Mechanical Stretching[MS1] Devices (for Louisiana Only)

Policy Number: CS077LA.M~~L~~
Effective Date: ~~June 1, 2025~~TBD

➲ Instructions for Use

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

Low-load prolonged-duration stretch devices (LLPS) as an adjunct to therapy are proven and medically necessary for treating existing joint contractures of the upper 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 upper and lower extremities due to insufficient evidence of efficacy:

- Static progressive stretch (SPS) splint devices
- Patient actuated serial stretch (PASS) devices (patient controlled mechanical stretching)

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the services requested.

The patient's medical record must contain documentation that fully supports the medical necessity for the requested services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

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 federal, state, or contractual requirements 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 and flexion device, includes soft interface material
*E1801	Static progressive stretch/patient actualized serial 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
*E1803	Dynamic adjustable elbow extension only device, includes soft interface material
*E1804	Dynamic adjustable elbow flexion only device, includes soft interface material
E1805	Dynamic adjustable wrist extension and 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
*E1807	Dynamic adjustable wrist extension only device, includes soft interface material
*E1808	Dynamic adjustable wrist flexion only device, includes soft interface material
E1810	Dynamic adjustable knee extension and flexion device, includes soft interface material
*E1811	Static progressive stretch/patient actualized serial 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
*E1813	Dynamic adjustable knee extension only device, includes soft interface material
*E1814	Dynamic adjustable knee flexion only device, includes soft interface material
E1815	Dynamic adjustable ankle extension and flexion device, includes soft interface material
*E1816	Static progressive stretch**/patient actualized serial** ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
*E1818	Static progressive stretch/patient actualized serial stretch forearm pronation/supination device, with or without range of motion adjustment, includes all components and accessories
E1822	Dynamic adjustable ankle extension only device, includes soft interface material
E1823	Dynamic adjustable ankle flexion only device, includes soft interface material
E1825	Dynamic adjustable finger extension and flexion device, includes soft interface material
E1826	Dynamic adjustable finger extension only device, includes soft interface material
E1827	Dynamic adjustable finger flexion only device, includes soft interface material
E1828	Dynamic adjustable toe extension only device, includes soft interface material
E1829	Dynamic adjustable toe flexion only device, includes soft interface material
E1830	Dynamic adjustable toe extension and 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
*E1832	Static progressive stretch finger device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories

HCPCS Code	Description
E1840	Dynamic adjustable shoulder flexion/abduction/rotation device, includes soft interface material
*E1841	Static progressive stretch/patient actualized serial stretch shoulder device, with or without range of motion adjustment, includes all components and accessories

Codes labeled with an asterisk (*) are not on the State of Louisiana Medicaid Fee Schedule and therefore are not covered by the State of Louisiana Medicaid Program.

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**, updated 2022**).

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:
- Low-load prolonged duration stretch (LLPS) devices (i.e., dynamic splinting for restoration of joint ROM)
- Static progressive stretch (SPS) (splinting) devices
- Patient-actuated serial stretch (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)

Randomized controlled trials (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.

Teytelbaum et al. (2024) conducted a prospective randomized controlled trial (RCT) to compare the effectiveness of an at-home high-intensity stretch (HIS) device to traditional physical therapy (PT) and to PT in combination with the HIS device. Thirty-four patients with idiopathic adhesive capsulitis and a minimum of 12 months follow-up were included in this study. Participants were randomized into one of the three groups: HIS device, PT alone, or HIS device + PT. Passive range of motion (ROM), American Shoulder and Elbow Surgeons (ASES), and Simple Shoulder Test (SST) scores were measured. Additionally, patient satisfaction, compliance and complications were recorded. Paired t-test, ANOVA and Chi-squared tests were used in analysis. Final ROM in all planes improved for all groups compared to baseline ($p < 0.001$), with only HIS device group able to restore > 95% of contralateral ROM in all planes at final follow-up. Patients with PT alone were on average slowest to improve ROM from baseline, at 3 months, 6 months, and 1 year in all planes except internal rotation. ASES and SST scores improved for all groups when compared to baseline ($p < 0.001$). Use of HIS-device resulted in greater improvement in SST and ASES Total scores compared to PT alone ($p = 0.045$, and $p = 0.048$, respectively). The authors concluded that use of an at-home high-intensity stretching device for conservative treatment of idiopathic adhesive capsulitis improves outcomes in ROM and in ASES and SST scores both when used as an adjunct to physical therapy and when used alone. This RCT has limitations. First, some early participants in the study did not have complete follow-up due to COVID-19 related protocol deviations (particularly occurring for patients randomized to PT group (n = 7) and combined HIS device and PT groups (n = 7)) and were withdrawn from the study. Despite being blinded before randomization, the treating surgeon was aware of the randomized group at follow-up visits. Further investigation is needed before the clinical usefulness of this device is proven.

