Mechanical Stretching Devices (for Ohio Only)

Policy Number: CS077OH.I – P
Effective Date: February 1, 2023

Instructions for Use

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Related Policies
None

Application

This Medical Policy only applies to the state of Ohio.

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

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/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

HCPCS Code	Description
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). (Accessed December 1, 2020)

ERMI Shoulder Flexionater® is intended to address the needs of individuals with decreased glenohumeral abduction and external rotation secondary to excessive scar tissue. It biomechanically and anatomically focuses treatment on the glenohumeral joint without stressing the other shoulder joints. Once customized, the Shoulder Flexionater can be used at home without assistance to perform serial stretching exercises, alternately stretching and relaxing the scar tissue surrounding the glenohumeral joint. The device has three sections, the main frame, arm unit and pump unit. The shoulder flexionator was listed with the FDA in 2001 and is Class I exempt.

ERMI Knee/Ankle Flexionater® is a self-contained device that facilitates recovery from decreased ROM of the knee and/or ankle joints. The Knee Flexionator is designed to address the needs of individuals with arthrofibrosis (excessive scar tissue within and around a joint). The Knee/Ankle Flexionator is a variable load/variable position device that uses a hydraulic pump and quick-release mechanism to allow individuals to perform dynamic stretching exercises in the home without assistance, alternately stretching and relaxing the scar tissue surrounding affected joints. The Knee/Ankle Flexionator includes a frame to house hydraulic components, a pump handle and quick release valve for individual control, supporting footplate and specially incorporated padded chair. The frame attaches to a folding chair and is adjustable to accommodate treatment of either extremity, or both extremities simultaneously. The load potential ranges from a few ounces up to 500 foot-pounds. The Knee/Ankle Flexionator was listed with the FDA in 2002 and is Class 1 exempt.

ERMI Knee Extensionater® and ERMI Shoulder Extensionater® provide serial stretching, using an individual-controlled pneumatic device that can deliver variable loads to the affected joint. The manufacturer claims that these are the only devices on the market that can "consistently stretch scar tissue, without causing vascular reinjury and thereby significantly reduce the need for additional surgery." The Extensionator telescopes to the appropriate length and is applied to the leg with Velcro straps. During a typical training session, the joint is stretched for 1-5 minutes, is allowed to recover for an equal length of time, and then is stretched again. A typical training session lasts 15 minutes, and the usual prescription is to perform 4-8 training sessions per day.

Clinical Evidence

Low-Load Prolonged-Duration Stretch Devices (LLPS)

Hayes performed an evidence review from 5 randomized controlled trials (RCTs) and 2 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 2020).

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. 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 (2013).

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.

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 postsurgery. 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.

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 postsurgery. At 4 weeks postsurgery, 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 postsurgery 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 postsurgery 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. 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 (2001).

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.

Clinical Practice Guidelines

American Academy of Neurology (AAN)/American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM)

In their combined evidence-based guideline on diagnosis and treatment of limb-girdle and distal dystrophies, the AAN and the AANEM directs clinicians to prescribe physical and occupational therapy, as well as bracing and assistive devices that are adapted specifically to the patient's deficiencies and contractures, in order to preserve mobility and function and to prevent contractures (Narayanaswami, et al. 2014).

Static Progressive Stretch (SPS) (Splinting) Devices

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, undated 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 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 differed 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 (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 non-operative 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.

While more studies are available for SPS treatment of joint contractures of the upper extremities, mainly for finger joints following finger extensor or flexor injuries, the evidence was insufficient to draw definitive conclusions. The evidence suggests that while adjunct SPS treatment may achieve the rehabilitation goal sooner than static splinting and PT, an active mobilization regimen combined with SPS treatment may not improve joint mobility beyond what can be achieved with a standard PT program.

Patient-Actuated Serial Stretch (PASS)

PASS devices supply a low to high-level load to the joint using pneumatic or hydraulic systems that can be adjusted by the patient. PASS devices are available for the knee/ankle, shoulder, or knee. 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.

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 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 December 1, 2020)

Patient-controlled stretch devices such as Dynasplint, Ultraflex, Pro-glide Knee, Elbow, Wrist (DeRoyal® Advance Dynamic ROM®) are approved as Class I devices and exempt from testing.

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Policy History/Revision Information

Date	Summary of Changes
02/01/2023	• Created state-specific policy version
05/01/2021	Template Update • Replaced content sub-heading titled “Professional Societies” with “Clinical Practice Guidelines” in *Clinical Evidence* section • Removed *CMS* section • Replaced reference to “MCG™ Care Guidelines” with “InterQual® criteria” in *Instructions for Use*
02/01/2021	Application • Reformatted content
01/01/2021	Template Update • Reformatted policy; transferred content to new template Supporting Information • Updated *Clinical Evidence*, *CMS*, and *References* sections to reflect the most current information • Archived previous policy version CS077.H

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.

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