1.03.05	Patient-Controlled End Range of Motion Stretching Devices		
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Section:	1.0 Durable Medical Equipment	**Page:**	Page 1 of 16

Policy Statement

I. Patient-controlled end range of motion stretching devices (static progressive and serial) are considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

There are HCPCS codes for these types of 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
- **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

Description

Patient-controlled stretching devices are used at home to increase range of motion in patients who have impaired functional status due to decreased range of motion. We address 2 types of commercially available devices. Static progressive stretch devices (e.g., Joint Active Systems, Static-Pro) provide low- to moderate-intensity stretching with a crank or ratchet that progressively increases the stretch within each session, and serial stretch devices (e.g., End Range of Motion Improvement [ERMI]) use hydraulics to alternate between periods of higher intensity stretch and relaxation.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

The U.S. Food and Drug Administration (FDA) has determined that devices classified as "Exerciser, Non-Measuring" are considered Class I devices and exempt from 510(k) requirements. This classification does not require submission of clinical data on efficacy, only notification to the FDA prior to marketing. FDA product code: ION

Rationale

Background

Range of Motion Impairments

Loss of full range of motion occurs in a significant proportion of patients following surgical procedures around a joint, such as total knee arthroplasty or anterior cruciate ligament reconstruction. The most common cause of severe postoperative motion loss is the development of intra-articular or extra-articular arthrofibrosis. Arthrofibrosis, characterized by periarticular fibrosis and bands of scar tissue, is described as a painful loss of end range of motion compared with the normal contralateral side. Loss of knee range of motion can lead to impairments in walking, sitting, rising from a chair, and navigating stairs. In 2010, Stephenson et al estimated that based on the annual rates of total knee arthroplasty and anterior cruciate ligament reconstruction, the number of major knee surgery patients affected by arthrofibrosis in the United States would be at least 85,000 per year, and approximately 21,000 patients each year would be at risk of requiring additional surgery.[1]

Treatment

Treatment of arthrofibrosis may include physical therapy, manipulation under anesthesia, arthroscopic or open lysis of adhesions, or revision surgery. Conservative treatment typically consists of postoperative physical therapy with pressure stretching techniques and home exercises. When rehabilitation has failed, serial casting, static braces, or dynamic splints that provide low-load prolonged stretch may be used. Dynamic splints use spring loading or elastic bands to provide low-intensity tension (less than that exerted by a physical therapist) and are designed to be worn over relatively long periods (i.e., 6-8 hours or overnight). The efficacy of a stretching regimen to permanently remodel tissue is considered to be a function of the intensity, length of the session, number of sessions per day, and number of days per week that stretching is performed.[2]

This evidence review focuses on patient-controlled mechanical devices that provide either moderate- to high-intensity stretch or static progressive stretch in the home. Patient-controlled stretching devices are used at home to increase range of motion in patients who have impaired functional status due to decreased range of motion. We address 2 types of commercially available devices. Static progressive stretch devices (e.g., Joint Active Systems (JAS), Static-Pro) provide low- to moderate-intensity stretching with a crank or ratchet that progressively increases the stretch within each session, and serial stretch devices (e.g., End Range of Motion Improvement [ERMI]) use hydraulics to alternate between periods of higher intensity stretch and relaxation.

Improvement in functional outcomes, such as the ability to perform activities of daily living, is the primary goal of this intervention. Joint range of motion is an intermediate outcome. In 2000, 1 small study by Rowe et al. correlated knee range of motion with functional parameters and concluded that 110° is considered the functional range of motion necessary to allow patients to perform common activities of daily living such as navigating stairs, rising from a low chair or commode, entering or

exiting a car, or tying one's shoes.[3] This threshold of range of motion is therefore used as a measure of treatment success for individual patients. Loss of knee range of motion of more than 15°, which occurs in about 1% to 2% of patients after anterior cruciate ligament reconstruction, has been associated with loss of quadriceps muscle strength and the development of osteoarthritis.[4] According to the knee examination form developed by the International Knee Documentation Committee (2000), an extension deficit of 6° to 10° or a flexion deficit of 16° to 25° when compared with the noninvolved knee is categorized "abnormal," and an extension deficit of more than 10° or a flexion deficit of more than 25° when compared with the noninvolved knee is categorized "severely abnormal."[5] Range of motion thresholds in joints other than the knee have been less clearly defined.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.
To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Static Progressive Stretch Devices

Clinical Context and Therapy Purpose

The purpose of static progressive stretch devices in patients who have functional limitations in range of motion is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of static progressive stretch devices improve the net health outcome in patients with functional limitations in range of motion?
The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with functional limitations in joint range of motion after injury or surgery.