Hayes performed an evidence review from ~~5~~ **five** randomized controlled trials (RCTs) and ~~2~~**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 10 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 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 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 8 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 23.5º 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 ±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 2 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 controlled, cohort study was conducted by Gaspar and Willis (2009) to examine the efficacy of dynamic splinting on patients with adhesive capsulitis (AC). The study was conducted at four physical therapy and sports medicine clinics in Texas and California. Sixty-two patients (mean age 55.6 ±7.9) diagnosed with Stage II adhesive capsulitis were grouped by intervention: Group I (control) (n = 15); Group II (physical therapy exclusively) (n = 15); Group III; (shoulder Dynasplint system exclusively) (n = 16); Group IV (combined treatment with shoulder Dynasplint and standardized physical therapy) (n = 16). The duration of this study was 90 days for all groups, and the main outcome measures were change in active, external rotation. Difference was noted for all treatment groups ($p < 0.001$) following a one-way ANOVA. The greatest change with the smallest standard deviation was for the combined treatment group IV, (mean change of 29 degrees). The authors concluded the difference for the combined treatment group was attributed to patients' receiving PT combined with structured "home therapy" that contributed an additional 90 hours of end-range stretching. This adjunct should be included in the standard of care for adhesive capsulitis.

An RCT by Chester et al. (2002) evaluated 54 patients with simple finger extension division in Verdan's zones 4-8. Patients were randomly assigned to 1 of 2 rehabilitation regimens; however, 18 patients were lost to follow-up leaving only 36 patients included in the data analysis. These patients had been assigned to receive early active mobilization combined with static splinting (group 1; n = 19 patients with 29 injured digits) or LLPS (group 2; n = 17 patients with 29 injured digits). The main outcome measures were metacarpophalangeal joint TAM, median extension lag, and median flexion deficit, assessed at 4 weeks and at 3 months post-surgery. At 4 weeks post-surgery, TAM was significantly improved for group 2 (87%) compared with group 1 patients (77%). However, this difference was not maintained, with follow-up TAM at 3 months being similar for both groups (group 1 = 100%; group 2 = 98%). While the median flexion deficit at 4 weeks post-surgery was significantly lower for group 2 (25 degrees) compared with group 1 (45 degrees), this difference was also not maintained at 3 months follow-up with the value being 0 degrees for both groups. No significant difference in median extensor lag was observed at both times. The authors concluded that while LLPS combined with active mobilization results in better TAM at 4 weeks post-surgery than static splinting combined with active mobilization, the long-term efficacy and safety is similar for both rehabilitation regimens.

~~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 8 weeks, there was no statistically significant difference between the 2 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.~~

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.

Kruse et al. (2023) conducted an observational, comparison study to analyze the effects of 8-week proprioceptive neuromuscular facilitation (PNF) stretching on the gastrocnemius medialis muscle-tendon properties, muscle strength, and the ankle joint in children with spastic cerebral palsy (SCP) in comparison to static progressive stretching. Twenty-four children with spastic cerebral palsy were randomly assigned to a static stretching (10.7 ±1.8 years) or PNF stretching group (10.9 ±2.6 years). Plantar flexors were manually stretched at home for 300 s and ~ 250-270 s per day four times a week for eight weeks, respectively. Assessments of ankle joint function (e.g., range of motion), muscle-tendon properties, and isometric muscle strength were conducted using 3D motion capture, 2D ultrasound, dynamometry, and electromyography. A mixed analysis of variance was used for the statistical analysis. Stretching adherence was high in the PNF stretching (93.1%) and static stretching group (94.4%). No changes ($p > 0.05$) were observed in ankle joint function, muscle-tendon properties, and isometric muscle strength after both interventions. Moreover, no differences ($p > 0.05$) were found between the stretching techniques. The authors concluded that the findings support the idea that manual stretching (neither PNF stretching nor static stretching) performed in isolation for eight weeks may not be appropriate to evoke significant changes in muscle-tendon properties, voluntary muscle strength, or joint function in children with spastic cerebral palsy. Limitations include small sample size (24 patients) and short duration of follow-up (eight weeks). Well designed, adequately powered, prospective, controlled clinical trials of static progressive stretching are needed to further describe safety and clinical outcomes (or efficacy).

