HEALTH PLANS
UNIVERSITY OF UTAH

Medical Policy

Dynamic Splint Devices

Policy MP-078

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Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

A joint contracture is characterized by a chronically reduced range of motion (ROM) secondary to structural changes in non-bony tissues including muscles, tendons, ligaments, and skin. This joint dysfunction occurs when elastic connective tissue is replaced with inelastic fibrous material, making the tissue resistant to stretching. Joint contractures may be the result of immobilization following an injury, surgery or disease; nerve damage, such as stroke or spinal cord injury; or muscle, tendon, or ligament disease. A number of different physical therapy (PT) modalities are used to treat or prevent joint contractures, including manual joint mobilization by a physical therapist, serial plastering, static splinting, mechanical stretching devices, continuous device-assisted passive motion (CPM), dynamic splinting (Dynasplint), massage, exercise, electrical stimulation, botulinum toxin, and surgery. An active or functional splint aids in initiating and performing movements by controlling the plane and range of motion of an injured part. There are no single techniques that has been identified as being superior to others, and often a combination of treatments is used to restore ROM.

Dynamic splinting systems are adjustable spring-loaded devices designed to provide Low-Load Prolonged-Duration Stretch Devices (LLPS) while individuals are asleep or at rest. Prefabricated units for both extension and flexion are available for the elbow, wrist, fingers, knee, ankle, and toes. These units are marketed for the treatment of joint stiffness due to immobilization or limited ROM. Custom dynamic splinting systems can be used when effective treatment cannot be provided with prefabricated units. Circumstances include but are not limited to limb size or shape as well as necessary load and material requirements. Dynamic load may be generated in

the form of a concentric joint or elastic strap. Examples of LLPS devices include, but may not be limited to Advance Dynamic ROM, Dynasplint, EMPI Advance Dynamic ROM, Proglide Advance Dynamic ROM, LMB Pro-Glide, SaeboFlex, SaeboReach, Stat-A-Dyne and Ultraflex.

Static Progressive Stretch (SPS) devices increase the angle of stretch slowly. The patient sets the device angle at the beginning of the session and every several minutes the angle is increased. Sessions usually last for 30 minutes and are completed several times a day. Example of SPS devices include (may not be an all-inclusive list): Joint Active System (JAS) Splints (e.g., JAS Ankle, JAS Elbow, JAS Knee, JAS Pronation-Supination, JAS Shoulder, JAS Wrist).

Flexionaters/extensionaters: also known as Patient-Actuated Serial Stretch (PASS) devices use a serial stretch load application and quick release mechanism. These devices allow resisted active and passive motion within a limited range. They are typically used in 15 minute increments, 4-8 times per day. Examples of a PASS devices include (may not be an all-inclusive list): the ERMI Knee/Ankle or Shoulder Flexionater®, ERMI Elbow or knee Extensionater®, and JAS EZ Systems (ankle, elbow, finger, knee extension, knee flexion, pronation/supination, shoulder, toe and wrist).

Policy Statement and Criteria

1. Commercial Plans

U of U Health Plans considers dynamic splinting devices for the knee, elbow, wrist or finger medically necessary durable medical equipment (DME) if either of the following two selection criteria is met:

A. As an adjunct to physical therapy in members with documented signs and symptoms of significant motion stiffness/loss in the sub-acute injury or post-operative period (i.e., at least 3 weeks after injury or surgery)

B. In the acute post-operative period for members who have a prior documented history of motion stiffness/loss in a joint and are having additional surgery or procedures done to improve motion to that joint.

U of U Health Plans considers the use of dynamic splinting experimental and investigational in the management of joint injuries of the shoulder, ankle and toe, for carpal tunnel syndrome, and for all other indications because there is a lack of scientific evidence regarding its effectiveness for these indications.

U of U Health Plans considers Static Progressive (SP), Low-Load Prolonged-Duration Stretch Devices (LLPS), and Patient-Activated Seral Stretch (PASS) devices experimental and investigational for all other indications.

2. **Medicaid Plans**
   Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: https://medicaid.utah.gov/utah-medicaid-official-publications/ or the Utah Medicaid code Look-Up tool

   CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

A 2016 systematic review (Mills et al) evaluated the efficacy of 10 different adjunct therapies post-botulinum toxin injection for treatment of limb spasticity in 17 RCTs from 1980 until mid-May 2015. Ten adjunct therapies were identified, which included dynamic splinting. Evidence (Level 2) suggests that adjunct use of dynamic splinting result in improved Modified Ashworth Scale scores by at least 1 grade. Level 1 evidence finds taping is better than electrical stimulation and stretching for outcomes including the Modified Ashworth Scale, ROM, and gait. The authors found a high level of evidence suggesting that adjunct therapies may improve outcomes following botulinum toxin injection. However, further studies would be more beneficial.