Interventions
Static progressive stretch devices provide a low- to moderate-intensity force to hold a joint at its end range and gradually increase the stretch. In contrast to the long periods of low-intensity stretch provided by dynamic splinting devices, patient-controlled serial stretch and static progressive stretch devices are designed to be used for 15 to 30 minutes, in up to 8 sessions per day. Static progressive stretch devices are available for the knee, shoulder, ankle, wrist, and for pronation and supination. Individuals are typically instructed to use them for 30 minutes, 3 times a day. During each session, individuals adjust their device by turning a ratchet or turnbuckle to the maximum tolerated position of end-range stretch. Each position is held for several minutes to allow for tissue relaxation to occur, and the device is then advanced to a new position of stretch. It is proposed that the systems unload the joint to reduce joint surface pressures during the stretch. Devices that provide static progressive stretch include JAS® (Joint Active Systems), Static-Pro® (DeRoyal), Stat-A-Dyne® (Ortho-Innovations), AliMed® Turnbuckle Orthosis (AliMed), and Mayo Aircast® (DJO).

Comparators
Conservative treatment typically consists of postoperative physical therapy with pressure stretching techniques and home exercises. When rehabilitation has failed, serial casting, static braces, or dynamic splints that provide low-load prolonged stretch may be used. Dynamic splints use spring loading or elastic bands to provide low-intensity tension (less than that exerted by a physical therapist) and are designed to be worn over relatively long periods (ie, 6 to 8 hours or overnight).

Outcomes
Improvement in functional outcomes, such as the ability to perform activities of daily living, is the primary goal of this intervention. Joint range of motion is an intermediate outcome. According to the knee examination form developed by the International Knee Documentation Committee (2000), an extension deficit of 6° to 10° or a flexion deficit of 16° to 25° when compared with the noninvolved knee is categorized "abnormal," and an extension deficit of more than 10° or a flexion deficit of more than 25° when compared with the noninvolved knee is categorized "severely abnormal."[5,]

For the elbow, normal range of motion is suggested to be 100° of flexion (range, 30° to 130°). The mean shoulder range of motion for activities of daily living has been described as 121° flexion, 46° extension, 128° of shoulder abduction, 116° of shoulder cross-body abduction, 90° of external rotation with abduction of 59°, and 102° of internal rotation with 0° of abduction. Functional range of motion for the wrist is considered to be 38° of wrist flexion and 40° of wrist extension. For the knee, 110° of flexion is an appropriate goal for activities of daily living such as stair climbing and sitting in a chair. [6,] Functional outcome measures include the Western Ontario and McMaster University Osteoarthritis Index (WOMAC) for the hip and knee, and Disabilities of the Arm Shoulder and Hand questionnaire (DASH) for the upper limb. The DASH is a 30-item questionnaire on symptoms and functional activities (5 levels ranging from a range of motion of no difficulty to unable to perform), which calculates a score ranging from 0 (no disability) to 100 (most severe disability).

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Randomized Controlled Trials

Three RCTs, 1 evaluating JAS devices in the knee, shoulder, and elbow, were identified. Characteristics and outcomes for the 3 RCTs are reported in Table 1 and described in greater detail below.

