Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
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Plan: AmeriHealth Caritas Pennsylvania	**Submission Date**: 3/1/2024
Policy Number: ccp.1479	**Effective Date:** 3/2021 **Revision Date:** February 1, 2024
Policy Name: Dynamic splinting	

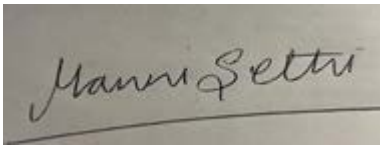
Type of Submission – Check all that apply:

New Policy
X 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:** 

AmeriHealth Caritas Pennsylvania

Dynamic splinting

Clinical Policy ID: CCP.1479

Recent review date: 2/2024

Next review date: 6/2025

Policy contains: Contracture; dynamic splinting; Dynasplint; knee; jaw; low-load prolonged stretching; mechanical stretching; toe.

AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' 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 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' 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's 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's clinical policies are not guarantees of payment.

Coverage policy

Dynamic splinting devices (also referred to as dynamic low-load prolonged stretching devices) are clinically proven and, therefore, may be medically necessary durable medical equipment when all of the following criteria are met (Aspinall, 2021; Furia, 2013; Hammond, 2012; Harvey, 2017; Hurn, 2022; Sameem, 2021; Sodhi, 2017; Veltman, 2015):

- For application to the elbow, finger, knee, toe, or wrist.
- Either:
    - Provided as part of a structured rehabilitative program to improve range of motion in a subacute injury or postoperative period (i.e., more than three weeks but less than four months following injury or surgery) with documented slow or no progress in increasing range of motion with occupational therapy or physical therapy and home exercise program.
    - Provided in the acute postoperative period (i.e., up to three weeks) following a procedure to improve motion to the joint with documented loss of motion or persistent stiffness.

A custom-fabricated dynamic splinting device may be considered medically necessary for a member with medical documentation that supports the need for a custom orthosis, including, but not limited to:

- Deformity or abnormal limb contour.
- A poor fit of a prefabricated device that compromises compliance.
- Intolerance of the prefabricated device due to skin breakdown.

A replacement dynamic splinting device may be medically necessary for members with documentation that both supports continued medical necessity of the orthosis and any of the following criteria:

- Device is lost or stolen or has irreparable damage.
- Repairs exceed 60% of replacement cost.
- Ordering physician determines that a change in the member's physiological condition results in poor orthosis fit or function, and the member's condition has stabilized since the change.

Limitations

Dynamic splinting devices should be monitored for improvement or benefit of use. An evaluation should be completed after a four-week period, and if no improvement is demonstrated, use of the dynamic splinting device should be discontinued.

All other uses for dynamic splinting devices are investigational/not clinically proven, because their effectiveness has not been established.

Alternative covered services

- Botulinum toxin injections.
- Continuous passive motion.
- Physical therapy with passive stretching.
- Sequential, serial casting.
- Static splinting.

Background

Contracture is a soft tissue condition involving the molecular shortening of connective tissue. Joint dysfunction occurs when elastic connective tissue is replaced with inelastic fibrous material, making the tissue resistant to stretching and resulting in reduced range of motion. Prolonged immobilization of joints following surgery or trauma is the most common cause of joint contractures. Other etiologies include excessive arthrofibrosis (e.g., following surgical procedures or burns), neural hypertonicity, obstruction, and idiopathic causes (U.S. National Library of Medicine, 2022).

Several modalities are used, either alone or in combination, to treat or prevent joint contractures. Nonsurgical modalities to reduce contracture involve protocols of sequential, serial casting, manual physical therapy with passive stretching, continuous passive motion, electrical stimulation, static splinting, and botulinum toxin. Non-motorized mechanical stretching devices have been developed as a means of permanently elongating the connective tissue and further increasing joint range of motion. These devices allow application of stretch over prolonged periods of time. Three types of mechanical stretching devices are available. They apply a static progressive stretch, a patient-actuated serial stretch, or a low-load prolonged stretch with sequential tension changes to the joint (also called dynamic splinting).