A 2017 systematic review and meta-analysis of RCTs and other controlled trials (Harvey et al) were assessed to determine the effects of stretch on contractures in people with, or at risk of developing, contractures. The outcomes of interest included joint mobility, quality of life (QOL), pain, activity limitations, participation restrictions, spasticity, and adverse events. A search was conducted using CENTRAL, DARE, HTA; MEDLINE; Embase; CINAHL; SCI-EXPANDED; PEDro and trials registries. A total of 49 studies with 2,135 participants met the inclusion criteria. Study participants had a variety of neurological and non-neurological conditions. Studies compared stretch to no stretch, often delivered with standard care for the disorder or another co-intervention e.g., exercise or botulinum toxin injection in the case of spasticity. The stretch was administered in a variety of different ways including through passive stretching (self-administered, therapist-administered, and device-administered), positioning, splinting and serial casting, and none of the studies performed stretch for more than 7 months. Of the 49 studies, 17 (787 participants) investigated the effect of splinting on joint mobility. The mean difference of splinting on joint mobility was 0° (95% CI, -1 to 2; I2 = 28%; P = 0.68). In conclusion, the authors found that the data does not support the hypothesis that any particular stretch intervention is superior to another, as well as the effects of stretch did not differ between large and small joints. Furthermore, stretch interventions are not effective for the treatment and prevention of contractures and do not have short-term effects on QOL and pain in people with non-neurological conditions. The short-term and long-term effects of stretch interventions on other outcomes in people with neurological and non-neurological conditions are simply not known.

In 2021, Aspinall et al conducted a systematic review to assess the effectiveness of medical stretching devices in the treatment of knee arthrofibrosis. The study included 558 participants, status post knee surgery, in a total of 13 studies. In addition to physiotherapy and home exercises, participants were placed on continuous passive motion (CPM) and load control [creep] (LC creep) or displacement control [stress relaxation] (DCSR) stretching devices were used (i.e., traction therapy, dynamic splints). The primary outcome measure in all studies was improved ROM. Secondary outcome measures included pain, stiffness, and physical function. In both the CPM device and manipulation under anesthesia (MUA)

group a mean increase in ROM and Western Ontario McMaster Universities (WOMAC) Osteoarthritis Index Score (total scores and sub scores of pain, stiffness, and function) was reported between pre-treatment evaluation and weeks 2 and 6 weeks ($P < 0.05$). No difference was found between groups in total or sub scores. All studies reviewed used the universal goniometer (UG) to measure the primary outcome of ROM, however, the authors questioned the reliability and validity of the UG due to multiple evaluators involved in joint measurement. In conclusion, the authors found that CPM, DCSR, and LC creep devices improve ROM in patients with knee stiffness. However, the research revealed difficulties understanding techniques that were being used and/or compared to as studies used different terms to describe procedures and stretching principles employed. They also found that there were large variations with the increase of ROM between participants and CPM results were inconsistent and inconclusive due to sample size and heterogeneity of subjects in the studies. Further, more robust studies are needed with randomized controlled trials.

Another 2021 systematic review (Pavone et al) evaluated the available literature to document the up-to-date evidence on conservative treatment of developmental dysplasia of the hip (DDH). A search of PubMed and Science Direct databases was performed by two independent authors (C.d.C. and A.V.) using the keywords "developmental dysplasia hip", "brace", "harness", "splint", "abduction brace" to evaluate studies of any level of evidence that reported clinical or preclinical results and dealt with conservative DDH treatment. The result of every stage was reviewed and approved by the senior investigators (V.P. and G.T.). A total of 1,411 articles were found. After the exclusion of duplicates, 367 articles were selected. At the end of the first screening, following the previously described selection criteria, the authors selected 29 articles eligible for full text reading. The included articles mainly focused on the Pavlik harness, Frejka, and Tubingen among the dynamic splint applications as well as the rhino-style brace, Ilfeld and generic abduction brace among the static splint applications. In conclusion, the authors found that dynamic splinting has a low contraindication and that these represent a valid therapeutic option for DDH in cases of instability and dislocation, especially if applied within 4-5 months of life. However, static bracing was found to be an effective option as well, but only for stable hips or residual acetabular dysplasia.

In a 2017 meta-analysis Khan et al. (2017) conducted a search to evaluate the effectiveness of non-pharmacological interventions to improve limb spasticity. Four reviews were published in the Cochrane Library database and 14 in other academic journals, conducted on 7,241 patients with a variety of neurological conditions: stroke (6), MS (1), brain injury (1), SCI (1), and Mixed or other neurological condition (9). The authors concluded that while a range of interventions are available to improve spasticity, they only found low-quality evidence of peer-reviewed literature where ROM is improved through occupational, manual therapy with dynamic elbow extension splinting in patients with stroke or other neurologic conditions. Further, more robust high quality studies are needed to better evaluate these interventions.