Table 1. Summary Characteristics of RCTs Using Static Progressive Stretch Devices to Treat Restricted Range of Motion

Author	Countries	Sites	Dates	Participants	Interventions	
					Active	*Comparator*
SS (ERMI Flexionater/Extensionater) device vs. SPS device						
Papotto and Mills (2012)[7,]	U.S.	1	NR	20 patients >65 y with arthrofibrosis after TKA	HIS (Knee Flexionater) for 5-10 min followed by 5-10 min recovery for 20-30 min a session, totaling 60 min/d	LIS (Static-Pro Knee); increase in force every 5 min for 30 min, 3 times/d
SPS device vs. PT						
Ibrahim et al (2012, 2014,) Hussein et al (2015) [8,9,10,]	U.S.	NR	2007-2010	60 patients with shoulder adhesive capsulitis	PT plus SPS: one 30-min session/d (wk 1), two 30-min sessions/d (wks 2-3), three 30-min sessions/d (wk 4)	PT
SPS device vs. dynamic splint						
Lindenhovius et al (2012)[11,]	U.S.	1	2003-2008	66 patients with posttraumatic elbow stiffness	SPS device (Joint Active Systems), for three 30-min sessions/d, to improvement plateau	Dynamic splints, 6-8 h/d continuously, to improvement plateau

ERMI: End Range of Motion Improvement ; HIS: high-intensity stretch; LIS: low-intensity stretch; NR: not reported; PT: physical therapy; RCT: randomized controlled trial; SPS: static progressive stretch; SS: serial stretch; TKA: total knee arthroplasty.

Knee

Randomized Controlled Trials

Papotto and Mills (2012) reported on a small (N=20) RCT that compared high-intensity serial stretch with lower intensity static progressive stretch devices for home therapy in patients who had undergone total knee arthroplasty.[7,] High-intensity stretch was performed with the End Range of Motion Improvement (ERMI) Knee/Ankle Flexionater. Patients in this high-intensity stretch group were instructed to stretch at an intensity that mimicked the intensity provided by their physical therapists during outpatient sessions and to use the device in 20- to 30-minute sessions, for a total of 60 minutes per day. The lower intensity stretch group used a static progressive stretch device (Static-Pro Knee), which consists of a brace secured to the upper and lower leg with cuffs and straps. These patients were instructed to use the Static-Pro Knee in three 30-minute sessions each day, increasing the force applied to the joint every 5 minutes. After an average of 7 weeks of treatment, patients treated with ERMI reported significantly greater improvement in knee flexion, change in range of motion, and WOMAC scores compared with the static progressive stretch patients (Table 2).

Table 2. Summary Results of RCTs Using Static Progressive Stretch Devices to Treat Restricted Knee Range of Motion

	After 7 Weeks of Treatment		
Study	**Knee Flexion >110°**	**Change in ROM**	**Change in WOMAC Scores**

	After 7 Weeks of Treatment		
Papotto and Mills (2012)[7,]			
HIS	91%	29.9°	25.6
LIS	22%	17.0°	12.4
p	<.001	.001	.048

HIS: high-intensity stretch; LIS: low-intensity stretch; RCT: randomized controlled trial; ROM: range of motion; WOMAC: Western Ontario and McMaster University Osteoarthritis Index.

Case Series

Several case series on JAS devices have been published by a group of investigators that include Bonutti (stockholder in Joint Active Systems), McGrath, Ulrich, and Mont. Bonutti et al (2008) reported on a series of 41 patients with refractory knee stiffness who used a static progressive stretch (JAS) device after failing physical therapy.[12,] Patients in this study had a total range of motion of less than 90° or a flexion contracture that impaired quality of life. Twenty-five patients had previously undergone manipulation under anesthesia. After a mean of 9 weeks of use (range, 3 to 27 weeks), mean range of motion increased by 33° (range, 0° to 85°), with mean final extension of -6° and flexion of 108°. Outcomes were comparable to those reported with other nonoperative treatments; however, improvements occurred in shorter treatment times with the static progressive stretch device.

