Stretch Devices for Joint Stiffness and Contractures Clinical Coverage Criteria

Overview

Joint stiffness or contractures are associated with a reduced range of motion caused by diseases, post-surgical issues, or trauma to the joint. Treatment options typically include physical therapy (inclusive of home exercises), manipulation, or further surgical interventions. Mechanical stretching devices are used to treat joint stiffness and contractures and restore range of motion. These devices are intended to be used by a patient in a home setting as an adjunct to physical therapy by providing frequent and consistent joint mobilization under controlled conditions.

Mechanical stretching devices differ from continuous passive motion devices in that they are non-motorized. There are three primary types of mechanical stretching devices:

- Low-load prolonged-duration stretching devices, also known as dynamic splinting devices - A device which permits resisted active and passive motion within a limited range. The device can maintain set levels of tension by means of incorporated springs. Low-load prolonged-duration stretching devices/dynamic splinting devices include but are not limited to Dynasplint (Dynasplint Systems, Severna Park, MD), JAS Dynamic (Joint Active Systems, Effingham, IL), and Pro-Glide (De Royal Industries, Powell, TN).
- Static progressive stretch devices - A device which holds the joint in a set position while allowing for manual modification of the joint angle (inelastic traction). This type of device does not exert a stress on the tissue and does not allow for motion (passive or active). Static progressive stretch devices include the Joint Active Systems SPS devices, including, JAS SPS Knee, JAS SPS Shoulder, JAS SPS Elbow, and JAS SPS Pronation/Supination, and Static-Pro Knee (DeRoyal Industries, Powell, TN).
- Patient-actuated serial stretch devices - A device that provides a low- to high-level load to the joint using pneumatic systems which can be adjusted by the patient. These devices include ERMI Knee/Ankle Flexionater, ERMI Elbow Extensionater, ERMI Knee/Ankle Flexionater, and ERMI Shoulder Flexionater (ERMI, Inc., Atlanta, GA).

Policy

This Policy applies to the following Fallon Health products:

☒ Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)
☒ MassHealth ACO
☒ NaviCare HMO SNP
☒ NaviCare SCO
☒ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
☒ Community Care

Fallon Health requires prior authorization for Stretch Devices for Joint Stiffness and Contractures. Medical records from the member's primary care physician and other providers who have diagnosed or treated the symptoms prompting this request are required.

Medicare Advantage (Fallon Medicare Plus, Fallon Medicare Plus Central)
Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity

determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for low-load prolonged-duration stretching devices, static progressive stretch devices, or patient-actuated serial stretch devices. Medicare does not have an NCD for low-load prolonged-duration stretching devices, static progressive stretch devices, or patient-actuated serial stretch devices.

Noridian Healthcare Solutions, LLC is the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) with jurisdiction in the Plan's service area. Noridian Healthcare Solutions, LLC does not have an LCD for low-load prolonged-duration stretching devices, static progressive stretch devices, or patient-actuated serial stretch devices (Medicare Coverage Database search 04/23/2024).

Coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, therefore, the Plan's coverage criteria are applicable.

MassHealth ACO
Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth does not have Medical Necessity Guidelines for low-load prolonged-duration stretching devices, static progressive stretch devices, or patient-actuated serial stretch devices, therefore the Plan's coverage criteria are applicable.

NaviCare HMO SNP, NaviCare SCO
For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

Fallon Health considers low-load prolonged-duration stretching devices /dynamic splinting devices experimental/investigational due to a lack of scientific literature supporting their definitive use. Fallon Health will review requests for low-load prolonged-duration stretching devices/dynamic splinting devices on an individual case-by-case basis and will require documentation to support such requests.

Fallon Health considers static progressive stretch devices and patient-actuated serial stretch devices experimental/investigational due to a lack of scientific literature supporting their definitive use. Fallon Health will review requests for static progressive stretch devices and patient-actuated serial stretch devices on an individual case-by-case basis and will require documentation to support such requests.

Exclusions

- Any use of mechanical stretching devices other than outlined above.

Summary of Evidence

Background

Arthrofibrosis is the abnormal proliferation of fibrous tissue around a joint, which leads to pain, stiffness, swelling, and decreased range of the knee joint, causing patients significant functional disability.

Surgery, including total knee arthroplasty, meniscus repair, and cartilage surgery, can lead to knee fibrosis. Arthrofibrosis is a common complication following total knee arthroplasty. Arthrofibrosis may also occur in other joints including the elbow and shoulder.

Although the exact cause of arthrofibrosis is poorly understood, a strong relationship with inflammatory markers, postoperative pain, and pain during rehabilitation has been observed.

