Anthem

# Medical Policy

**Subject:** Static Progressive Stretch (SPS) and Patient-Actuated Serial Stretch (PASS) Devices
**Document #:** DME.00038
**Status:** Reviewed
**Publish Date:** 06/28/2023
**Last Review Date:** 05/11/2023

## Description/Scope

This document addresses static progressive stretch (bi-directional static progressive stretch) and patient-actuated serial stretch devices.

Mechanical stretching devices are designed to provide a low intensity, prolonged duration of stretch beyond the limit of the contracted range of motion (ROM) in order to cause permanent elongation of the connective tissue. Mechanical stretching devices are not motorized and may be prefabricated or custom fabricated. This document specifically addresses two types of mechanical stretching devices used as a treatment of joint stiffness and contracture:

- the bi-directional static progressive devices (for example, Joint Active Systems (JAS) splints and Air Cast®); and
- the patient-actuated serial stretch (PASS) devices (for example, Elite Seat®, ERMI Knee Extensionater®, ERMI Elbow Extensionater®, ERMI Knee/Ankle Flexionater®, and ERMI Shoulder Flexionater®).

**Note:** For additional information, please see the following documents:

- CG-DME-05 Cervical Traction Devices for Home Use
- CG-DME-39 Dynamic Low-Load Prolonged-Duration Stretch Devices
- SURG.00008 Mechanized Spinal Distraction Therapy

## Position Statement

**Investigational and Not Medically Necessary:**

Static progressive stretch (SPS) devices are considered **investigational and not medically necessary.**

Patient-actuated serial stretch (PASS) devices are considered **investigational and not medically necessary.**

## Rationale

Various types of physical therapy are often prescribed to restore normal joint mobility, particularly after surgical intervention. Techniques include active and passive ROM exercises, manual stretching, splinting and serial casting. Manual physical therapy involves the use of passive stretching with progressively greater loads of force to extend the joint beyond its limited ROM. Manual physical therapy is limited in terms of the number and duration of sessions, and stretching devices may be considered when physical therapy is unable to achieve treatment goals.

***Static progressive stretch (bi-directional static progressive stretch) devices***

Static progressive stretch (SPS) devices (also known as bi-directional SPS devices) are used for multiple short treatment sessions per day with the joint angle progressively advanced at each session. SPS devices essentially allow the individual to duplicate physical therapy by therapists who apply a new positional stretch multiple times throughout the session. Examples of this type of device include but are not limited to the Joint Active Systems (JAS) splints (for example, JAS Elbow, JAS Shoulder, JAS Ankle, JAS Knee, JAS Wrist, and JAS Pronation-Supination) and Air Cast.

Research on SPS devices, (including but not limited to the JAS device), is limited to case reports and small uncontrolled studies.

*Ankle*

Costa and colleagues (2012) evaluated an SPS orthosis for the treatment of post-traumatic chronic ankle stiffness in 26 individuals (26 ankles). Study participants began treatment using an SPS orthosis at a mean of 47 weeks (range, 6 to 272 weeks) following their initial injury. According to the patient-directed protocol, the SPS orthosis was used for a period of 30 minutes, 1 to 3 times per day, until the range of motion (ROM) was considered to have plateaued. Mean treatment time was 10 weeks (range, 3 to 19 weeks). Treatment duration, range of motion, and complications with the device were assessed. The overall mean improvement in motion (combined dorsiflexion and plantar flexion) was 17° (range, 2 to 44°); a mean improvement in dorsiflexion of 9° (range, -2 to 20°), and a mean improvement of 8° of plantar flexion (range, -10 to 35°). There were no reports of numbness or skin problems. Based on the study findings, the authors concluded that a patient-directed treatment protocol using a static progressive stretch orthosis was an effective ancillary method for the treatment of chronic post-traumatic ankle stiffness that was refractory to standard physical therapy techniques.

