Patient Controlled End of Range Motion Stretching Devices

**Policy**
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for Patient-Actuated End Range Motion Stretching Devices. This is considered investigational.

**When Policy Topic is covered**
n/a

**When Policy Topic is not covered**
Patient controlled end range of motion stretching devices are considered investigational.

**Description of Procedure or Service**

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<th>Interventions</th>
<th>Comparators</th>
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<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
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<tr>
<td>With functional limitations in</td>
<td>• Static progressive stretch devices and physical</td>
<td>• Physical therapy alone</td>
<td>• Symptoms</td>
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<tr>
<td>range of motion</td>
<td>therapy</td>
<td>• Static or dynamic splints</td>
<td>• Change in disease status</td>
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Patient-controlled stretching devices are used at home to increase range of motion (ROM) in patients who have impaired functional status due to decreased ROM. We address 2 types of commercially available devices. Static progressive stretch (SPS) devices (eg, 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 (eg, ERMI) that use hydraulics to alternate between periods of higher intensity stretch and relaxation.

For individuals who have functional limitations in ROM who receive SPS devices and physical therapy, the evidence includes randomized controlled trials (RCTs), a systematic review, and case series. Relevant outcomes include symptoms, change in disease status, functional outcomes, and quality of life. Three RCTs have evaluated SPS devices, but comparators in each differed (physical therapy, a dynamic splint, and a serial stretch device). One RCT reported significant improvements in Disabilities of the Arm Shoulder and Hand (DASH) questionnaire scores and shoulder ROM compared to physical therapy alone at the end of 4 weeks of treatment, with significant improvements maintained at the 2-year follow-up. A second RCT evaluating SPS in the elbow found comparable improvements in most ROM outcomes compared with dynamic splinting, with the exception of better DASH scores in the SPS group at 6 months and better flexion contracture in the dynamic splinting group at 12 months. A third RCT which compared SPS with serial stretch devices, found greater improvement in Western Ontario and McMaster University Osteoarthritis Index and knee flexion scores with the serial stretch devices. A systematic review and meta-analysis of case reports and series found that similar clinical efficacy for increasing elbow ROM and flexion can be achieved using dynamic splints, SPS devices, and static braces. It is not known whether patient compliance is higher with SPS devices, because results have indicated these devices improve ROM faster than comparators. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have functional limitations in ROM who receive serial stretch devices and physical therapy, the evidence includes 1 RCT and observational studies. Relevant outcomes include symptoms, change in disease status, functional outcomes, and quality of life. The best evidence consists of serial stretching with ERMI devices used to treat knee ROM. One small RCT and 1 larger retrospective comparative study have reported that high-intensity stretching with ERMI devices improved ROM more than lower intensity stretching devices in patients who were post injury or surgery. Other available data consist of retrospective case series that have demonstrated improved ROM in patients whose ROM had plateaued with physical therapy. The clinical significance of gains in this surrogate outcome measure is unclear. Further high-quality comparative trials are needed to determine whether these patient-controlled devices improve functional outcomes better than alternative treatments and identify the patient populations that might benefit. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Background**

Loss of full range of motion (ROM) occurs in a significant proportion of patients following surgical procedures around a joint, such as total knee arthroplasty (TKA) or anterior cruciate ligament (ACL) reconstruction. The most common cause for 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 ROM compared with the
normal contralateral side. Loss of knee ROM 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 TKA and ACL 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 (ie, 6-8 hours or overnight).

This evidence review focuses on patient-controlled mechanical devices that provide either moderate- to high-intensity stretch or static progressive stretch (SPS) in the home. 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 SPS devices, such as JAS® devices (Joint Active Systems), 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 SPS devices are designed to be used for periods of 15 to 30 minutes, in up to 8 sessions per day.

SPS devices are available for the knee, shoulder, ankle, wrist, and for pronation and supination. Patients are typically instructed to use them for 30 minutes, 3 times a day. During each session, patients adjust their device by turning a ratchet or turn-buckle 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 SPS include JAS (Joint Active Systems), Static-Pro® (DeRoyal), Stat-A-Dyne® (Ortho-Innovations), AliMed® Turnbuckle Orthosis (AliMed), and Mayo Aircast® (DJO).

Patient-controlled serial stretch devices in the home include the ERMI (ERMI Inc.) line. Specific ERMI devices are the Shoulder Flexionater, Knee Flexionater, Knee Extensionater, Elbow Extensionater, and the MPJ Extensionater (all ERMI, Atlanta, GA). They are intended primarily to address excessive scar tissue around the joint by alternating progressive stretching with periods of relaxation, at a torque similar to that applied by physical therapists that is near or at the pain threshold. The patient uses a hydraulic pump to control the load, which can range from a few ounces to 500 pounds. For example, to use the ERMI Knee/Ankle Flexionater, patients pull a lever to increase knee flexion angle, and the amount of torque
being applied to the joint. The hydraulic system amplifies the force of the lever into a greater torque applied to the knee for 5 to 10 minutes. Periods of flexion are interspersed by 5- to 10-minute recovery intervals where the knee is released back into extension.