Shoulder

Randomized Controlled Trials

Ibrahim et al (2012) published an evaluator-blinded RCT of 60 patients with shoulder adhesive capsulitis randomized to 4 weeks of treatment with a static progressive stretch (JAS) device plus physical therapy compared with physical therapy alone.[8,] Ibrahim et al (2014) and Hussein et al (2015) provided additional follow-up at 1 and 2 years.[9,10,] The trial was independently funded, with devices provided by Joint Active Systems. Patients were evaluated for range of motion, functional outcomes with the DASH questionnaire, and the visual analog scale for pain. Improvements in range of motion were statistically greater with the static progressive stretch device than with physical therapy alone (Table 3), but this did not translate into a difference in pain and function at 4 weeks or in pain at 2 years. As noted above, the mean shoulder range of motion for activities of daily living has been described as 128° of shoulder abduction and 90° of external rotation with abduction of 59°. Final DASH scores were 2.5 in the static progressive stretch group compared with 36.2 in the control group (p<.001). It is unclear why functional limitations would increase in the control group over 2 years when adhesive capsulitis is generally a self-limiting condition. Authors reported that there were no losses to follow-up over 2 years. A limitation of the study is that the comparator of physical therapy alone was not provided with the same duration as physical therapy plus static progressive stretch (Tables 4 and 5). Use of an active comparator such as dynamic splinting would provide greater certainty on the effectiveness of this technology.

Table 3. Summary Results of RCTs Using Static Progressive Stretch Devices to Treat Restricted Shoulder Range of Motion

	After 4 Weeks of Treatment					Mean at 2-year Follow-Up				
Study	**VAS (SD)**	**DASH (SD)**	**Active Abduction in degrees (SD)**	**Passive Abduction in degrees (SD)**	**External Rotation in degrees (SD)**	**VAS**	**DASH Scores (Range)**	**Active Abduction in degrees (SD)**	**Passive Abduction in degrees (SD)**	**External Rotation in degrees (SD)**
Ibrahim et al (2012, 2014,) Hussein et al (2015) [8,9,10,]										
static progressive stretch + PT	1.10 (0.92)	5.25 (7.144)	141.93 (12.22)	162.50 (11.48)	73.17 (6.37	1.17 (0.91)	2.53 (3.89)	176.71 (3.80)	177.50 (3.11)	86.63 (3.01)
PT	0.83 (0.79)	15.27 (4.51)	114.27 (16.22)	136.13 (14.32)	51.93 (7.34)	1.70 (1.29)	36.24 (26.28)	101.37 (15.34)	148.37 (18.59)	49.67 (13.52)

	After 4 Weeks of Treatment					Mean at 2-year Follow-Up				
Diff (95% CI)	0.27 (-0.57 to 1.10)	-10.03 (-21.5 to 1.44)	27.67 (20.12 to 35.21)	26.37 (17.23 to 35.50)	21.23 (16.27 to 26.19)	-0.53 (-1.37 to 0.31)	-33.71 (-45.19 to -22.24)	75.34 (67.79 to 82.89)	29.13 (20.00 to 38.27)	49.67 (13.52)
p	>.05	>.05	<.001	<.001	<.001	>.05	<.001	<.001	<.001	<.001

CI: confidence interval; DASH: Disabilities of the Arm Shoulder and Hand questionnaire; PT: physical therapy; RCT: randomized controlled trial; SD: standard deviation; VAS: visual analog scale.

Table 4. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Ibrahim et al (2012, 2014,) Hussein et al (2015)[8,9,10,]			3. In this study, the treatment was given in addition to standard physical therapy.		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 5. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Ibrahim et al (2012, 2014,) Hussein et al (2015)[8,9,10,]		1. Patients were not blinded to treatment, although assessors of the range of motion measurements were.	2. Hussein et al (2015) did not report that this was the same study as Ibrahim et al (2012).			

