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.

Plan: Plan: AmeriHealth Caritas Pennsylvania & Keystone First	**Submission Date**: 9/1/2024
Policy Number: CCP.1174	**Effective Date:** 10/2015 **Revision Date:** August 1, 2024
Policy Name: Dynamic movement orthoses (suit therapy)	

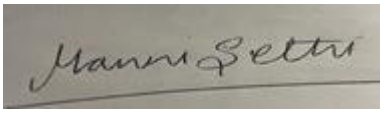
Type of Submission – Check all that apply:

☐ **New Policy**
☒ **Revised Policy***
☐ **Annual Review – No Revisions**
☐ **Statewide PDL**

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

Please provide any clarifying information for the policy below:

See tracked changes below

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

Keystone First
Family of Health Plans

Dynamic movement orthoses (suit therapy)

Clinical Policy ID: CCP.1174

Recent review date: 8/2024

Next review date: 12/2025

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

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First'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 Keystone First, 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. Keystone First'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. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's 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, 2023). 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 (2023) has approved dynamic movement orthoses/suit therapy products typically as class 1 orthoses, and, therefore, the manufacturer is not required to inform efficacy.

Findings

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 3 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.

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

In 2018, we added one systematic review (Almeida, 2017) of 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. No policy changes are warranted. The policy ID was changed from CP# 14.02.05 to CCP.1174.

In 2019, we added a narrative literature review to the policy. 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 the stabilization of voluntary movements in persons with Childhood Dyskinesia. No policy changes are warranted.

In 2020, we added the results of a small, single-blinded, randomized controlled study (Clinicaltrials.gov identifier NCT03191552; Giray, 2020; n = 24) and a systematic review (Karadağ-Sayg, 2019) to the policy. The new information would not change previous findings, and no changes to coverage are warranted. Karadağ-Saygi (2019) identified contraindications and adverse events that should be considered in any case-by-case evaluation. We 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 found a study that detailed a randomized controlled trial (Clinicaltrials.gov identifier NCT05271149; Emara, 2024; n = 34) that examined the effects of dynamic orthotic garments on children with spastic diplegic cerebral palsy over 12 weeks. Compared to conventional physical therapy alone, the group using dynamic orthotic garments showed significantly greater improvements in foot pressure distribution ($p<0.005$ for all regions), balance (six-point median increase on Pediatric Berg Balance Scale vs. two-point increase in control, $p<0.001$), trunk control (six-point median increase on Trunk Control Measurement Scale vs. two-point increase in control, $p=0.001$), and endurance (50.23m vs. 36.26m increase in six-minute walk distance, $p=0.029$). Limitations included the small sample size and the restriction to children with spastic diplegic cerebral palsy, limiting the generalizability to other types of cerebral palsy or conditions. No policy changes are warranted.References

On July 11, 2024, 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. Published 2021 Nov 5. Doi:10.3390/children8111016.

Emara, H.A., Al-Johany, A.H., Khaled, O.A., et al. Effect of the dynamic orthotic garment on postural control, and endurance in children with spastic diplegic cerebral palsy: a randomized controlled trial. *Journal of Multidisciplinary Healthcare*. 2024;17 (419-428). Doi:10.2147/JMDH.S438474.

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.

Maguire C, Sieben JM, Frank M, Romkes J. Hip abductor in walking following stroke — the immediate effect of canes, taping, and TheraTogs on gait. *Clin Rehabil*. 2010;24(1):37-45. Doi: 10.1177/0269215509342335.

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 2023.

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 May 23, 2023 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.