Multiple studies have correlated increased perioperative pain with arthrofibrosis and decreased range of motion (ROM) in total joint arthroplasty patients. Therefore, a multimodal approach to decreasing inflammation and controlling pain can improve patient mobilization and prevent arthrofibrosis (Thompson et al., 2019). Salmons et al., 2023 report a reduced risk of arthrofibrosis associated with perioperative NSAID use (odds ratio, 0.67, p=0.045). Arthrofibrosis was defined as ROM ≤90° for ≥12 weeks postoperatively or as ROM ≤90° requiring manipulation under anesthesia (MUA), was diagnosed in 454 of 12,735 knees (4%). Postoperative, supervised physical therapy remains the first line of defense against the development of arthrofibrosis. The effectiveness of rehabilitation on functional outcomes depends on the appropriate timing, intensity, and progression of the program (Cheuy et al., 2017).

The use of continuous passive motion machines has been a debated topic regarding the prevention of arthrofibrosis following total knee arthroplasty because there has been inconclusive evidence of its ability to improve range of motion and reduce the need for MUA (Thompson et al., 2019).

Physical therapy is the first line treatment for arthrofibrosis following knee arthroplasty.

For total knee arthroplasty patients who continue to experience functionally limiting knee flexion, manipulation under anesthesia (MUE) is the first line operative treatment. Timing plays a critical role in the extent of knee flexion regained. The current orthopedic literature strongly supports MUA as an effective first-line intervention in the setting of unsatisfactory knee flexion and function and should ideally be performed within 12 weeks of surgery. Arthroscopic lysis of adhesions is a minimally invasive approach that allows for direct visualization and treatment of pathologic fibrous scar tissue, and successful results have been reported up to one year following knee arthroplasty (Fackler et al., 2022). As a last resort, some patients may ultimately require revision total knee arthroplasty (Thompson et al., 2019).

Arthrofibrosis is also a well-documented complication of anterior cruciate ligament (ACL) surgery. The incidence of arthrofibrosis has decreased with improved surgical techniques for ACL reconstruction and postoperative rehabilitation emphasizing early range of motion.

A classification system for arthrofibrosis was described by Shelbourne et al, 1996:

- Type 1: < 10º of extension loss and normal flexion
- Type 2: > 10º of extension loss and normal flexion
- Type 3: > 10º extension loss and > 25º flexion loss with decreased medial and lateral movement of the patella (patellar tightness) and no patella infera
- Type 4: > 10º extension loss, ≥ 30º flexion loss and objective patella infera with marked patellar tightness

More recently, Mayr and colleagues (2004) defined arthrofibrosis as the presence of scar tissue in any compartment of the joint leading to restricted ROM.

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.

When physical therapy fails to improve arthrofibrosis, noninvasive assistive devices, such as various knee orthotics, have shown promise (Thompson et al., 2019).

Low-load prolonged-duration stretching devices/dynamic splinting devices

Low load prolonged-duration stretch devices, also known as dynamic splinting devices, are designed to provide a low load, prolonged stretch to joints that have reduced range of motion secondary to immobilization, surgery, contracture, fracture, dislocation, or a number of additional non-traumatic disorders. The objective of stretch therapy is to improve range of motion without compromising the stability and quality of the connective tissue and joint. These devices are set at a fixed joint angle and worn over long periods (6-8 hours/day or overnight). Dynamic splinting devices provide extension as well as flexion and are available for various joints including the elbows, wrists, fingers, knees, ankles, and toes.

Low-load prolonged-duration stretching devices/dynamic splinting devices include but are not limited to Dynasplint (Dynasplint Systems, Severna Park, MD), JAS Dynamic (Joint Active Systems, Effingham, IL), and Pro-Glide (De Royal Industries, Powell, TN).

Elbow

Randomized Controlled Trials

Lindenhovius et al., 2012, reported on results of a randomized controlled trial that compared static progressive stretch using a JAS device (n=35) to dynamic splinting (n=31) in 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. Elbow function was measured at enrollment and at three, six, and twelve months later. Patients completed the DASH questionnaire at enrollment and at the six and twelve-month evaluation. Three patients asked to be switched to static progressive splinting. The analysis was done according to intention-to-treat principles and with use of mean imputation for missing data. 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. There were no significant differences in flexion arc at any time point. Improvement in the arc of flexion (dynamic versus static) averaged 29 degrees versus 28 degrees at 3 months (p=0.87), 40 degrees versus 39 degrees at 6 months (p=0.72), and 47 degrees versus 49 degrees at 12 months after splinting was initiated (p=0.71). The average DASH score (dynamic versus static) was 50 versus 45 points at enrollment (p=0.52), 32 versus 25 points at 6 months (p<0.05), and 28 versus 26 points at 12 months after enrollment (p=0.61). The authors conclude that post-traumatic elbow stiffness can improve with exercises and dynamic or static splinting over a period of six to twelve months, and patience is warranted. There were no significant differences in improvement in motion between static progressive and dynamic splinting protocols, and the choice of splinting method can be determined by the patients and their physicians.