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Elbow

Randomized Controlled Trials

Lindenhovius et al (2012) reported on results of a range of motion RCT that compared static progressive stretch using a JAS device to dynamic splinting in 66 patients with posttraumatic elbow stiffness.[11,] Patients included had lost more than 30° in flexion or extension after an elbow injury or surgery and had failed to improve for at least 4 weeks with regular stretching exercises. The evaluation was conducted by an investigator not involved in the care of the patients but who did not appear to have been blinded. Ten percent of patients in the dynamic splinting cohort asked for a change in treatment due to discomfort with the splint. Follow-up at 12 months was available for 80% of patients in the static progressive stretch group and 68% of patients in the splinting group, potentially reflecting lower patient satisfaction with dynamic splinting. Improvements were comparable between the groups in most outcomes (flexion-extension arc, flexion, forearm rotation), with the exception of DASH scores (significantly better in the static progressive stretch group at 6 months but equivalent at 12 months) and flexion contracture (equivalent at 6 months but significantly better in the splinting group at 12 months; Table 6). Statistical analysis was intention-to-treat but did not account for repeated measures or baseline covariates. Range of motion was similar between groups at all time points.

Table 6. Summary Results of RCTs Using Static Progressive Stretch Devices to Treat Restricted Elbow Range of Motion

	Mean at 6-Month Follow-Up	
Study	**Flexion Arc (Range)**	**Change in DASH Scores (Range)**
Lindenhovius et al (2012)[11,]		
static progressive stretch	91° (50°-140°)	25 (3-50)
DS	93° (15°-130°)	32 (5-83)
p	.80	<.05

DASH: Disabilities of the Arm Shoulder and Hand questionnaire; DS: dynamic splinting; RCT: randomized controlled trial.

Case Series

Ulrich et al (2010) reported on the use of a static progressive stretch (JAS) elbow device in 37 patients. Patients with deficits in flexion or extension had undergone at least 6 weeks of exercise with at least 2 weeks of minimal motion gain (<5°).[13,] After 1 to 3 daily, 30-minute sessions for a mean treatment time of 10 weeks (range, 2 to 23 weeks), mean range of motion increased by 26° (range, 2° to 60°) to a final range of motion of 107° (range, 70° to 140°). Results were compared with the literature on other upper-extremity stretch devices (e.g., splints), which achieved similar success rates (81% to 88%) with 6 to 10 hours of daily wear over 6 to 10 months.

Systematic Reviews

A systematic review by Muller et al (2013) compared the effectiveness of dynamic splint, static splint, or static progressive stretch in patients with posttraumatic or postoperative elbow stiffness.[14,] They included 13 case series and case reports (N=247 patients; range, 1 to 37 patients). Mean duration from the incident to the start of treatment was 6.9 months. The greatest increase in range of motion was obtained with dynamic splints (46°), followed by static progressive stretch devices (40°), and static splints (34°). These differences were statistically significant (p<.001) but might not be clinically significant. None of the selected studies assessed patient compliance, which is potentially affected by the duration of wear and comfort of the device. This systematic review was limited by the inclusion of low-quality studies, including case reports.

Forearm Rotation

Case Series

McGrath et al (2009) reported on a series of 38 consecutive patients with limitations in forearm rotation who had plateaued with physical therapy.[15,] Treatment with a static progressive stretch (JAS) pronation/supination device began at an average of 21 weeks (range, 6 to 75 weeks) after the upper-extremity injury. At the start of treatment, mean range of motion was 96° (range, 20° to 150°). After an average of 12 weeks of treatment (range, 3 to 57 weeks), mean range of motion increased to 138° (range, 70° to 180°).

Wrist

Case Series

McGrath et al (2008) also reported on the use of a static progressive stretch (JAS) wrist device in 47 consecutive patients with posttraumatic or postsurgical wrist stiffness.[16,] All patients' range of motion had plateaued (67°; range, 18° to 114°) after a mean of 12 weeks of physical therapy (range, 6 to 28 weeks) and was not expected to improve with standard therapeutic modalities. After a mean of 10 weeks of static progressive stretch treatment (range, 4 to 26 weeks), range of motion increased to 101° (range, 60° to 156°).

Lucado et al (2008) retrospectively reviewed 25 patients with distal radius fractures who had been treated with a JAS Flexion/Extension device or JAS forearm Pronation/Supination device at their institutions.[17,] The mean time from injury to the initiation of treatment with a static progressive stretch device was 94 days (range, 48 to 188 days), and duration of use was 75 days (range, 14 to 160 days). There were significant improvements in range of motion and DASH scores. The median DASH score improved from 43 to 19 (on a scale from 100 to 0) after static progressive stretch therapy.

