

Mechanical Stretching Devices (for Kentucky Only)

Policy Number: CS077KY.04
Effective Date: February 1, 2024

[Instructions for Use](#)

Table of Contents	Page
Application	1
Coverage Rationale	1
Applicable Codes	1
Description of Services	2
Clinical Evidence	3
U.S. Food and Drug Administration	7
References	8
Policy History/Revision Information	9
Instructions for Use	9

Related Policies
None

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

Mechanical Stretching Devices of the upper extremities (except forearm) are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Orthoses, Upper Extremity.

Click [here](#) to view the InterQual® criteria.

Low-load prolonged-duration stretch devices (LLPS) as an adjunct to therapy are proven and medically necessary for treating existing joint contractures of the forearm and lower extremities.

The following are unproven and not medically necessary, alone or combined with standard physical therapy (PT), for treating joint contractures of the forearm and lower extremities due to insufficient evidence of efficacy:

- Static progressive stretch (SPS) splint devices

The following is unproven and not medically necessary, alone or combined with standard physical therapy (PT), for treating joint contractures of the upper and lower extremities due to insufficient evidence of efficacy:

- Patient actuated serial stretch (PASS) devices

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may

require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
E1399	Durable medical equipment, miscellaneous
E1800	Dynamic adjustable elbow extension/flexion device, includes soft interface material
E1801	Static progressive stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1802	Dynamic adjustable forearm pronation/supination device, includes soft interface material
E1805	Dynamic adjustable wrist extension/flexion device, includes soft interface material
E1806	Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
E1810	Dynamic adjustable knee extension/flexion device, includes soft interface material
E1811	Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1812	Dynamic knee, extension/flexion device with active resistance control
E1815	Dynamic adjustable ankle extension/flexion device, includes soft interface material
E1816	Static progressive stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
E1818	Static progressive stretch forearm pronation/supination device, with or without range of motion adjustment, includes all components and accessories
E1825	Dynamic adjustable finger extension/flexion device, includes soft interface material
E1830	Dynamic adjustable toe extension/flexion device, includes soft interface material
E1831	Static progressive stretch toe device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1840	Dynamic adjustable shoulder flexion/abduction/rotation device, includes soft interface material
E1841	Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories

Description of Services

Joint stiffness or contracture may be caused by immobilization following surgery, disease, or trauma. Joint contracture is associated with reduced range of motion (ROM) due to structural changes in non-bony tissues, including muscles, tendons, ligaments, and skin.

Mechanical stretching devices are used for the prevention and treatment of joint contractures of the extremities, with the goal to maintain or restore ROM to the joint. These devices are intended to replace some physical therapist-directed sessions by providing frequent and consistent joint mobilization under controlled conditions in a hospital setting or in the individual's home (Hayes, 2018).

A number of different PT modalities are used to treat or prevent joint contractures, including manual joint mobilization by a physical therapist, static splinting, mechanical stretch devices, massage, and exercise. There is no single technique that has been identified as being superior to others, and often a combination of treatments is used to restore ROM (Farmer et al., 2001; Thien et al., 2004).

Mechanical stretch devices (also known as dynamic splinting systems) include:

- LLPS
- SPS (splint) devices, and
- PASS devices

Dynamic splinting systems are adjustable spring-loaded devices designed to provide LLPS while individuals are asleep or at rest. Prefabricated units for both extension and flexion are available for 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.

SPS (splinting) devices hold the joint in a set position but allow for manual modification of the joint angle (inelastic traction). This type of device does not exert a stress on the tissue and does not allow for active or passive motion.

PASS devices provide a low- to high-level load to the joint using pneumatic (Extensionaters, End Range of Motion Improvement, Inc. [ERMI, Inc.]) or hydraulic (Flexionaters, ERMI Inc.) systems that can be adjusted by the individual. Different PASS devices are available for use depending on the joint being treated (knee/ankle, knee, and shoulder). Protocols for use include a customized treatment plan and individualized education (ERMI Inc. website).

Clinical Evidence

Low-Load Prolonged-Duration Stretch Devices (LLPS)

Hayes performed an evidence review from five randomized controlled trials (RCTs) and two uncontrolled studies) assessing the improvement in ROM with the use of LLPS devices versus static splinting for finger contractures following surgical extensor injury and repair. 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 (2018, updated 2022).