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 ≥ 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 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~~ **six** 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~~ **four** weeks). Further research with randomized controlled trials is needed to validate these findings.

Pompe et al. (2022) conducted an observational study to evaluate static progressive stretch as a treatment method for hemophilic patients with decreased range of motion (ROM) after total knee arthroplasty (TKA). Static progressive stretch was used to improve ROM in patients with a postoperative extension lag of more than 10° and flexion of less than 80°. A total of ~~7~~ **seven** knees were treated after TKA. Each patient had previously received standard physiotherapy. The patients were additionally treated with the JAS orthosis, which utilized the principles of static progressive stretch for a mean of 21.7 weeks (range ~~9~~ **nine**-30 weeks). Statistical increases in ROM and in Knee Society Score were observed when comparing pre-treatment and post-treatment values. The authors concluded that static progressive stretch using an orthotic device could be a successful adjuvant method for treating joint stiffness in patients with hemophilia after total knee arthroplasty. This study has several limitations. The analysis was performed in hemophilic patients 65 months (range 16-190 months) after TKA. This might contribute to the inferior clinical results in hemophilic compared with non-hemophilic populations. The study evaluated only ~~7~~ **seven** knees in ~~5~~ **five** patients. Due to the small study group and the short observation period, further studies are necessary to assess the value of these results.

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 2022).

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 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). 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.

Willis and Fowler (2016) conducted a longitudinal study to determine whether Dynasplint stretching (immediately after diagnosis) influenced an individual's decision to seek surgical treatment for carpal tunnel syndrome (CTS). Fifty patients (10 men, 40 women, mean age 51.2 ± 12 years) were recruited for this randomized, controlled, longitudinal trial. Participants were diagnosed with CTS by physical examination and nerve conduction studies. The intervention used was Dynasplint stretching that delivered a prolonged duration of low load stretching. Patients who were randomly chosen for the experimental category wore the device for two 30-minute sessions per day with regular increases in splint tension for 60 days. Control patients received nonsteroidal anti-inflammatory medication plus instructions on daily home stretching. The final, longitudinal outcome showed a 72% reduction in surgery chosen by the experimental group (n = 25), compared with 38% reduction for control patients (n = 25). In the previous controlled trial, the Levine-Katz symptom survey scores showed a significant reduction for experimental participants from 45.5 to 32.4 after 60 days (P < .001). Control group participants displayed increased symptom scores of 44.3 to 46.0 after 60 days. The authors concluded that immediate treatment with Dynasplint stretching showed a 2 to 1 reduction in surgery, with abundant financial savings. The limitations of this study include that only a small population was tested and that this trial was conducted at only one site. Another limitation is that the experimental treatment duration was limited to 60 days. Future research should be conducted in a multicenter trial to measure effects with longer, 10-year durations of Dynasplint stretching treatment regimes.

Veltman et al. (2015) conducted a systematic review to evaluate the best current evidence for nonoperative treatment options for posttraumatic elbow stiffness. Eight studies (1 RCT and 7 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, 3 sessions per week for 4 weeks. In addition, the experimental group used a SPS device for 4 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 2 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 2 postoperative total knee arthroplasty (TKA) mobilization regimens. All 160 patients underwent unilateral TKA and were then assigned to 1 of 2 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 2 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 1 day prior to surgery and at 6 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 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. 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 20~~**June 3**, ~~2024~~**2025**)

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Policy History/Revision Information

Date	Summary of Changes
TBD	**Medical Records Documentation Used for Reviews** • Added language to indicate: ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested ○ The patient's medical record must contain documentation that fully supports the medical necessity for the requested services ○ This documentation includes but is not limited to relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures ○ Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request **Applicable Codes** • Revised description for HCPCS code E1816 • Added notation to indicate HCPCS codes E1803, E1804, E1807, E1808, E1813, E1814, and E1832 are not on the State of Louisiana Medicaid Fee Schedule and therefore are not covered by the State of Louisiana Medicaid Program **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS077LA.L

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 may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies 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.