


MEDICAL POLICY	Mechanical Stretching Devices for Joints of the Extremities
Effective Date: 7/1/2022  7/1/2022	Medical Policy Number: 44 Medical Policy Committee Approved Date: 12/10; 2/11; 4/13; 4/14; 5/15; 3/16; 4/17; 3/18; 8/19; 12/19; 6/2020; 03/2021; 4/2022
Medical Officer Date	

See Policy HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Note: This policy does not address low-load prolonged-duration stretch (LLPS) devices/dynamic stretch devices (e.g., Dynasplint® System, Ultraflex® System, Pro-Glide™ Dynamic Splints), which may be considered medically necessary.

- I. Static progressive (SP) stretch devices (e.g., Joint Active Systems® [JAS]) are considered **not medically necessary and are not covered** for any indication.
- II. Patient-actuated serial stretch (PASS) devices (e.g., ERMI, Inc. Flexionater®/Extensionater®) are considered **not medically necessary and are not covered** for any indication.

Link to [Policy Summary](#)

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HCPCS CODES

All Lines of Business	
Not Covered	
Static Progressive (SP) Stretch Devices	
E1801	Static progressive stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1806	Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
E1811	Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
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
E1821	Replacement soft interface material/cuffs for bi-directional static progressive stretch device
E1831	Static progressive stretch toe device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1841	Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories
<p style="text-align: center;">Unlisted Codes</p> <p>All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as not covered.</p>	
Patient-Actuated Serial Stretch (PASS) Devices	
E1399	Durable medical equipment, miscellaneous

DESCRIPTION

Joint Contracture

A joint contracture is characterized by a chronically reduced range of motion (ROM) secondary to structural changes in non-bony tissues, including muscle, tendons, ligaments, and skin. This joint dysfunction is due to elastic connective tissue being replaced with inelastic fibrous material, which is most commonly due to prolonged immobilization following surgery or trauma. Treatment and prevention of joint contractures include manual joint mobilization by a physical therapist, serial plastering, static splinting, mechanical stretching devices, continuous device-assisted passive motion (CPM), massage, exercise, electrical stimulation, botulinum toxin, and surgery.

Static Progressive (SP) Stretch Devices

SP stretch devices hold the joint in a set position while allowing for modification of the joint angle and may also allow for active motion without resistance. The SP device does not exert stress on the tissue unless the joint angle is set to maximum range of motion.

Static progressive (SP) stretch devices include:

- Joint Active Systems® (JAS) Static Progressive Stretch devices (finger, wrist, elbow, shoulder, knee, ankle)

Patient-Actuated Serial Stretch (PASS) Devices

PASS devices allow for resisted active and passive motion within a limited range. PASS devices are adjusted by the patient and provide a low-to-high level load to the joint using pneumatic (e.g., Extensionator®) or hydraulic (e.g., Flexionator®) systems.

Patient-actuated serial stretch (PASS) devices include:

- ERMI, Inc. Knee Extensionator®
- ERMI, Inc. Knee/Ankle Flexionator®
- ERMI, Inc. Shoulder Flexionator®
- ERMI, Inc. MPJ Extensionator®
- ERMI, Inc. Elbow Extensionator®

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of static progressive (SP) and patient-actuated serial (PASS) stretch devices as a treatment of joint contracture. Below is a summary of the available evidence identified through February 2022.

Static Progressive (SP) and Patient-Actuated Serial (PASS) Stretch DevicesSystematic Reviews

In 2018 (updated 2021), Hayes conducted an evidence review to the efficacy and safety of mechanical stretching devices for contracture of any joint due to any cause.¹ A search of the peer-reviewed literature identified 23 studies as eligible for inclusion; however, very few of these studies evaluated static progressive (SP) and patient-actuated serial (PASS) stretch devices. The majority and highest quality studies evaluated low-load prolonged-duration stretch (LLPS) devices. Studies enrolled 21 to 192 patients and the outcome measures included range of motion (ROM), joint function, joint pain, and type and rate of complications. Nine of the studies did not assess outcomes beyond the end of treatment. The remaining studies follow-up periods ranged from 1 to 39 months post-treatment. The following sections summarize the available evidence identified by Hayes for SP and PASS devices.

Knee

Of the included studies that evaluated static progressive (SP) stretch devices for the knee (1 prospective, nonrandomized controlled study and 1 prospective uncontrolled study), there was no evidence of long-term treatment benefit. There was a small short-term treatment benefit for SP devices as an adjunct to physical therapy when compared to a static extension regimen. However, Hayes stated, “the difference in ROM was small and may not be clinically meaningful.”¹ Only one retrospective study was identified that evaluated PASS for the treatment of knee contractures. The study found no statistically significant difference in mean passive extension.

