Prior Authorization Review Panel

MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.

Policies submitted without this form will not be considered for review.

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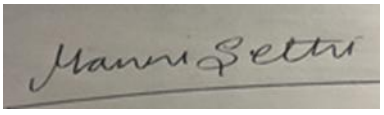
|---|---|
| Plan: AmeriHealth Caritas Pennsylvania & Keystone First | Submission Date: 9/1/2025 |
| Policy Number: CCP.1174 | Effective Date: 10/1/2015<br>Revision Date: 8/1/2025 |
| Policy Name: Dynamic movement orthoses (suit therapy) | |

| Type of Submission: | Type of Policy: |
|---|---|
| ☐ New Policy | ☒ Prior Authorization Policy |
| ☒ Revised Policy* | ☐ Base Policy |
| ☐ Annual Review- no revisions | ☒ Experimental/Investigational Policy |
| | ☐ Statewide PDL |
| | ☐ Other: |

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

| Name of Authorized Individual (Please type or print): | Signature of Authorized Individual: |
|---|---|
| Manni Sethi, MD, MBA, CHCQM |  |

# Dynamic movement orthoses (suit therapy)

Clinical Policy ID: CCP.1174

Recent review date: 8/2025

Next review date: 12/2026

Policy contains: Cerebral palsy; dynamic movement orthoses; motor-related problems; suit therapy.

*AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania 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 AmeriHealth Caritas Pennsylvania on a case by case basis 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. AmeriHealth Caritas Pennsylvania 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. AmeriHealth Caritas Pennsylvania clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania clinical policies are not guarantees of payment.*

## Coverage policy

Dynamic movement orthoses (suit therapy) is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

Absolute contraindications to use of lycra-based suit orthoses include, but are not limited to (Karadağ-Saygi, 2019):

- Severe restricted pulmonary function.
- Refractory cyanosis.
- Lycra allergy.

Relative contraindications include, but are not limited to (Karadağ-Saygi, 2019):

- Severe reflux symptoms.
- Uncontrolled epilepsy.
- Cardiovascular circulatory disorders.
- Diabetes diagnosis.
- High degree of spasticity.
- Hip dislocation.
- Severe scoliosis.
- Hydrocephalus.

- Myopathies.
- Progressive encephalopathies.
- Psychiatric or behavioral disorders.

Alternative covered services

- Casting.
- Orthopedic therapy.
- Physical therapy.
- Rigid orthoses.

## Background

Patients with motor dysfunction typically have problems with gait and other aspects of movement. Intensive physical therapy is sometimes given to children suffering from certain motor-related disorders, with cerebral palsy being the most common (MyChild, 2025). Treatment tends to be short term, i.e., several weeks, featuring a daily regimen lasting several hours per day.

Dynamic movement orthoses, also known as suit therapy, are lycra-based devices used as a bracing alternative for those who have not responded well to traditional bracing, and were first created in the late 1960s in Russia for use by astronauts (Semenova, 1997). Therapeutic suits or clothing associated with or without protocols have been used for children with cerebral palsy in rehabilitation, for their potential positive effects on posture, balance, motor coordination, and gait (Almeida 2017). The suit, which consists of a vest, kneepads, shoes, and sometimes a headpiece, stabilizes the torso to allow coordinated movement of the limbs by retraining the brain to recognize and initiate proper movement of the muscles.

While orthoses can improve motor functions of many body parts, 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 (Almeida, 2017).

The U.S. Food and Drug Administration (2025) has approved dynamic movement orthoses/suit therapy products typically as class 1 orthoses, and, therefore, the manufacturer is exempt from a premarket notification application and regulatory clearance requirement before marketing the device.

## Findings

Guidelines

We identified no professional clinical practice guidelines for this policy.

Evidence review

Current evidence consists of small observational studies and randomized studies of very low quality that investigated the use of dynamic suit orthoses for children with various movement disorders. The evidence does not permit conclusions about the benefits or harms of suit therapy.

A systematic review of 12 studies (four randomized controlled, three case series, three quasi-experimental designs, two single-subject experimental designs) investigated the effects of dynamic suit orthosis on spatio-temporal gait parameters. A total of 158 children, ages three to14 years, were studied with the same type of distribution and clinical phenotype of cerebral palsy. The Adeli suit, Theratogs, and an external strap orthosis

were used for the treatment of walking speed, stride length, step length, cadence and single-double support time. Although evidence was limited, dynamic suit orthosis appeared to have positive effects, especially in speed, cadence, and stride length. Despite those results, interventions using combined approaches demonstrated more improvement (Belizón-Bravo, 2021).

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.

One systematic review analyzed 13 studies of therapeutic suits: Full Body Suit (two studies); Dynamic Elastomeric Fabric Orthoses (two studies); TheraTogs (three studies); and Thera Suit/Adeli Suit protocols (six studies). The overall quality was classified as very low or low based on the Grading of Recommendations Assessment, Development, and Evaluation protocol. The results were inconclusive for improving body structure, function, and activity outcomes based on poor quality data (Almeida, 2017).

A critical review of the literature (Garavaglia, 2018) inclusive of three small clinical studies, one systematic review, and an overview of systematic reviews found insufficient evidence supporting the efficacy of therapeutic suits for the dynamic control of posture and stabilization of voluntary movements in persons with childhood dyskinesia.