Section Summary: Static Progressive Stretch Devices

Three RCTs have evaluated static progressive stretch devices but comparators in each differed (physical therapy, a dynamic splint, and serial stretch device). The evidence on static progressive stretch devices does not currently support an improvement in pain and function with static progressive stretch compared to alternative treatments such as dynamic splinting. One RCT found greater improvements in range of motion and WOMAC scores with serial stretch devices for the knee compared with static progressive stretch devices. Another RCT evaluating static progressive stretch for shoulder adhesive capsulitis found significant differences in shoulder range of motion compared with physical therapy alone at the end of 4 weeks of treatment, with no difference in pain and function at this time point. At longer follow-up, the physical therapy group showed a decline in function. Use of an active comparator would provide greater certainty on the effectiveness of this technology. A third RCT found comparable improvements in most outcomes for the static progressive stretch device compared with dynamic splinting, and a systematic review of case reports and series found similar clinical efficacy for increasing elbow range of motion between static progressive stretch devices and dynamic splints. Dynamic splints are used for 8 to 24 hours per day while static progressive stretch devices require several 30 minute sessions. It is not known whether patient compliance would be higher with the static progressive stretch devices resulting in an improvement in clinical outcomes.

Serial Stretch Devices

Clinical Context and Therapy Purpose

The purpose of serial stretch devices in patients who have functional limitations in range of motion is to provide a treatment option that is an alternative to or an improvement on existing therapies.
The question addressed in this evidence review is: Does the use of serial stretch devices improve the net health outcome in patients with functional limitations in range of motion?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with functional limitations in joint range of motion after injury or surgery.

Interventions
Serial stretch devices (e.g., ERMI) use hydraulics to alternate between periods of higher intensity stretch and relaxation.

Comparators
Conservative treatment typically consists of postoperative physical therapy with pressure stretching techniques and home exercises. When rehabilitation has failed, serial casting, static braces, or dynamic splints that provide low-load prolonged stretch may be used. Dynamic splints use spring loading or elastic bands to provide low-intensity tension (less than that exerted by a physical therapist) and are designed to be worn over relatively long periods (ie, 6 to 8 hours or overnight).

Outcomes
Improvement in functional outcomes, such as the ability to perform activities of daily living, is the primary goal of this intervention. Joint range of motion is an intermediate outcome. According to the knee examination form developed by the International Knee Documentation Committee (2000), an extension deficit of 6° to 10° or a flexion deficit of 16° to 25° when compared with the noninvolved knee is categorized "abnormal," and an extension deficit of more than 10° or a flexion deficit of more than 25° when compared with the noninvolved knee is categorized "severely abnormal."[5,] Range of motion thresholds in joints other than the knee are noted above.

Functional outcome measures include the WOMAC for the hip and knee and DASH for the upper limb.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Review of Evidence
Knee
Randomized Controlled Trials
The small RCT by Papotto and Mills (2012; described above) compared a serial stretch (ERMI Knee/Ankle Flexionater) device with a static progressive stretch (Static-Pro) device for home therapy in 20 patients who had undergone total knee arthroplasty.[7,] After an average of 7 weeks of therapy, treatment with the serial stretch device resulted in a 29.9° gain in motion compared with 17.0° with the static progressive stretch ($p<.001$). Knee flexion of 110° or more was obtained in 91% of the serial stretch group compared with 22% of the static progressive stretch group ($p<.001$). Improvement on the 100-point WOMAC was significantly greater in the serial stretch group (25.6) than in the static progressive stretch group (12.4; $p=.048$) (Table 2).