Wrist

One study (prospective uncontrolled) was identified that evaluated SP stretching devices for the treatment of wrist contracture in 47 patients. The results suggested that SP increases wrist ROM in wrist contractures that no longer improve with physical therapy; “however, the study had several limitations that decreased the study quality—including lack of a control or comparator group, small sample size, criteria determining whether a wrist was refractory to physical therapy not defined, and lack of long-term follow-up—thus precluding definitive conclusions.”¹

Elbow

One retrospective controlled study involving 42 patients evaluated SP (n=23) or physical therapy (n=19) for the treatment of posttraumatic elbow contracture. The results suggested that SP as an adjunct to physical therapy may not improve elbow ROM but may decrease the need for repeat surgery; however, there were several limitations including the retrospective design, lack of randomization, and lack of blinding. Additionally, the control and experimental groups were not treated the same; thus, Hayes states the “study results have to be interpreted with caution.”¹

Overall, very few studies were available for SP and PASS devices, and the body of evidence was of low quality due to limitations in study design. Due to this limited evidence, systematic review was not possible. Ultimately, Hayes concluded the following:

- D1 for use of low-load prolonged-duration stretch (LLPS) mechanical stretching devices for treatment of finger joint contractures following extensor injury and repair.
- D2 for use of LLPS, static progressive stretch (SPS) or patient-actuated serial stretch (PASS) mechanical stretching devices for treatment of other types of contractures of the finger joint.
- D2 for use of LLPS, SPS, or PASS mechanical stretching devices for treatment of contractures in any other joint for any indication.

Static Progressive (SP) Stretch DevicesRandomized Controlled Trials (RCTs)

The evidence review identified the following RCTs evaluating SP stretch devices for joint contracture of the elbow, shoulder, and foot.

- In 2014, Ibrahim et al. conducted a prospective randomized study to evaluate the efficacy of a static progressive stretch (SPS) device as an adjunct to physical therapy in treating adhesive capsulitis of the shoulder.² A total of sixty patients were randomly assigned to receive three physical therapy sessions per week for 4 weeks with the addition of a SPS device for 4 weeks (experimental group only). The primary outcome was shoulder range of motion and secondary outcome measures were function (measured by the Disabilities of the Arm, Shoulder, and Hand [DASH] questionnaire) and pain (measured using the visual analog scale [VAS]).

The results indicated statistically significant differences between groups for all outcome measures—0.3 for mean VAS scores, -10.1 for DASH scores, 21.2 degrees for shoulder passive external rotation, 26.4 degrees for shoulder passive abduction, and 27.7 degrees for shoulder active abduction. At 12 months follow-up, the differences between groups were maintained.

Strengths of this study include the randomized controlled design, use of a comparator group. However, limitations are present in the small sample size, lack of blinding, subjective outcome measures, and short follow-up. Although the results suggest SPS devices may have beneficial effects on shoulder joint contracture, the evidence remains insufficient to support long-term efficacy and improvement in patient health outcomes compared to standard therapy or other mechanical stretching devices (e.g., low-load prolonged-duration stretch [LLPS] devices).

- In 2012, Lindenhovius and colleagues conducted a prospective randomized controlled trial of dynamic versus static progressive elbow splinting for posttraumatic elbow stiffness.³ A total of 66 patients with posttraumatic elbow stiffness were randomized to static progressive splints (n=35) or dynamic splinting (n=31)(e.g., low-load prolonged-duration stretch [LLPS] devices). The primary outcome of interest was function measured using the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire at 6 and 12 months follow-up.

There were no statistically significant differences between groups in flexion at any time point. “The average DASH score (dynamic versus static) was 50 versus 45 points at enrollment ($p = 0.52$), 32 versus 25 points at six months ($p < 0.05$), and 28 versus 26 points at twelve months after enrollment ($p = 0.61$).”³

Strengths of this study include the randomized controlled design, use of intention to treat analysis, and use of a comparator group. Methodological limitations are present in the lack of blinding, small sample size, subjective primary outcome measures, and short follow-up period. The authors concluded, “(p)osttraumatic elbow stiffness can improve with exercises and dynamic or static splinting over a period of six to twelve months...there were no significant differences in improvement in motion between static progressive and dynamic splinting protocols...”³

- In 2010, Sharma et al. conducted a randomized controlled trial to evaluate a static progressive stretch brace as a treatment of pain and functional limitations associated with plantar fasciitis.⁴ A total of 13 patients were randomized to either an exercise (control) group (n=8) or a brace (experimental) group (n=9) for an 8-week treatment period and 1-month follow-up. The primary outcomes of interest were pain and functional limitations measured with the Foot Functional Index pain subscale, the American Orthopaedic Foot and Ankle Society Ankle-Hindfoot Scale, and great toe extension motion.

Data was only available for 7 subjects in the exercise group and 6 subjects in the brace group. Overall, pain ($p=0.04$), morning pain ($p=0.02$), and functional rating ($p=0.005$) improved in both groups as compared to baseline measures. No changes were seen in either group with great toe extension range of motion.