Results of small randomized controlled studies provide additional evidence, albeit inconclusive. Giray (2020; Clinicaltrials.gov identifier NCT03191552) randomized 24 children aged three to nine with spastic diplegic cerebral palsy to one of three groups: children receiving conventional exercise therapy or children wearing a dynamic elastomeric fabric orthosis for either two hours or four hours. Children were followed for 12 weeks. Compared to conventional physical therapy alone, the group using dynamic orthotic garments showed significantly greater improvements in foot pressure distribution ($P < .005$ for all regions), balance ($P < .001$), trunk control ($P = .001$), and the six-minute walk distance ($P = .029$). To improve sitting balance, wearing dynamic elastomeric fabric orthosis vest for two hours during therapy was as effective as wearing it for six hours.

Emara (2024; Clinicaltrials.gov identifier NCT05271149) examined the effects of TheraTog dynamic orthotic garments in 34 children with spastic diplegic cerebral palsy worn over 12 weeks. Compared to conventional physical therapy alone, the group using TheraTogs showed significantly greater improvements in foot pressure distribution ($P < .005$ for all regions), balance (six-point median increase on Pediatric Berg Balance Scale vs. two-point increase in control, $P < .001$), trunk control (six-point median increase on Trunk Control Measurement Scale vs. two-point increase in control, $P < .001$), and endurance (50.23m vs. 36.26m increase in six-minute walking distance, $P < .029$). Limitations included the small sample size and the restriction to children with spastic diplegic cerebral palsy.

A single-blinded randomized controlled trial of 22 children with spastic cerebral palsy (Gross Motor Function Classification System levels 1 and 2) were randomized to receive physiotherapy (n = 13, three dropped out) or physiotherapy and a lower body and pelvis dynamic elastomeric fabric orthosis (n = 13, one dropped out) worn for eight hours daily. Both groups received treatment twice a week for eight weeks. Among the gait parameters measured, stride length ($P = .035$) and pelvic tilt in the frontal plane axis ($P = .014$) significantly improved in the dynamic elastomeric fabric orthosis group compared to the physiotherapy-only group. There was no change in gait speed, cadence, or balance scores between the groups (Bezgin, 2025).

In 2017, we found no new information to add. Therefore, no policy changes are warranted.

In 2018, we updated the references. No policy changes are warranted. The policy ID was changed from CP# 14.02.05 to CCP.1174.

In 2019, we updated the references. No policy changes are warranted.

In 2020, we added updated the references and added statements for absolute and relative contraindications to the policy limitations to guide determination of medical necessity where state Medicaid authority permits.

In 2021, we found no new relevant information to add to the policy. No policy changes are warranted.

In 2022, we found no new relevant information to add to the policy. No policy changes are warranted.

In 2023, we found no newly published, relevant information to add to the policy. No policy changes are warranted.

In 2024, we updated the references. No policy changes are warranted.

In 2025, we updated the references, reorganized the findings, and made no policy changes to coverage.

## References

On June 16, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Adeli suit,” “dynamic movement,” “Penguin suit,” “Polish suit,” “suit therapy,” “Thera suit,” “TheraTogs” and “cerebral palsy/rehabilitation (MeSH).” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

Almeida KM, Fonseca ST, Figueiredo PRP, Aquino AA, Mancini MC. Effects of interventions with therapeutic suits (clothing) on impairments and functional limitations of children with cerebral palsy: A systematic review. *Braz J Phys Ther*. 2017;21(5):307-320. Doi: 10.1016/j.bjpt.2017.06.009.

Belizón-Bravo N, Romero-Galisteo RP, Cano-Bravo F, et al. Effects of dynamic suit orthoses on the spatio-temporal gait parameters in children with cerebral palsy: A systematic review. *Children (Basel)*. 2021;8(11):1016. Doi: 10.3390/children8111016.

Bezgin S, Novak I, Çobanoğlu G, Elbasan B. Effects of dynamic elastomeric fabric orthoses in children with cerebral palsy: A single-blind randomized controlled trial. *Prosthet Orthot Int*. 2025;49(2):220-227. Doi: 10.1097/pxr.0000000000000425.

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Garavaglia L, Pagliano E, Baranello G, Pittaccio S. Why orthotic devices could be of help in the management of movement disorders in the young. *J Neuroeng Rehabil*. 2018;15(1):118. Doi: 10.1186/s12984-018-0466-8.

Giray E, Karadağ-Saygi E, Ozsoy T, Gungor S, Kayhan O. The effects of vest-type dynamic elastomeric fabric orthosis on sitting balance and gross manual dexterity in children with cerebral palsy: A single-blinded randomised controlled study. *Disabil Rehabil.* 2020;42(3):410-418. Doi: 10.1080/09638288.2018.1501098.

Karadağ-Saygı E, Giray E. The clinical aspects and effectiveness of suit therapies for cerebral palsy: A systematic review. *Turk J Phys Med Rehabil.* 2019;65(1):93-110. Doi: 10.5606/tftrd.2019.3431.

Martins E, Cordovil R, Oliveira R, et al. Efficacy of suit therapy on functioning in children and adolescents with cerebral palsy: A systematic review and meta-analysis. *Dev Med Child Neurol*. 2016;58(4):348-360. Doi: 10.1111/dmcn.12988.

MyChild at CerebralPalsy.org. About cerebral palsy. https://www.cerebralpalsy.org/about-cerebral-palsy. Published 2025.

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;27(6):639-643. Doi: 10.1007/BF02461920.

U.S. Food and Drug Administration. Product classification database searched on June 16, 2025 using product code MRI. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm.

## Policy updates

6/2015: initial review date and clinical policy effective date: 10/2015

6/2016: Policy references updated.

6/2017: Policy references updated.

6/2018: Policy references updated. Policy ID changed.

6/2019: Policy references updated.

8/2020: Policy references updated. Limitation statements added.

8/2021: Policy references updated.

8/2022: Policy references updated.

8/2023: Policy references updated.

8/2024: Policy references updated.

8/2025: Policy references updated.