**Outcome Measures**

Improvement in functional outcomes, such as the ability to perform activities of daily living, is the primary goal of this intervention. Joint ROM is an intermediate outcome. One small study (2000) correlated knee ROM with functional parameters and concluded that 110\(^\circ\) is considered the functional ROM 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 from a car, or tying one’s shoes.\(^3\) This threshold of ROM is therefore used as a measure of treatment success for individual patients. Loss of knee ROM of more than 15\(^\circ\), 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\(^\circ\) to 10\(^\circ\) or a flexion deficit of 16\(^\circ\) to 25\(^\circ\) when compared with the noninvolved knee is categorized “abnormal,” and an extension deficit of more than 10\(^\circ\) or a flexion deficit of more than 25\(^\circ\) when compared with the noninvolved knee is categorized “severely abnormal.”\(^5\) ROM thresholds in joints other than the knee have been less clearly defined.

**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 FDA prior to marketing.

**Rationale**

This evidence review was created in January 2015 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through January 8, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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 a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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. RCTs 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. The following is a summary of the key literature to date.

Static Progressive Stretch Devices
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. Also, 3 RCTs, one evaluating JAS devices in the knee, shoulder, and elbow, and a systematic review of case reports and case series were identified. Characteristics and outcomes for the 3 RCTs are reported in Tables 1 and 2.

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 (SPS) devices for home therapy in patients who had undergone total knee arthroplasty. High-intensity stretch was performed with the 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 an SPS 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, range of motion (ROM), and Western Ontario and McMaster University Osteoarthritis Index (WOMAC) scores compared with the SPS patients (see Table 1).

Case Series
Bonutti et al (2008) reported on a series of 41 patients with refractory knee stiffness who used an SPS (JAS) device after failing physical therapy. Patients in this study had a total ROM 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, 3-27 weeks), mean ROM increased by 33° (range, 0°-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 SPS 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 an SPS (JAS) device plus physical therapy compared with physical therapy alone. The trial was independently funded, although devices were provided by Joint Active Systems. Patients were evaluated for ROM, functional outcomes with the Disabilities of the Arm Shoulder and Hand (DASH) questionnaire, and a visual analog scale for pain. Improvements in ROM and DASH scores were significantly greater with the SPS device than with physical therapy alone (see Table 1). Over 24 weeks of follow-up, these improvements were maintained in the JAS group but declined in the group treated with physical therapy alone. Ibrahim et al (2014) and Hussein et al (2015) provided additional follow-up at 1 year and 2 years. At 1- and 2-year follow-ups, ROM was substantially greater in the SPS group (p<0.001), due primarily to an increase in DASH scores (higher scores indicate a decrease in ROM) for the group treated with physical therapy over 2 years. The difference between groups in ROM at 2 years was 47.6° for passive external rotation, 29.1° for passive abductions, and 75.3° for active abduction. Final DASH scores were 2.5 in the SPS group compared with 36.2 in the control group (p<0.001). Visual analog scale scores for pain were low in both the SPS (1.2) and control (1.7; p=0.05) groups. Because there was no reporting of losses to follow-up over 2 years or references to the prior publications, results of this study might have been biased. It is also unclear why functional limitations would increase in the control group when adhesive capsulitis is generally a self-limiting condition.

**Elbow**

*Randomized Controlled Trials*

Lindenhovius et al (2012) reported on results from an RCT that compared SPS using a JAS device with dynamic splinting in 66 patients with posttraumatic elbow stiffness. 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 SPS 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 SPS 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) (see Table 1). Statistical analysis was intention-to-
treat but did not account for repeated measures or baseline covariates. ROM was similar between groups at all time points.

**Case Series**
Ulrich et al (2010) reported on the use of an SPS (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°). After 1 to 3 daily, 30-minute sessions for a mean treatment time of 10 weeks (range, 2-23 weeks), mean ROM increased by 26° (range, 2°-60°) to a final ROM of 107° (range, 70°-140°). Results were compared with the literature on other upper-extremity stretch devices (eg, splints), which achieved similar success rates (81%-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 SPS in patients with posttraumatic or postoperative elbow stiffness. They included 13 case series and case reports (total N=247 patients; range, 1-37 patients). Mean time from the incident to the start of treatment was 6.9 months. The greatest increase in ROM was obtained with dynamic splints (46°), followed by SPS devices (40°) and static splints (34°). These differences were statistically significant (p<0.001), 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. Treatment with an SPS (JAS) pronation/supination device began at an average of 21 weeks (range, 6-75 weeks) after the upper-extremity injury. At the start of treatment, mean ROM was 96° (range, 20°-150°). After an average of 12 weeks of treatment (range, 3-57 weeks), mean ROM increased to 138° (range, 70°-180°).