Hurn et al. (2021) conducted a systematic review and meta-analysis investigating the effectiveness of nonsurgical interventions for hallux valgus (HV). Medline, CINAHL, Embase, and the Cochrane Library were searched to April 2020, including parallel-group and crossover studies investigating nonsurgical interventions for HV. Two reviewers independently screened articles for inclusion, extracted data, determined risk of bias, and made assessments using the Grading of Recommendations, Assessment, Development, and Evaluation methodology. Risk of bias was assessed using version 2 of the Cochrane risk-of-bias tool. Effect sizes (mean differences or risk ratios, and 95% confidence intervals) were calculated and pooled where possible for the primary outcomes, foot pain, and HV angle. Eighteen included studies investigated a wide range of nonsurgical interventions for HV. Most studies had small sample sizes and concerns regarding risk of bias. Five separate meta-analyses for foot orthoses, splints, manual therapy, and taping added to foot exercises showed no effects on primary outcomes. However, results from 8 studies showed a pain reduction with the use of foot orthoses, night splints, dynamic splints, manual therapy, taping added to foot exercises, a multifaceted physical therapy program, and Botox injections. Four studies reported a reduction in HV angle with night splints, foot exercises, multifaceted physical therapy, and Botox injections. The authors concluded there is a low level of certainty surrounding the effectiveness of nonsurgical interventions for HV, but a reduction in pain appears more likely than improvement in HV angle. There are several limitations to this review. First, several studies were limited by only measuring HV angle and not reporting on symptoms or self-reported function. Second, longer follow-up periods would be advisable, as only 6 studies followed participants for ≥ 12 months. Finally, investigation of potential harms or adverse outcomes were not reported, and thus could not be evaluated. Long-term evaluations of the results and prospective randomized studies are still needed. Plaass et al. (2020), who were previously cited in this policy, are included in this systematic and meta-analysis review.

Pavone et al. (2021) conducted a systematic review to analyze the available literature to document the up-to-date evidence on conservative treatment of developmental dysplasia of the hip (DDH). A systematic review 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. The main findings of the included articles were summarized. The authors concluded that dynamic splinting for DDH represents a valid therapeutic option in cases of instability and dislocation, especially if applied within 4-5 months of life. Dynamic splinting has a low contraindication. Static bracing is an effective option too, but only for stable hips or residual acetabular dysplasia.

Plaass et al. (2020) conducted a prospective randomized trial to evaluate the effect of a dynamic hallux valgus (HV) splint. Between May 2011 and October 2013, 70 patients scheduled for a surgical HV correction were included in this trial. All patients underwent a meticulous clinical analysis at baseline and during the final follow-up. The following clinical parameters were documented: MTP 1 range of motion (ROM), metatarsalgia and any lesser toe deformities. The American Orthopedic Foot and Ankle Society - hallux metatarsophalangeal interphalangeal scale (AOFAS), the short form-36 (SF-36), foot and ankle outcome score (FAOS) and a numeric rating scale (NRS) for pain were evaluated. All patients in the intervention group were asked to judge the splint comfort on a 10-point Likert scale. Patients with a HV were treated using a dynamic splint or underwent no treatment. Clinical and radiological parameters were evaluated. There were no changes in hallux valgus angle, intermetatarsal I-II angle, AOFAS score, FAOS or SF-36 score between the groups. However, a between-group difference was found for pain during walking and running and in the FAOS subscale for pain and pain at rest at follow-up. The authors concluded that wearing a dynamic HV splint does provide some pain relief in patients with a symptomatic HV but showed no effect on HV position. Further investigation is needed before clinical usefulness of this procedure is proven.

Khan et al. (2017) examined 18 systematic review/meta-analyses 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). While a range of interventions are available to improve spasticity, the authors found only low-quality evidence addressed in the peer-reviewed literature where ROM is improved through occupational, manual therapy with dynamic elbow extension splinting in patients with stroke or other neurologic conditions. Additional studies are needed to better evaluate these interventions.

Mills et al. (2016) conducted a systematic review of 17 RCTs from 1980 until mid-May 2015 assessing the efficacy of ten different adjunct therapies post-botulinum toxin injection for treatment of limb spasticity. 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 one 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 concluded that there is high level evidence suggesting that adjunct therapies may improve outcomes following botulinum toxin injection, and that further studies would be of benefit.