*Elbow*

In 2000, Gelinas and colleagues published the results of a study which assessed the effectiveness of static progressive turnbuckle splinting in 22 individuals (15 women and 7 men) with an elbow contracture who had failed to improve with supervised physiotherapy and splinting for at least 2 months. The mean period from the time of the original injury or from surgery was 4 months. Of the 11 subjects who used the static progressive stretch device to improve both extension and flexion, 2 used the device to improve elbow extension and 9 to improve elbow flexion. The stretching device was used for 20 hours per day for a mean duration of 4.5 ± 1.8 months. The mean range of flexion prior to static progressive stretching was from 32 ± 10° to 108 ± 19° and afterwards from 26 ± 10° ($p=0.02$) to 127 ± 12° ($p=0.0001$). A total of 18 of the 22 participants (82%) completed the study. Functional arc of movement, defined as at least 30° to 130°, was achieved in 11 subjects. Eight subjects experienced improved movement with turnbuckle splinting, but the functional arc was not achieved; 6 of these were satisfied with the results of splinting and did not wish to proceed with surgical intervention, but 2 did opt to undergo surgical release of the elbow contracture. Three participants did not experience improvement in movement with the use of the turnbuckle splint. Of the 18 participants who completed the study and returned for an independent

follow-up, 2 had lost more than 10° of movement of the elbow after discontinuing the splint. The mean rating of patient satisfaction on the visual analogue scale was 7.3 ± 1.3, with a score of 10 indicating the individual was very satisfied with the results. Study participants expressed difficulty in sleeping and completing activities of daily living while wearing the stretching device. As a result, most of the subjects could only tolerate wearing the splint for a mean of 15 ± 3 hours daily. The researchers were unable to correlate splinting compliance and the improvement in ROM because the subjects were unable to recall the number of hours spent daily in the splint. The researchers concluded that turnbuckle splinting is a safe and effective treatment for individuals with established elbow contractures who have failed to respond to conventional physiotherapy; however, the study is small and has several methodologic concerns.

Ulrich and colleagues (2010) evaluated the result of a patient-directed SPS device to improve ROM in individuals who had posttraumatic elbow contractures. A total of 37 elbows were treated with a 30-minute stretching protocol performed in 1 to 3 sessions daily for a mean duration of 10 weeks (range, 2-22 weeks). The mean increase in ROM was 26° (range, 2-60°). Increases in motion were noted in 35 of 37 elbows. Study participants lowered their analgesic use and were highly satisfied with the device (mean satisfaction score of 8.5 of 10 points, where 10 indicated that the subject was very happy). The authors concluded that consistent improvements in restoring ROM can be achieved with short treatment times by using a device based on the principles of SPS and stress relaxation in subjects with posttraumatic elbow contractures. This study is a small study with methodologic concerns.

Muller and colleagues (2013) conducted a meta-analysis to assess and compare the effectiveness of dynamic, static, or static progressive bracing in individuals with elbow stiffness of traumatic or postoperative origin and without evidence of ossification. A total of 13 eligible studies were used to provide data on 14 treated groups in 247 participants. The mean age of the participants was 34.5 ± 10.4 years with female subjects comprising 46% ± 12%. The mean duration of treatment from the incident to the start of brace treatment was 6.9 ± 5.1 months. The mean improvement in ROM during the treatment period was 38.4 ± 8.9° (95% confidence interval, 39.5°-41.8°). The authors concluded that current evidence supports the use of static-progressive stretching devices when used 3 times 30 minutes per day in each direction (flexion and extension) as a first line of treatment in individuals with post-traumatic and postsurgical elbow stiffness. The authors also recommend that if this treatment fails or if causes for stiffness other than soft-tissue incompliance are identified, then surgical interventions should be considered. The authors acknowledged that limitations of the meta-analysis include the fact that the findings are highly dependent on the quality of the primary studies included and none of the included studies systematically evaluated participant compliance. Because there is a paucity of high-quality randomized controlled trials on elbow bracing, the results are subject to bias. Additionally, there is significant heterogeneity among the studies evaluated including but not limited to differences in treatment regimens and study populations.