Strengths of this study include the randomized controlled design and the use of a comparator group. However, significant methodological limitations are present in the very small sample size, lack of blinding, losses to follow-up, and short follow-up period. The authors concluded “(b)oth interventions (static, exercise, and brace stretching) were beneficial for treating pain and functional limitations, suggesting that static progressive stretch brace is an effective alternative option to static stretching exercises for people with plantar fasciitis.”⁴

Nonrandomized Studies

Several additional nonrandomized studies were identified that evaluated SP stretch devices for the treatment of contractures of various joints.⁵⁻¹² Although the results of these studies indicate SP stretch devices may be useful in the treatment of joint contracture, significant methodological limitations diminish the validity and reliability of these conclusions. All studies are limited in their design (case series, retrospective nonrandomized studies), small sample sizes, lack of follow-up, lack of a comparator group, and lack of statistical analysis. Additionally, this evidence does not indicate SP stretch devices improve patient health outcomes compared to standard treatment options (e.g., physical therapy).

Patient-Actuated Serial Stretch (PASS) Devices

Randomized Controlled Trials (RCTs)

In 2012, Papotto and Mills conducted a randomized controlled trial to assess high and low intensity mechanical therapy for the treatment of severe flexion deficits following total knee arthroplasty.¹³ A total of 20 patients were randomized to receive high-intensity stretch home mechanical therapy ($n=11$)(Group 1)(i.e., patient-actuated serial stretch device) or low-intensity stretch home mechanical therapy ($n=9$)(Group 2). The outcomes of interest included passive knee flexion and functional range of motion.

The high intensity group showed significantly greater gains in both passive knee and flexion outcome scores. “The change in passive knee flexion significantly correlated with the change in outcome scores, and a significantly greater number of patients in the HIS group (91%) were able to achieve a functional range of motion $>110^\circ$ than those in the LIS group (22%, $p < .001$).”¹³

The results of the study indicated that high intensity home mechanical therapy devices are more effective compared to low intensity devices for the treatment of postoperative arthrofibrosis; however, the very small sample size, lack of long-term follow-up, lack of blinding, and lack of intention to treat analysis significantly impact the reliability and validity of this conclusion.

Nonrandomized Studies

The evidence review identified one additional nonrandomized study Branch et al, which evaluated PASS for loss of knee flexion.¹⁴ A total of 34 patients underwent PASS therapy following failure of physical therapy alone. Overall 91.2% (31) patients regained functional flexion (defined as flexion to 115 degrees) after 6.7 weeks. On average, knee flexion progressed during treatment from 70.8 degrees to 130.6 degrees. Two patients required surgical intervention. Although these results indicate PASS may improve knee flexion and reduce the need for surgical intervention, the methodological limitations of this study do not permit meaningful conclusions regarding PASS for knee contractures.

CLINICAL PRACTICE GUIDELINES

No clinical practice guidelines were identified for the use of static progressive (SP) stretch or patient-actuated serial stretch (PASS) devices for the treatment of joint contractures.

CENTERS FOR MEDICARE & MEDICAID

Under Medicare, only medically reasonable and necessary services are covered (*Title XVIII* of the Social Security Act, §1862(a)(1)(A)). As of March 8, 2022, no specific Medicare coverage policy or guidance (e.g., manual, national coverage determination [NCD], local coverage determination [LCD] article [LCA], etc.) was identified which addresses mechanical stretching devices for joints of the extremities. In the absence of a NCD, LCD, or other Medicare policy, Medicare guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an objective, evidence-based process, based on authoritative evidence. (*Medicare Managed Care Manual, Ch. 4, §90.5*) Therefore, this Company coverage review will be applied for medical necessity decision-making.

POLICY SUMMARY

The available peer-reviewed literature demonstrating the effectiveness of static progress (SP) stretch devices is limited. All studies are limited due to small-sample sizes, short follow-up periods, and non-randomized design; therefore, the impact of SP stretch devices on long-term patient health outcomes remains unknown. Additional studies, of good methodological quality, with longer follow-up periods are required to establish SP stretch devices as a beneficial alternative to physical therapy or low-load prolonged-duration stretch devices. Furthermore, no clinical practice guidelines were identified which assessed SP stretch devices for the treatment of joint contracture.

There is a paucity of peer-reviewed medical literature evaluating patient-actuated serial stretch (PASS) devices. The available evidence is insufficient to demonstrate the safety, efficacy, and long-term health outcomes for the treatment of joint contractures. Additional studies of good methodological quality are required to establish device effectiveness and to determine if PASS devices are superior to physical therapy or other mechanical stretching devices. Furthermore, no clinical practice guidelines were identified which assessed PASS devices for the treatment of joint contracture.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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