A systematic review was performed by Furia et al. (2013) to evaluate the safety and efficacy of dynamic splinting as it is used to treat joint contracture in lower extremities, and to determine if duration on total hours of stretching had an effect on outcomes. A total of 354 abstracts were screened and eight studies with 487 subjects met the inclusion criteria. The primary outcome measure was change in active ROM (AROM). The mean aggregate change in AROM was 23.5° in the collective studies. Dynamic splinting with prolonged, passive stretching as home therapy treatment showed a significant direct, linear correlation between the total number of hours in stretching and restored AROM. The authors concluded that dynamic splinting is a safe and efficacious treatment for lower extremity joint contractures.

Heymann (2012) conducted a randomized, prospective, single-center study to compare the efficacy and tolerance of static orthoses (ratchet KAFO) with dynamic orthoses (Ultraflex KAFO) in the treatment of knee flexion contracture in children with cerebral palsy. This study included a total of 30 children with cerebral palsy (age 11.2 years \pm 4.2, 14 ambulant), presenting unilateral or bilateral knee flexion contracture greater or equal to 10° (in total: 48 legs, 24 dynamic and 24 static orthoses). The study was performed without the use of serial casting or botulinum toxin. The main assessment criterion was goniometric measurement of knee extension. Secondary criteria were measurement of popliteal angle, dorsiflexion of the ankle with knee extended, hamstrings and triceps surae spasticity level, orthoses' tolerance and compliance. Measurements were performed by the same physiotherapist for consistency at 1, 3, 6 and 8 months. The test of Student, adjusted with the method of Tukey ($\alpha = \alpha/\sqrt{6}$) was used to compare groups at 6 and 8 months, with regard to inclusion. Results revealed notable efficacy of the dynamic orthosis (both for ambulant and non-ambulant): for reduction of knee flexion contracture at 6 months (9,38 vs 2,88; $p <$

0.001), at 8 months (12,58 vs 3,58; $p < 0.0001$); for reduction of gastrocnemius contracture ($p = 0.0003$) and reduction of the gastrocnemius spasticity ($p = 0.0003$); reduced hamstrings spasticity ($p = 0.0262$); orthoses tolerance ($p = 0.009$). The author concluded that results of this study represent the first prospective comparative effectiveness evidence showing the advantage of dynamic versus static KAFO orthoses, and that these orthoses should be a first line conservative intervention for dynamic and static hamstring and gastrocnemius contractures in children with cerebral palsy.

Sameem et al. (2011) evaluated which rehabilitation protocol yielded the best outcomes with respect to ROM and grip strength in extensor zones of the hand. A comprehensive literature review and assessment was undertaken by two independent reviewers. Methodological quality of RCTs and cohort studies was assessed using the Scottish Intercollegiate Guidelines Network scale. A total of 17 articles were included in the final analysis. The authors concluded that the available level 3 evidence suggested better outcomes when using dynamic splinting over static splinting. Moreover, they stated that additional studies comparing dynamic and early active motion protocols are needed before a conclusive recommendation can be made.

A prospective uncontrolled study by Cetin et al. (2001) evaluated 37 patients (74 digits) with repaired flexor tendon injuries using a regimen of LLPS combined with passive and active early mobilization exercises. Based on the Buck-Gramcko system and TAM results, this regimen achieved excellent results in 73% of fingers, good results in 24% and fair in 1.5%. The authors concluded that LLPS combined with passive and active early mobilization exercises may be an effective treatment for repaired flexor tendon injuries.

Khandwala et al. (2000) conducted an RCT of 100 patients with complete divisions of the extensor tendons in Verdan's zones 5 and 6 of the hand. Patients were randomly assigned to be rehabilitated postoperatively through use of LLPS and active mobilization (group 1, $n = 50$) or palmar block static splinting and active mobilization (group 2, $n = 50$). Total active motion (TAM) and Miller's assessment of tendon repair (Miller et al., 1942) were the main outcome measures, assessed 4- and 8-weeks post-surgery. At eight weeks, there was no statistically significant difference between the two groups: 50% of patients assigned to group 1 achieved excellent TAM versus 49% of those assigned to group 2; and good TAM was achieved by 48% and 46% of patients in groups 1 and 2, respectively. Miller's assessment demonstrated good or excellent results in 95% of group 1 and 93% of group 2 patients. The results suggest the efficacy and safety of LLPS, and active mobilization regimen may be similar to that of static splinting combined with active mobilization program.