*Knee*

Bonutti and colleagues (2010) evaluated an SPS device as a means of treating refractory knee stiffness subsequent to total knee arthroplasty. Twenty-five participants who experienced knee stiffness and no improvement with conventional physical therapy modalities were treated with the device. After a median of 7 weeks (range, 3-16 weeks), participants experienced a median increase in ROM of 25° (range, 8-82°) and a median gain in knee active flexion of 19° (range, 5-80°). A total of 92% of the participants were satisfied with the results. The authors concluded that static progressive stretching devices may be an effective method for increasing the ROM and satisfaction levels of individuals who develop arthrofibrosis after total knee arthroplasty. This study is a small study with methodologic concerns.

Aspinall and colleagues (2021) reported the results of a systematic review that assessed the effectiveness of medical stretching devices in the treatment of knee arthrofibrosis. The study included 13 studies and 558 participants status post knee surgery. In addition to home exercises and physiotherapy, participants were placed on continuous passive motion (CPM) and long duration stretch (load control [LC] creep) or static progressive (displacement control [stress relaxation]) stretching devices. The primary outcome measure in all studies was improved ROM. Secondary outcome measures included stiffness, pain, 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 stiffness, pain and function) was reported between pre-treatment evaluation and weeks 2 and 6 weeks ($p<0.05$). No difference was observed between groups in total or sub scores. All studies reviewed utilized the universal goniometer (UG) to quantify the primary outcome of ROM, however, the authors questioned the reliability and validity of the UG due to multiple assessors involved in measuring the joint. The authors concluded that CPM, static progressive stretch and long duration stretch devices improve ROM in subjects with knee stiffness. However, the authors also state that “the heterogeneity of studies identified, does not lend itself to a meta-analysis. Currently there are only two randomised clinical trials investigating this topic. When more are completed with appropriate and comparable designs a meta-analysis will be possible.” Furthermore: “Further research using randomised controlled trial designs is required to investigate efficacy of home medical stretching devices and longer term follow up of patients […] (minimum 6 months).” (Aspinall, 2021).

*Shoulder*

In 2012, Ibrahim and colleagues prospectively compared standard physical therapy alone to a combination of physical therapy with a SPS orthosis in the treatment of shoulder adhesive capsulitis. A prospective, randomized, blinded, controlled study was conducted with a total of 60 participants diagnosed with shoulder adhesive capsulitis (control group, n=30, treatment group, n=30). The control group received physical therapy for 4 weeks, while the treatment group received physical therapy in addition to using an SPS shoulder device for 4 weeks. Active and passive abduction, passive external rotation, DASH scores, and VAS pain scores were recorded for all of the participants at 4, 12, and 24 weeks follow-up. Use of the SPS orthosis compared to physical therapy alone demonstrated a significantly greater mean improvement in all range of motion categories. Mean passive abduction was 162° with the orthosis versus 136° in physical therapy alone group. Mean active abduction was 141° and 114°, respectively. Mean external rotation was 73° and 52°, respectively. DASH scores improved when the SPS orthosis was used (5 vs.15 points). Use of an SPS orthosis for subjects with shoulder adhesive capsulitis resulted in significantly better ROM and DASH scores within 1 month of beginning treatment than physical therapy alone. While this study has reasonable study design, it is a small study with limited follow-up, limiting the generalizability and clinical utility.

Published, peer-reviewed, scientific literature demonstrating the effectiveness of bi-directional SPS devices is limited. Because most of the studies involve small sample sizes and non-randomized study designs, the impact of these devices on net health outcomes remains uncertain and these devices have not yet been shown in appropriately designed studies to be as beneficial as any established alternative or shown improvement outside the investigational setting.

***Patient-actuated serial stretch (PASS) devices***

Patient-actuated serial stretch (PASS) devices allow resisted active and passive motion within a limited range. PASS devices supply a low- to high-level load to the joint, using tensioning (pneumatic, hydraulic or rachet) systems that can be adjusted by the individual. Examples of PASS devices include the Elite Seat, ERMI Knee Extensionater, ERMI Elbow Extensionater, ERMI Knee/Ankle Flexionater, and ERMI Shoulder Flexionater.