The goal of dynamic splinting is to stress scarred or shortened connective tissue with a low-load prolonged stretch to promote non-traumatic, more permanent tissue remodeling without compromising the stability and quality of the connective tissue and joint. Most of these devices are adjustable-tension, spring-loaded units that provide a continuous dynamic stretch within a limited tension range during sleep or at rest. Prescribed use varies from six to 12 hours daily for up to four months.

Examples of dynamic splinting systems include Dynasplint® Systems (Dynasplint Systems Inc., Severna Park, Maryland) and Ultraflex™ (Ultraflex Systems Inc., Pottstown, Pennsylvania), Pro-Glide™ (DeRoyal Industries Inc.,

Powell, Tennessee). The U.S. Food and Drug Administration classifies dynamic splinting devices as Class I medical devices (U.S. Food and Drug Administration, 2023).

Findings

We identified numerous systematic reviews, six individual studies, and no guidelines for this policy. The goals of stretching interventions represented in the literature are to prevent and treat contracture caused by surgery, trauma, and chronic neurological and non-neurological conditions affecting joints of the lower extremity and jaw.

The most common outcome used to determine the success of stretch interventions is joint mobility. Other outcomes included measures of impairment, activity limitations, and participation restrictions. The challenge in interpreting the research is the ability to isolate the effects of stretching on outcomes from other factors.

Limited low- to moderate-quality evidence suggests both active and passive early mobilization protocols achieve quicker recovery of motion than static immobilization, but there is no clear consensus on the optimal protocol for rehabilitating lower extremity joints following surgery or acute trauma. There is a need to balance protecting the repair site by limiting premature mobilization with preventing tendon adhesions due to prolonged immobilization.

Dynamic splinting is a safe treatment when used as an adjunct to standard rehabilitation following surgery or trauma to the knee or toe joint. It offers advantages over other stretch interventions in that it can be applied by the patient or caregiver at home, especially at night, and can avoid common adverse events associated with serial casting, such as skin breakdown. However, dynamic splinting is bulky and cumbersome and requires more frequent follow-up visits. Dynamic splinting appears to be suitable for patients who require an early return to activities and would comply with the constraints of the rehabilitation.

There is insufficient evidence to support the efficacy of dynamic splinting for the treatment of contractures of the jaw, or for chronic joint stiffness or fixed contractures caused by spasticity, arthritic conditions, neuromuscular disease, stroke, cerebral palsy, plantar fasciitis, or long-term lack of motion in the joint. In some cases, a practitioner may attempt splinting before making a decision about the need for surgical correction, but the evidence supporting the superiority of dynamic splinting over other stretching alternatives is inconclusive.

A Cochrane review of 22 studies (n = 8,813), six of which were randomized, addressed the ability of dynamic splinting to manage developmental dysplagia of the hip in children under age six months. Authors judged the evidence to be of low certainty on effects of treatment, with limited evidence of different severities of the dysplagia. However, delayed splinting may reduce the number of babies requiring treatment with a harness (Dwan, 2022).

A systematic review of 13 studies (n = 558) of knee arthrofibrosis found load control devices, including dynamic splinting, improved range of movement, significant at $P < .001$ (Aspinall, 2021).

A systematic review of hip dysplasia treatment found dynamic splining to be a valid therapeutic option in cases of instability and dislocation, especially if treatment began within four to five months (Pavone, 2021).

A systematic review included eight studies that showed hallux valgus was successfully treated (i.e., pain reduced) with dynamic splints, along with foot orthoses, night splints, manual therapy, taping added to foot exercises, multifaceted physical therapy program and Botox injections (Hurn, 2022).

A systematic review of 11 studies of post-stroke patients showed dynamic splinting reduced upper extremity spasticity (low evidence), increased hand function (moderate evidence), and improved functional tasks (moderate evidence) (Kerr, 2020).

A survey of 18 systematic reviews found low-quality evidence for the use of non-pharmacological approaches of treat spasticity in adults, including dynamic elbow splinting (Khan, 2019).