RCTs, observational studies, case series, and medical community acceptance confirm the benefits of dynamic LLPS devices when used to relieve persistent joint stiffness that can occur after injury or surgery. However, there is minimal evidence supporting the effectiveness of dynamic LLPS devices for the rehabilitation of joints other than finger, wrist, elbow, knee, and toe. There is insufficient evidence in the published peer-reviewed literature to support the use of dynamic LLPS devices for the treatment of conditions such as, but not limited to, chronic joint stiffness or chronic fixed contractures caused by chronic medical conditions such as RA, cerebral palsy, or plantar fasciitis.

Static Progressive Stretch (SPS) (Splinting) Devices

Clinical evidence is not sufficient to demonstrate that use of static progressive devices is an effective treatment option for treating joint contractures.

Op de Coul et al. (2022) conducted a randomized controlled trial (RCT) with one-year follow-up to compare the treatment of elbow flexion contractures using a dynamic orthosis or serial circular casting. Children with an elbow flexion contracture of $\geq 30^\circ$ 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 concluded 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. Well designed, comparative studies with larger patient populations are needed to further describe safety and clinical outcomes.

Rauzi et al. (2022) conducted a retrospective cohort comparison to determine the treatment effect, including variability, and feasibility of a multimodal physical therapy program as compared to manipulation under anesthesia. 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. This study is limited by its retrospective cohort design, very small sample size (10 patients) and short duration of follow-up (4 weeks). Further research with randomized controlled trials is needed to validate these findings.

A Hayes technology report indicates that the evidence is insufficient to draw conclusions about the efficacy of SPS, PASS, or LLPS stretching devices for any indication or etiology of joint contractures (other than finger extensor injury) of the knee, hand, wrist, elbow, shoulder, or toes because there are no studies or only a limited number of studies that address each application, which precludes the ability to determine consistency of the evidence and to draw conclusions regarding treatment efficacy. No evidence suggests unique safety considerations for these devices (2018, updated 2020).

Harvey et al. (2017) conducted systematic review and meta-analysis of RCTs and other controlled trials 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, 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 seven 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). The authors concluded that the data does not support the hypothesis that any particular stretch intervention is superior to another, and that the effects of stretch did not differ between large and small joints. Furthermore, the authors concluded that stretch is not effective for the treatment and prevention of contractures and does not have short-term effects on quality of life and pain in people with non-neurological conditions, and the short-term and long-term effects of stretch on other outcomes in people with neurological and non-neurological conditions are not known.

Veltman et al. (2015) conducted a systematic review to evaluate the best current evidence for nonoperative treatment options for posttraumatic elbow stiffness. Eight studies (one RCT and seven retrospective cohort studies, participants = 232) were included. SPS was evaluated in 160 patients, where the average pre-splinting ROM was 72°. Dynamic splinting was evaluated in 72 patients with an average pre-splinting ROM of 63°. Post-splinting ROM results were slightly better in the patients who received SPS versus dynamic splinting, with arc of motion measured at 108° and 100°, respectively. The authors concluded that both nonoperative treatment options showed good results for treating elbow stiffness, regardless of etiology. The choice for one treatment over the other is based on the preference of the surgeon and patient. They recommended dynamic or static bracing until patients stop seeing improvement in elbow ROM, up to 12 months.

Ibrahim et al. (2014) conducted a prospective RCT to compare a SPS device plus traditional PT versus traditional PT alone for the treatment of adhesive capsulitis of the shoulder. Sixty patients were equally divided into the experimental or the control group. Both groups received traditional PT, three sessions per week for four weeks. In addition, the experimental group used a SPS device for four weeks. The primary outcome measure was shoulder ROM (active and passive shoulder abduction, and passive shoulder external rotation). Secondary outcome measures were function and pain, measured using the Disabilities of the Arm, Shoulder and Hand questionnaire and the Visual Analog Scale, respectively. Follow up was at 4, 12, 24, and 52 weeks,

and no patients were lost to follow up. At baseline, there were no differences between the two groups. However, after the intervention, there were significant improvements for all outcome parameters in the experimental group. The authors concluded that traditional PT with adjuvant SPS device therapy results in significant improvements in functional and clinical outcomes over traditional PT alone for patients with adhesive capsulitis of the shoulder. Further studies are needed, comparing SP stretch and dynamic splinting as treatment methods for this patient demographic.