**Wrist**

**Case Series**
McGrath et al (2008) also reported on the use of an SPS (JAS) wrist device in 47 consecutive patients with posttraumatic or postsurgical wrist stiffness. All patients’ ROM had plateaued (67°; range, 18°-114°) after a mean of 12 weeks of physical therapy (range, 6-28 weeks) and was not expected to improve with standard therapeutic modalities. After a mean of 10 weeks of SPS treatment (range, 4-26 weeks), ROM increased to 101° (range, 60°-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. Mean time from injury
to the initiation of treatment with an SPS device was 94 days (range, 48-188 days), and duration of use was 75 days (range, 14-160 days). There were significant improvements in ROM and DASH scores. Median DASH score improved from 43 to 19 (/100) after SPS therapy.

### Table 1. Summary Characteristics of RCTs Using SPS Devices to Treat Restricted ROM

<table>
<thead>
<tr>
<th>Author</th>
<th>Countries</th>
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<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
<th>Comparator</th>
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<tr>
<td>Serial stretch (ERMI Flexionater/Extensioner) device vs SPS device</td>
<td></td>
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<tr>
<td>Papotto and Mills (2012)§</td>
<td>U.S.</td>
<td>1</td>
<td>NR</td>
<td>20 patients  &gt;65 y with arthrofibrosis after TKA</td>
<td>HIS (Knee Flexionater) for 5-10 min followed by 5-10 min recovery for 20-30 min a session, totaling 60 min/d</td>
<td>LIS (Static-Pro Knee); increase in force every 5 min for 30 min, 3 times/day</td>
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<tr>
<td>SPS device vs PT</td>
<td></td>
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<tr>
<td>Ibrahim et al (2012)§</td>
<td>U.S.</td>
<td>NR</td>
<td>NR</td>
<td>60 patients  with shoulder adhesive capsulitis</td>
<td>PT plus SPS: one 30-min session/day (week 1), two 30-min sessions/day (weeks 2-3), three 30-min sessions/day (week 4)</td>
<td>PT</td>
</tr>
<tr>
<td>SPS device vs dynamic splint</td>
<td></td>
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<tr>
<td>Lindenhoius et al (2012)¹¹</td>
<td>U.S.</td>
<td>1</td>
<td>2003-2008</td>
<td>66 patients  with posttraumatic elbow stiffness</td>
<td>SPS device (Joint Active Systems), for three 30-min sessions/day, to improvement plateau</td>
<td>Dynamic splints, 6-8 h/d continuously, to improvement plateau</td>
</tr>
</tbody>
</table>

HIS: high-intensity stretch; LIS: low-intensity stretch; NR: not reported; PT: physical therapy; RCT: randomized controlled trial; SPS: static progressive stretch; TKA: total knee arthroplasty

### Table 2. Summary Results of RCTs Using SPS Devices to Treat Restricted ROM

<table>
<thead>
<tr>
<th>Study</th>
<th>After 7 Weeks of Treatment</th>
<th>After 4 Weeks of Treatment</th>
<th>Mean at 6-Month Follow-Up</th>
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<tr>
<td></td>
<td>Knee Flexion &gt;110°</td>
<td>Change in ROM</td>
<td>Change in WOMAC Scores</td>
</tr>
<tr>
<td>Papotto and Mills (2012)§</td>
<td>HIS 91%</td>
<td>29.9°</td>
<td>25.6</td>
</tr>
<tr>
<td></td>
<td>LIS 22%</td>
<td>17.0°</td>
<td>12.4</td>
</tr>
<tr>
<td></td>
<td>p &lt;0.001</td>
<td>0.001</td>
<td>0.048</td>
</tr>
<tr>
<td>Ibrahim et al (2012)§</td>
<td>SPS 76°</td>
<td>64°</td>
<td>53°</td>
</tr>
<tr>
<td></td>
<td>PT 46°</td>
<td>37°</td>
<td>30°</td>
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<table>
<thead>
<tr>
<th>Lindenhovius et al (2012)</th>
<th>SPS</th>
<th>DS</th>
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<tbody>
<tr>
<td>Peanut</td>
<td>91° (50°-140°)</td>
<td>93° (15°-130°)</td>
</tr>
<tr>
<td>(p=0.80, &lt;0.05)</td>
<td>25 (3-50)</td>
<td>32 (5-83)</td>
</tr>
</tbody>
</table>