In 2003, Branch and colleagues conducted a prospective study to determine the effectiveness of using patient-controlled home

mechanical therapy to increase knee ROM in individuals with knee contracture who had failed to reach full ROM with a 6-week regimen of conventional physical therapy. The sample size included 34 subjects who developed knee contractures following anterior cruciate ligament (ACL) injury (n=14), peripatellar injury (n=7), fracture (n=4), or other, unspecified causes (n=9). Subjects used a patient-controlled device (the ERMI Knee/Ankle Flexionater) 4 to 8 times daily for 15 minutes, from 2 to 12 weeks. Thirty-one (91.2%) of these individuals regained functional flexion after 6.7 weeks. Full ROM was regained by 74% of the individuals and mean knee flexion progressed from 70.8° to 130.6°. Two individuals in this study required surgical manipulation. Conclusions regarding this study are limited by the small sample size and lack of a control group. Furthermore, due to the limited number of published studies investigating PASS devices, no conclusion can be drawn regarding their efficacy or clinical utility.

## Background/Overview

A joint contracture is characterized by chronically reduced ROM secondary to structural changes in non-bony tissues including muscle, tendons, ligaments, and skin. Prolonged immobilization of joints following surgery or trauma is the most common cause of joint contractures. While immobilization may prevent excess tension to the joint and prevent disruption of the healing of repaired tissues, it can also cause pathologic conditions that contribute to the development of joint contractures. Other causes of joint contractures include spasticity secondary to nerve damage, such as stroke or spinal cord injury, and muscle weakness due to muscle, tendon, or ligament disease including paralysis.

***Static progressive stretch (bi-directional static progressive stretch) devices***
Static progressive stretch (SPS) devices apply a prolonged stretch to joints using a low load that is typically increased every few minutes by the individual. These devices permit full ROM (flexion and extension). The period of device utilization is typically 30 minutes, used 2-3 times a day.

***Patient-actuated serial stretch (PASS) devices***
PASS devices supply a low to high-level load to the joint using pneumatic or hydraulic systems that can be adjusted by the individual. These devices are custom fitted.

## Coding

*The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.*

**When services are Investigational and Not Medically Necessary:**
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

**HCPCS**

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| 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 |

**ICD-10 Diagnosis**

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|---|---|
| | All diagnoses |

## References

**Peer Reviewed Publications:**


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systematic review and meta-analysis of 13 studies. J Shoulder Elbow Surg. 2013; 22(8):1146-1152.
12. Ulrich SD, Bonutti PM, Seyler TM, et al. Restoring range of motion via stress relaxation and static progressive stretch in posttraumatic elbow contractures. J Shoulder Elbow Surg. 2010; 19(2):196-201.

## Index



**The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.**

## Document History

| Status | Date | Action |
|---|---|---|
| Reviewed | 05/11/2023 | Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References and History sections. |
| Reviewed | 05/12/2022 | MPTAC review. Updated Rationale, References and History sections. |
| Reviewed | 05/13/2021 | MPTAC review. Updated References and History sections. |
| Reviewed | 05/14/2020 | MPTAC review. Updated History section. |
| Reviewed | 06/06/2019 | MPTAC review. Added the Elite Seat device to this document as an example. Updated Description/Scope, Rationale, and History sections. Updated Coding section; removed E1399 NOC, not applicable for PASS devices. |
| Reviewed | 09/13/2018 | MPTAC review. Updated review date, Rationale and History sections. |
| Reviewed | 11/02/2017 | MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated review date and History sections. |
| Reviewed | 11/03/2016 | MPTAC review. Updated review date, Rationale, References and History sections. |
| Reviewed | 11/05/2015 | MPTAC review. Updated review date, References and History sections. Removed ICD-9 codes from Coding section. |
| New | 11/13/2014 | MPTAC review. Initial document development. |

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