A review of 42 studies found dynamic elbow bracing had similar (37 degrees) average increases in range of movement versus static progressive stretch. For shoulder treatment, both had excellent pain outcomes, but elbow bracing required use nearly 24 hours a day, and required a longer period (two months versus six weeks). For knee treatment, dynamic bracing had a lower improvement in mean flexion (7 versus 22 degrees).
Authors recommend static progression stretch as the preferred treatment (Sodhi, 2017).

A comprehensive Cochrane review (Harvey, 2017) examined the effects of stretching on prevention and treatment of joint contractures of the upper and lower extremities in patients with chronic neurological and non-neurological conditions. The review considered sustained passive stretching (self-administered, therapist-administered, and device-administered), positioning, splinting, and serial casting, applied alone or as adjuncts to usual care to the upper and lower limbs. The outcomes of interest were joint mobility, quality of life, pain, activity limitations, participation restrictions, spasticity, and adverse events.

All outcomes were measured after seven months or less of treatment. There was sufficient high-quality or moderate-quality evidence to conclude that stretch did not have a clinically important short-term effect on joint mobility in people with neurological conditions (mean difference 2 degrees, 95% confidence interval 0 degrees to 3 degrees; 26 studies, n = 699 participants) or with non-neurological conditions (standardized mean difference 0.2, 95% confidence interval 0 to 0.3, 19 studies, n = 925 participants). There was no evidence that the effects of stretch differed between large joints (e.g. shoulder, elbow, hip, and knee) and small joints (e.g. wrist, ankle, hand, and foot). For other outcome measures, the evidence supporting short-term effects was inconclusive. The authors recommended directing future research toward clarifying the long-term effects of stretch only in clinical populations where stretch might routinely be performed over long time periods (for example, patients with stroke, spinal cord injuries, or cerebral palsy), but only if a short-term effect can be demonstrated.

A systematic review of eight studies (n = 232 adults with elbow stiffness) showed similar improvements after static progressive splinting (up 36 degrees) and dynamic splinting (up 37 degrees). Authors recommend either non-surgical treatment for 12 months, or until progression in range of elbow motion stops (Veltman, 2015).

A systematic review (Furia, 2013) of eight controlled trials, cohort studies, and case series (n = 487 total participants, including 17 preclinical subjects) examined the effects of dynamic splinting on contracture reduction of the knee (four studies), ankle (two studies), and toe (three studies) joints. Study duration ranged from three to 25 weeks. Dynamic splinting as home therapy treatment showed a significant direct, linear correlation between the total numbers of hours in stretching and restored active range of motion. The authors reported that “joint-specific stretching protocols accomplished greater durations of end-range stretching, which may be responsible for connective tissue elongation.” The mean change in active range of motion was 23.5 degrees (range 7 degrees to 31 degrees). No adverse events were reported.

A systematic review of eight studies of 1,277 extensor tendon injuries found favorable functional results (although quantifying results was not possible) and low complication rates for static splinting (4.1%), dynamic splinting (4.3%), and active motion (1.8%) (Hammond, 2012).

A systematic review of 17 articles covering treatments after surgery to repair extensor tendons of the hand concluded that based on available evidence, dynamic splinting resulted in better outcomes than after static splinting (Sameem, 2011).

A number of randomized trials had small numbers of participants (27 to 76 each) and have not found consistent effectiveness of dynamic splinting (John 2011, Plaass 2020, Sheridan 2010, van der Geer 2020, Zatarain 2018).

References

On November 27, 2023, 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 “range of motion, articular” (MeSH), “dynamic splinting,” “exercise therapy/instrumentation” (MeSH), “exercise therapy/methods” (MeSH), “mechanical stretching,” “Dynasplint,” “EMPI,” “Pro-glide,” “SaeboFlex,” and “Ultraflex.” 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.

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Policy updates

2/2021: initial review date and clinical policy effective date: 3/2021

2/2022: Policy references updated.

2/2023: Policy references updated.

2/2024: Policy references updated.