

DMOs/suit therapy products have been approved for use by the U.S. Food and Drug Administration (FDA). However, these devices are typically considered class 1 orthoses, which means the manufacturer is not required to inform the FDA on efficacy.

**Searches**

Arbor Health Plan 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 (CMS).

We conducted searches in May 2015. USearch terms were: “Adeli suit”, “Penguin suit,” “Polish suit,” “SPIO/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**

Earliest studies: Caregivers have been using various forms of suit therapy for decades. As early as 1999, United Cerebral Palsy reported on randomized controlled trials (RCTs) in the Assef Harofeh Medical Center in Israel and Children’s Hospital in Michigan on children with CP. While these studies were never
published in the peer-reviewed literature, they showed only marginal differences in improvement in children with CP who wore Adeli suits (United Cerebral Palsy (UCP) Research & Education Foundation).

RCTs: A search of the medical literature found seven RCTs on suit therapy, all subsequent to the initial studies in Israel and Michigan. One of these was just a description of methods, with no results as of May 2015. The trials included a relatively small number of participants (13, 20, 24, 30, 36 and 57).

Some of these reports documented efficacy, i.e., some showed suit therapy to improve gait and other motor functions compared to baseline and controls. One study showed improvement in gait using TheraTogs, a type of suit therapy, and orthoses in children with CP (El Kafy). Another showed that TheraTogs and hip abductor taping significantly improved gait speed and hip abductor activity in stroke patients (Maguire 2010). Alagesan and Khayatzdeh both found significantly greater improvement in gross motor function among children with CP using modified suit therapy.

But Bailes found no significant difference in gross motor function measure (GMFM) change between CP children wearing TheraSuits and controls. Bar-Haim found no significant differences in GMFM improvement between CP children wearing Adeli suits versus controls, but did find significantly greater improvements in Mechanical Efficiency Index (EIHB).

Pitchay published conference proceedings in 2012, using eight studies of suit therapy on children with CP; only two of these were RCTs. Of the eight reports, all but one supported the use of suit therapy to improve functional outcomes, gait analysis, posture, walking speed and mechanical efficiency.

Other studies: Additional studies that are not RCTs analyzed changes in motor functions for children with CP. Two of these reviewed use of TheraSuit (Christy) and TheraTog garments (Flanagan); the former found improvement in GMFM, but not in walking amount or intensity, while the latter found improved gait. Matthews identified greater gait velocity in five of eight subjects and consistency (four of eight subjects) with CP that used dynamic elastomeric fabric orthoses.

Other articles that focused on a single child with CP found improvements in gait, GMFM, and balance (Ko) and in-toeing (Richards).

**Glossary**

**Adeli suit** — One of several suits to improve movement, often in children with CP.

**Cerebral palsy (CP)** — A disorder of the brain, typically beginning in pregnancy or soon after birth, affecting movement, balance and posture.

**Dynamic movement orthoses (DMO)** — A garment used to improve movement, typically walking and gait, in children with motor-related disorders.

**Gross motor function measure** — A means of calculating motor function, often used in studies of suit therapy.
Suit therapy — See dynamic movement orthoses.

Professional society guidelines/other:
None

Peer-reviewed references:


Other references:


Summary of clinical evidence

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content</th>
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| **Randomized controlled trials** | *El-Kafy (2014)* **Key points:**  
  • N=57, CP, 12 weeks Rx, measures gait speed, cadence, stride length.  
  • No orthotic management, TheraTogs only, TheraTogs and ankle foot orthoses groups.  
  • TheraTogs and ankle foot orthoses had greatest improvement in gait. |
<p>| <strong>Maguire (2012)</strong> | <em>Key points:</em>                                                           |</p>
<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>Key points:</th>
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| Bales (2011) | • N=20, CP, nine weeks Rx, measures GMFM-66.  
• TheraSuit and control suit groups.  
• No significant differences found between groups. |
| Khayatzdeh (2011) | • N=36, CP, measures GMFM.  
• Modified Adeli suit therapy, Adeli suit therapy, neurodevelopment therapy.  
• All show significant improvement, especially MAST. |
• Modified suit therapy + physiotherapy significantly greater improvements. |
• Hip abductor taping, TheraTogs, cane in non-hemiplegic hand.  
• Hip abductor taping and TheraTogs showed significantly better progress. |
• Adeli Suit, neurodevelopmental treatment.  
• No significant difference in GMFM.  
• Significantly greater improvement in EIHB for Adeli suit group. |

Related policies:

Arbor Health Plan Utilization Management program description.

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

**Local Coverage Determinations (LCDs):**
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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