Static Progressive Stretch Devices

Following knee procedures, such as total knee arthroplasty, arthroscopy anterior cruciate ligament reconstruction, or traumatic events, a percentage of patients are at risk for developing post-operative complications. Arthrofibrosis, stiffness, and contracture of the knee are all possible problems that can affect range of motion (ROM) and can lead to limitations in activities of daily living. Physical therapy and patient active exercise are considered first-line treatment for restoring joint ROM. Historically, the treatment of ROM dysfunction consisted of early manipulation under anesthesia (MUA) or surgical exploration (e.g., arthroscopy, lysis of adhesions, revision arthroplasty). However, when patients are not responding or plateau with physical therapy, then adjunctive bracing can be a treatment option. Bracing types for the knee typically include dynamic and static progressive stretch (SPS) devices. Dynamic braces apply a low intensity, constant load over extended periods of time (i.e., 8 to 12 hours) across the joint and usually requires 2 devices, one for each direction. However, given the low load, this bracing option can be very slow and inefficient, requiring months of continued therapy. SPS bracing applies an incrementally adjusted static load, which can promote both relaxation and elongation of the joint tissues. SPS braces are applied for up to 30 minutes, 2 to 3 times per day, considerably less time compared to 8- to 12-hour Dynamic brace protocols, and SPS devices are typically bi-directional, requiring only one device for treatment of both directions of motion. These devices have been designed to simulate the work of a therapist, such that for the knee, a force is applied at the proximal femur and distal tibia in the plane of joint motion, but with the patient in control of how much force to apply. SPS braces can provide the appropriate amount of force over time, i.e., appropriate “clinical dosage” of stretch of the soft tissue to improve ROM (Bhave et al., 2019).

Static progressive stretch devices include the Joint Active Systems SPS devices, for example, JAS SPS Knee, JAS SPS Shoulder, JAS SPS Elbow, and JAS SPS Pronation/Supination, and Static-Pro Knee (DeRoyal Industries, Powell, TN).

Knee

Randomized Controlled Trials

A small RCT conducted by Papotto and Mills (2012) compared a high-intensity serial stretch device with lower intensity static progressive stretch device for home therapy in patients who had undergone total knee arthroplasty and were experiencing arthrofibrosis. High-intensity stretch was performed with the End Range of Motion Improvement (ERMI) Knee/Ankle Flexionater. Patients in the high-intensity stretch group (n=11) 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. Patients in the lower intensity stretch group (n=9) 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 therapy, treatment with the serial stretch device resulted in a 29.9° gain in motion compared with 17.0° with the static progressive stretch ($p = 0.048$). A significantly greater number of patients in the HIS group (91%) were able to achieve a functional range of motion >110° than those in the LIS group (22%, $p < .001$).

Uncontrolled Studies

Two studies by Bonutti et al., one in 2008 and then in 2010 both demonstrated that patients had improved knee ROM outcomes with the use of static progressive stretch devices.
Bonutti et al. 2008 reported on the use of a static progressive stretch device (JAS SPS Knee, Joint Active Systems) in 41 patients with knee stiffness who had not improved with conventional physical therapy modalities (21 total knee arthroplasty, 9 cruciate ligament repairs, 2 distal femur fractures, 9 unspecified). 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°. The authors found that all groups had a significant increase in total arc of motion ($p < 0.001$); specifically in evaluation of the patients who were treated following TKA, there was a mean increase of total arc motion of 25 degrees (from a mean of 74 degrees to 99 degrees). Additionally, they analyzed patient satisfaction with the use of the device and reported a mean satisfaction of 7.6 points (range, 0–10).

In the subsequent study, Bonutti et al., 2010, evaluated the use static progressive stretch orthosis to improve ROM in 25 patients with refractory knee stiffness after TKA. After a median of 7 weeks (range, 3-16 weeks), the median increase in range of motion was 25 degrees (range, 8-82 degrees). The median gain in knee active flexion was 19 degrees (range, 5-80 degrees). Ninety-two percent of patients were satisfied with the results.