One prospective, nonrandomized, comparative clinical study investigated SPS devices for joint contractures of the lower extremities (n = 160). Hewitt and Shakespeare (2001) compared two postoperative total knee arthroplasty (TKA) mobilization regimens. All 160 patients underwent unilateral TKA and were then assigned to one of two rehabilitation regimens: group 1 (n = 86) had a SPS flexion regimen which involved the patient's knee being placed on a 90° splint for 10 minutes followed by 10 minutes of passive extension combined with exercises every two hours. Group 2 (n = 74) had a regimen of static extension splinting combined with physical therapist-guided flexion exercises. Outcome measures included knee joint ROM, stability, and alignment; extensor lag; pain and mobility aids used. These outcomes were assessed one day prior to surgery and at six weeks post-surgery. Six weeks after surgery, group 1 had better ROM and improved maximum knee flexion compared with group 2. Blood loss and analgesic requirements were similar for both groups. The authors concluded that, as an adjunct treatment to physical therapist-guided exercises, a SP flexion regimen may be superior to a static extension regimen in the rehabilitation of unilateral TKA. Short follow-up and lack of blinding were the main limitations of this study. While the preliminary evidence suggests that this technique may be beneficial, it is unclear whether a therapeutic benefit, beyond that achieved with active PT or passive mobilization, can be achieved. A regimen of active PT and SPS was superior to active PT combined with static splinting.

Patient-Actuated Serial Stretch (PASS)

Clinical evidence is not sufficient to demonstrate that use of patient-actuated serial stretch devices is an effective treatment option for treating joint contractures.

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of the use of PASS devices for any indication. Well-designed clinical trials that evaluate these devices are lacking. It is not possible to determine based on the available evidence whether the addition of these devices when used alone or as an adjunct to a PT program provide improved patient outcomes.

Aspinall et al. (2021) performed a systematic review to evaluate 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 two and six 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. The authors concluded that CPM, DCSR, and LC creep devices improve ROM in patients with knee stiffness. However, the authors also stated that reviewed research revealed authors using different terms describing procedures and stretching principles employed which created difficulties understanding techniques being used and/or compared. The studies showed large variation in increase in ROM between participants. CPM results were inconsistent and inconclusive due to sample size and heterogeneity of subjects and further research with randomized controlled trials is needed.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Mechanical stretching devices, such as Dynasplint, Ultraflex, Pro-glide Knee, Elbow, Wrist (DeRoyal® Advance Dynamic ROM®), are classified by the FDA as Class I medical devices. Class I devices have the least amount of regulatory control; manufacturers of these devices are exempt from premarket notification procedures and are not required to provide safety and effectiveness data prior to marketing.

Mechanical stretching devices are categorized under product code ION and are Class I, 510(k) exempt devices. Additional information is available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed May 19, 2023)