In a 2022 randomized controlled trial (RCT) assessing the one year follow up of patients receiving dynamic splinting, Op de Coul et al compared the treatment of elbow flexion contractures using a dynamic orthosis or serial circular casting. Children with an elbow flexion contracture of ≥ 30° were treated with either a night-worn dynamic orthosis for one year or serial casting for four weeks followed by night splinting. For practical reasons, some participants were included in an open part of this study, and this group was analyzed separately. Degree of contracture and goal attainment scaling was evaluated at baseline and after 8, 20 and 54 weeks. A total of 55 patients were analyzed in this trial, 32 of whom were randomized to treatment. At one-year follow-up of the randomized group, both dynamic splinting (median -8.5°, interquartile range [IQR] -13.5, -5) and serial casting (median -11.0°, IQR -16, -5) resulted in reduction of contracture ($P < 0.001$). The reduction was greater with serial casting in the first

20 weeks, but not at one-year follow-up (P = 0.683). In the entire cohort, the individual functional goals had been reached in 24 out of 32 cases (80%) of dynamic splinting and 18 out of 23 cases (82%) of serial casting, respectively. The authors found that the dynamic night orthosis is comparable to serial casting for treating elbow flexion contractures in children with brachial plexus birth injury. The authors recommend selecting one of these treatment modalities in close consultation with parents and patients. While this RCT included randomized patients, the children were treated with their choice of modality, which created selection bias. In addition, it is unknown if instructions were closely followed during the course of treatment as results were reported retrospectively. However, they recommend more robust and well designed, comparative studies with larger patient populations to further describe safety and clinical outcomes.

In 2022 a retrospective cohort, Rauzi et al compared a multimodal physical therapy program and manipulation under anesthesia to determine the treatment effect, including variability, and feasibility. Ten consecutive patients (aged 64 ±9 years, 7 females) with early stage arthrofibrosis were enrolled 6 weeks after primary total knee arthroplasty and participated in the multimodal physical therapy program. The multimodal physical therapy program consisted of manual therapy, therapeutic exercise, and static progressive splinting delivered over 4 weeks. The outcomes included knee range of motion (ROM), adherence, patient satisfaction, and safety. Data were compared to a retrospective cohort of 31 patients with arthrofibrosis (aged 65 ±9 years, 20 females) who underwent manipulation under anesthesia followed by physical therapy. Overall, knee ROM outcomes were similar between multimodal physical therapy (110° ±14) and manipulation under anesthesia (109° ±11). Seven out of ten patients achieved functional ROM (≥ 110°) and avoided manipulation under anesthesia with the multimodal physical therapy program. Three out of 10 multimodal physical therapy patients required manipulation under anesthesia secondary to failure to demonstrate progress within 4 weeks of the multimodal physical therapy program. Adherence to the multimodal physical therapy program was 87 ±9%. The median patient satisfaction with the multimodal physical therapy program was "very satisfied." Safety concerns were minimal. The authors concluded that the use of a multimodal physical therapy program is feasible for treating early-stage arthrofibrosis after total knee arthroplasty, with 70% of patients avoiding manipulation under anesthesia. However, this study is limited by its retrospective cohort design, very small sample size (10 patients) and short duration of follow-up (4 weeks). Further, more robust research with RCTs are needed to validate these findings.

Hayes (2018, updated 2022) conducted a health technology assessment evaluating the improvement in ROM with the use of LLPS devices versus static splinting for finger contractures following surgical extensor injury and repair. Five randomized controlled trials (RCTs) and 2 uncontrolled studies met criteria. While the body of evidence was noted as fair-to-low, the treatment benefit was small with the final outcome being similar to that achieved with static splinting. LLPS did not significantly improve hand function and grip strength, indicating that the small short-term gains in ROM may not be clinically meaningful and that LLPS may not improve final outcomes. There was a paucity of studies investigating mechanical stretching devices for other indications, including contracture of the fingers following flexor injury or trauma, the hand, wrist, elbow, shoulder, and the knee. Factors reducing the quality of these studies were small sample sizes, no or short-term follow-up, lack of intention-to-treat analysis, lack of blinding, large dropout rates, or failure to use recommended methods of randomization. There were no safety issues identified with any of the mechanical stretching devices in the reviewed studies. The authors found that there is insufficient evidence to draw conclusions regarding efficacy of any type of mechanical stretching devices for any indication.

Applicable Coding

CPT Codes

Covered if criteria met

29126 Application of short arm splint (forearm to hand); dynamic

29131 Application of finger splint; dynamic

HCPCS Codes

Covered if criteria met

E1801 Dynamic adjustable elbow extension/flexion device, includes soft interface material

E1800 Dynamic adjustable elbow extension/flexion device, includes soft interface material

E1802 Dynamic adjustable forearm pronation/supination device, includes soft interface material

E1805 Dynamic adjustable wrist extension/flexion device, includes soft interface material

E1812 Dynamic knee, extension/flexion device with active resistance control

E1815 Dynamic adjustable ankle extension/flexion device, includes soft interface material

E1825 Dynamic adjustable finger extension/flexion device, includes soft interface material

E1830 Dynamic adjustable toe extension/flexion device, includes soft interface material

E1840 Dynamic adjustable shoulder flexion/abduction/rotation device, includes soft interface material

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