Nonrandomized Comparative Studies
Stephenson et al (2010) reported on an industry-funded retrospective comparative study of high-intensity stretch devices, low-intensity stretch devices, and no devices, based on claims data for 60,359 patients who had a diagnosis of arthrofibrosis following knee injury or surgery.[1,] There were 143 patients who used a high-intensity stretch device, 607 who used a low-intensity stretch device, and 59,609 who did not use any stretching device. To make the groups comparable in terms of

severity, the lower intensity stretch and no device patients were required to have a diagnosis relating to osteoarthrosis, ankyloses, contracture/fracture, or stiffness in the lower leg. After controlling for baseline differences in the type of knee surgery and musculoskeletal disease, the high-intensity stretch group had significantly lower rates of rehospitalization than low-intensity stretch and no device patients. Significantly more patients with no device (47.4%) had a subsequent knee event within 6 months after the index surgery compared with high-intensity (24.5%) or low-intensity (22.2%) stretch patients.

Uncontrolled Trials

A frequently cited study was reported by Branch et al (2003; Branch was medical director at ERMI).[18,] Patients (N=34) in this prospective series who did not have full knee range of motion after 6 weeks of physical therapy were prescribed a serial stretch (ERMI Knee/Ankle Flexionater) device. The 2 patients in the study who had a range of motion greater than 115° at the start of therapy regained full range of motion. Of the 6 patients with a range of motion between 90° and 115° at the start of therapy, 5 regained full range of motion; and of the 16 patients with a range of motion between 60° and 90° at the start of therapy, 13 regained full range of motion. For the 10 patients who began mechanical therapy with a range of motion between 0° and 60°, only 4 regained full range of motion but this group regained the most range of motion (mean, 79°) of the 4 groups. With functional range of motion defined as 115° or more, 31 (91%) of the 34 patients met this goal, and the improvement in range of motion for the entire group was highly significant. A retrospective review from this group found that passive knee extension deficits that had plateaued with physical therapy decreased range of motion 10.5° to 2.0° with the ERMI Knee Extensionater.

Shoulder

Case Series

An industry-funded retrospective series (2011) with 36 patients was identified; it evaluated a serial stretch (ERMI Shoulder Flexionater) device.[19,] Patients with adhesive capsulitis who had failed 6 weeks of physical therapy (glenohumeral abduction and external rotation not equal to the opposite uninvolved limb) were treated with the serial stretch device in combination with continued physical therapy. Patients were instructed to perform 6 daily, 10-minute sessions of end-range stretching at home, using an intensity that was uncomfortable but not painful. Blinded evaluation at the end of treatment found that range of motion of the involved limb equaled that of the opposite limb. Scores on the American Shoulder and Elbow Society Standardized Shoulder Assessment Form showed significant improvement ($p<.05$), and patients with greater pain at baseline had the greatest improvement in American Shoulder and Elbow Society scores (gain of 50 points of 100 total).

Section Summary: Serial Stretch Devices

The evidence includes a small RCT and a larger retrospective comparative study that reported high-intensity stretching using serial stretch (ERMI) devices improved range of motion more than lower intensity stretching devices in patients who were post-injury or surgery. Other available data consist of retrospective case series demonstrating improvements in range of motion among patients whose range had plateaued with physical therapy. The clinical significance of gains in this surrogate outcome measure is unclear.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in January 2023 did not identify any ongoing or unpublished trials that would likely influence this review.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	None	
HCPCS	E1399	Durable medical equipment, miscellaneous
	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

Type	Code	Description
	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

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
04/30/2015	BCBSA Medical Policy adoption
09/01/2016	Policy title change from Patient-Actuated End Range Motion Stretching Devices Policy revision without position change
05/01/2017	Policy revision without position change
05/01/2018	Policy revision without position change
05/01/2019	Policy revision without position change
05/01/2020	Annual review. No change to policy statement. Literature review updated.
05/01/2021	Annual review. No change to policy statement. Literature review updated.
06/01/2022	Annual review. No change to policy statement. Literature review updated.
05/01/2023	Annual review. Policy statement and literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an

authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE Red font: Verbiage removed	AFTER Blue font: Verbiage Changes/Additions
Patient-Controlled End Range of Motion Stretching Devices 1.03.05 **Policy Statement:** Patient-controlled end range of motion stretching devices are considered **investigational**.	**Patient-Controlled End Range of Motion Stretching Devices 1.03.05** **Policy Statement:** I. Patient-controlled end range of motion stretching devices (static progressive and serial) are considered **investigational**.

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