DASH: Disabilities of the Arm Shoulder and Hand questionnaire; HIS: high-intensity stretch; LIS: low-intensity stretch; PT: physical therapy; RCT: randomized controlled trial; ROM: range of motion; SPS: static progressive stretch; WOMAC: Western Ontario and McMaster University Osteoarthritis Index

**Section Summary: SPS Devices**
The evidence on SPS devices is limited and conflicting. One RCT found greater improvements in ROM and WOMAC scores with serial stretch devices for the knee compared with SPS devices. Another RCT evaluating SPS for shoulder adhesive capsulitis found significant differences in DASH scores and shoulder ROM compared with physical therapy alone at the end of 4 weeks of treatment, with the differences maintained after 2 years. A third RCT found comparable improvements in most outcomes for the SPS device compared with dynamic splinting, except better DASH scores in the SPS group at 6 months and better flexion contracture in the dynamic splinting group at 12 months. A systematic review of case reports and series found similar clinical efficacy for increasing elbow ROM between SPS devices and dynamic splints. It is not known whether patient compliance was higher with the SPS devices because results have indicated these devices improve ROM faster than other modalities.

**Serial Stretch Devices**

**Knee**

**Randomized Controlled Trials**
The small RCT by Papotto and Mills ([2012] described above) compared a serial stretch (ERMI Knee/Ankle Flexionater) device with an SPS (Static-Pro) device for home therapy in 20 patients who had undergone total knee arthroplasty. 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 SPS (p<0.001). Knee flexion of 110° or more was obtained in 91% of the serial stretch group compared with 22% of the SPS group (p<0.001). Improvement on the 100-point WOMAC was significantly greater in the serial stretch group (25.6) than in the SPS group (12.4; p=0.048) (see Table 1).

**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. 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 knee event within 6 months from 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). Patients (N=34) in this prospective series who did not have full knee ROM after 6 weeks of physical therapy were prescribed a serial stretch (ERMI Knee/Ankle Flexionater) device. The 2 patients in the study who had ROM greater than 115° at the start of therapy regained full ROM. Of the 6 patients with ROM between 90° and 115° at the start of therapy, 5 gained full ROM; and of the 16 patients with ROM between 60° and 90° at the start of therapy, 13 regained full ROM. For the 10 patients who began mechanical therapy with ROM between 0° and 60°, only 4 regained full ROM, but this group regained the most ROM (mean, 79°) of the 4 groups. With functional ROM defined as 115° or more, 31 (91%) of the 34 patients met this goal, and the improvement in ROM 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 from 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. 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 ROM 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<0.05), 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 ROM 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 ROM among patients whose ROM had plateaued with physical therapy. The clinical significance of gains in this surrogate outcome measure is unclear.

**Summary of Evidence**
For individuals who have functional limitations in ROM who receive SPS devices and physical therapy, the evidence includes RCTs, a systematic review, and case series. Relevant outcomes include symptoms, change in disease status, functional outcomes, and quality of life. Three RCTs have evaluated SPS devices, but comparators in each differed (physical therapy, a dynamic splint, and a serial stretch device). One RCT reported significant improvements in Disabilities of the Arm Shoulder and Hand questionnaire scores and shoulder ROM compared with physical therapy alone at the end of 4 weeks of treatment, with significant improvements maintained at the 2-year follow-up. A second RCT evaluating SPS in the elbow found similar improvements in most ROM outcomes compared with dynamic splinting, except better Disabilities of the Arm Shoulder and Hand scores in the SPS group at 6 months and better flexion contracture in the dynamic splinting group at 12 months. A third RCT, which compared SPS with serial stretch devices, found greater improvements in Western Ontario and McMaster University Osteoarthritis Index and knee flexion scores with the serial stretch devices. A systematic review and meta-analysis of case reports and series found that similar clinical efficacy for increasing elbow ROM and flexion can be achieved using dynamic splints, SPS devices, and static braces. It is not known whether patient compliance is higher with SPS devices because results have indicated these devices improve ROM faster than comparators. The evidence is insufficient to determine the effects of the technology on health outcomes.

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**Supplemental Information**

**Practice Guidelines and Position Statements**
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
Currently unpublished trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>Unpublished</td>
<td>A Prospective Randomized Trial of Rehabilitation With or Without Static Progressive Splinting for Wrist Stiffness</td>
<td>60</td>
<td>Jan 2015 (completed)</td>
</tr>
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</table>

NCT: national clinical trial.

References

Billing Coding/Physician Documentation Information

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

Additional Policy Key Words
N/A

Policy Implementation/Update Information
8/1/15 New Policy. Considered Investigational.
8/1/16 No policy statement changes.
8/1/17  Policy title changed to “Patient-Controlled End Range of Motion Stretching Devices”. No policy statement changes.
8/1/18  No policy statement changes.

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