References

- Aspinall SK, Bamber ZA, Hignett SM, et al. Medical stretching devices are effective in the treatment of knee arthrofibrosis: a systematic review. *J Orthop Translat.* 2021 Feb 8;27:119-131.
- Cetin A, Dincer F, Kecik A, M. Rehabilitation of flexor tendon injuries by use of a combined regimen of modified Kleinert and modified Duran techniques. *Am J Phys Med Rehabil.* 2001; 80(10):721-728.
- End Range of Motion Improvement (ERMI, Inc.) website: <http://www.getmotion.com/>. Accessed May 19, 2023.
- Farmer SE, James M. Contractures in orthopaedic and neurological conditions: a review of causes and treatment. *Disabil Rehabil.* 2001;23(13):549-558.
- Furia JP, Willis FB, Shanmugam R, et al. Systematic review of contracture reduction in the lower extremity with dynamic splinting. *Adv Ther.* 2013 Aug;30(8):763-70.
- Harvey LA, Katalinic OM, Herbert RD, et al. Stretch for the treatment and prevention of contractures. *Cochrane Database of Systematic Reviews* 2017, Issue 1. Art. No.: CD007455.
- Hayes, Inc. Medical Technology Directory. Mechanical Stretching Devices for the Treatment of Joint Contractures of the Extremities. Hayes Inc.: Lansdale, PA: May 9, 2018, updated September 3, 2020.
- Hewitt B, Shakespeare D. Flexion vs. extension: a comparison of post-operative total knee arthroplasty mobilization regimes. *Knee.* 2001;8(4):305-309.
- Heymann, I. Dynamic orthosis with low load prolonged stretch: best tolerance and efficacy – application in cerebral palsy knee flexum contracture. *Ann Phys Rehabil Med.* 2012 Oct 1. Volume 55, Pages e88-e88.
- Hurn SE, Matthews BG, Munteanu SE, et al. Effectiveness of nonsurgical interventions for hallux valgus: a systematic review and meta-analysis. *Arthritis Care Res (Hoboken).* 2022 Oct;74(10):1676-1688.
- Ibrahim M, Donatelli R, Hellman M, et al. Efficacy of a static progressive stretch device as an adjunct to physical therapy in treating adhesive capsulitis of the shoulder: a prospective, randomised study. *Physiotherapy.* 2014 Sep;100(3):228-34.
- Khan F, Amatya B, Bensmail D, et al. Non-pharmacological interventions for spasticity in adults: An overview of systematic reviews. *Ann Phys Rehabil Med.* 2017 Oct 16. pii: S1877-0657(17)30415-3.
- Khandwala AR, Webb J, Harris SB, et al. A comparison of dynamic extension splinting and controlled active mobilization of complete divisions of extensor tendons in zones 5 and 6. *J Hand Surg [Br].* 2000;25(2):140-146.
- Miller H. Repair of severed tendons of the hand and wrist: statistical analysis of 300 cases. *Surg Gynecol Obstet.* 1942; 75:693-698.
- Mills PB, Finlayson H, Sudol M, et al. Systematic review of adjunct therapies to improve outcomes following botulinum toxin injection for treatment of limb spasticity. *Clin Rehabil.* 2016 Jun;30(6):537-48.
- Narayanaswami P, Weiss M, Selcen D, et al. Evidence-based guideline summary: Diagnosis and treatment of limb-girdle and distal dystrophies. *The American Academy of Neurology and the American Association of Neuromuscular & Electrodiagnostic Medicine. Neurology.* October 14, 2014. Vol. 83, No. 16:1453-1463.
- Op de Coul LS, Bleeker S, de Groot JH, et al. Elbow flexion contractures in neonatal brachial plexus palsy: a one-year comparison of dynamic orthosis and serial casting. *Clin Rehabil.* 2022 Aug 24:2692155221121011.
- Pavone V, de Cristo C, Vescio A, et al. Dynamic and static splinting for treatment of developmental dysplasia of the hip: a systematic review. *Children (Basel).* 2021 Feb 4;8(2):104.
- Plaass C, Karch A, Koch A, et al. Short term results of dynamic splinting for hallux valgus - A prospective randomized study. *Foot Ankle Surg.* 2020 Feb;26(2):146-150.
- Rauzi MR, Foran JRH, Bade MJ. Multimodal conservative management of arthrofibrosis after total knee arthroplasty compared to manipulation under anesthesia: a feasibility study with retrospective cohort comparison. *Pilot Feasibility Stud.* 2022 Mar 25;8(1):71.

Sameem M, Wood T, Ignacy T, et al. A systematic review of rehabilitation protocols after surgical repair of the extensor tendons in zones V-VIII of the hand. *J Hand Ther.* 2011;24(4):365-372.

Thien TB, Becker JH, Theis JC. Rehabilitation after surgery for flexor tendon injuries in the hand. *Cochrane Database Syst Rev.* 2004(4):CD003979.

Veltman ES, Doornberg JN, Eygendaal D, et al. Static progressive versus dynamic splinting for posttraumatic elbow stiffness: a systematic review of 232 patients. *Arch Orthop Trauma Surg.* 2015 May;135(5):613-7.

Policy History/Revision Information

Date	Summary of Changes
02/01/2024	<p>Coverage Rationale</p> <ul style="list-style-type: none"> Added language to indicate mechanical stretching devices of the upper extremities (except forearm) are proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Orthoses, Upper Extremity Replaced language indicating: <ul style="list-style-type: none"> “Low-load prolonged-duration stretch devices (LLPS) as an adjunct to therapy are proven and medically necessary for treating existing joint contractures of the <i>upper</i> and lower extremities” with “low-load prolonged-duration stretch devices (LLPS) as an adjunct to therapy are proven and medically necessary for treating existing joint contractures of the <i>forearm</i> and lower extremities” “Static progressive stretch (SPS) splint devices are unproven and not medically necessary, alone or combined with standard physical therapy (PT), for treating joint contractures of the <i>upper</i> and lower extremities” with “static progressive stretch (SPS) splint devices are unproven and not medically necessary, alone or combined with standard physical therapy (PT), for treating joint contractures of the <i>forearm</i> and lower extremities” <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information Archived previous policy version CS077KY.03

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and/or Utilization Review Guidelines that have been approved by the Kentucky Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.