Shoulder

Randomized Controlled Trials

Ibrahim et al (2012) published a randomized controlled trial 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 4 weeks of physical therapy alone. The primary outcome measure was shoulder range of motion (active and passive shoulder abduction, and passive shoulder external rotation). The secondary outcome measures were function measured by the Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire, and pain measured using a visual analogue scale (VAS). Active and passive abduction, passive external rotation, DASH scores, and VAS pain scores were recorded for all patients at 4, 12, 24, 52 and 104 weeks follow-up. Ibrahim et al. (2014) and Hussein et al. (2015) reported on follow-up at 1 and 2 years, respectively. The trial was independently funded, with devices provided by Joint Active Systems.

At baseline, there were no differences between the two groups. However, at 4 weeks after the intervention, there were significant ($p < 0.05$) differences between the groups for all outcome parameters: 0.3 for mean VAS scores [95% confidence interval (CI) −0.6 to 1.1], −10.1 for DASH scores (95% CI −21.0 to 0.9), 21.2 for shoulder passive external rotation (95% CI 16.8 to 25.7), 26.4 for shoulder passive abduction(95% CI 17.4 to 35.3), and 27.7 for shoulder active abduction (95% CI 20.3 to 35.0).

At 12-month follow-up, the differences between the groups were maintained and even increased for mean shoulder range of motion, VAS scores and DASH scores, with significant differences ($p < 0.001$) between the groups: −2.0 for VAS scores (95% CI −2.9 to −1.2), −53.8 for DASH scores (95% CI −64.7 to −42.9), 47.9 for shoulder passive external rotation (95% CI 43.5 to 52.3), 44.9 for shoulder passive abduction (95% CI 36.0 to 53.8), and 94.3 for shoulder active abduction (95% CI 87.0 to 101.7).

At 24-month follow-up, statistical analysis demonstrated that traditional physical therapy and the SPS device resulted in significantly increased mean shoulder active and passive abduction, and passive external rotation ROM degrees, and reduced mean DASH scores compared to traditional physical therapy alone ($p < 0.001$). Although the mean VAS scores were markedly reduced in both groups, the difference between the two was not significant ($p > 0.05$). At 104 weeks, the mean shoulder active abduction remained increased by 111°, passive abduction by 79° and passive external rotation by 66°, the mean DASH scores remained decreased by 97% and VAS pain scores by 71% in the experimental group compared to 33°, 49° and 28°, 50% and 63%, respectively, in the control group.

Elbow

Randomized Controlled Trials

Lindenhovius et al., 2012, reported on results of a randomized controlled trial that compared static progressive stretch using a JAS device (n=35) to dynamic splinting (n=31) in 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. Elbow function was measured at enrollment and at three, six, and twelve

months later. Patients completed the DASH questionnaire at enrollment and at the six and twelve-month evaluation. Three patients asked to be switched to static progressive splinting. The analysis was done according to intention-to-treat principles and with use of mean imputation for missing data. 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. There were no significant differences in flexion arc at any time point. Improvement in the arc of flexion (dynamic versus static) averaged 29 degrees versus 28 degrees at 3 months (p=0.87), 40 degrees versus 39 degrees at 6 months (p=0.72), and 47 degrees versus 49 degrees at 12 months after splinting was initiated (p=0.71). The average DASH score (dynamic versus static) was 50 versus 45 points at enrollment (p=0.52), 32 versus 25 points at 6 months (p<0.05), and 28 versus 26 points at 12 months after enrollment (p=0.61). The authors conclude that post-traumatic elbow stiffness can improve with exercises and dynamic or static splinting over a period of six to twelve months, and patience is warranted. There were no significant differences in improvement in motion between static progressive and dynamic splinting protocols, and the choice of splinting method can be determined by the patients and their physicians.

Patient-Actuated Serial Stretch Devices

These devices use hydraulic or pneumatic technology to allow for patient actuated serial stretch, examples include ERMI Knee/Ankle Flexionater, ERMI Elbow Extensionater, ERMI Knee/Ankle Flexionater, and ERMI Shoulder Flexionater.

Knee

Flexion contractures are not uncommon following major knee surgery, and the loss of knee extension has been described as the most common complication after anterior cruciate ligament reconstruction (ACLR). Postoperative loss of knee extension, sometimes referred to as flexion contractures, has been reported in 8% to 25% of patients having undergone total knee arthroplasty (TKA) or ACLR. TKA patients with losses of knee extension of less than 10° in the first 3 postoperative months generally regain motion over the course of the first two postoperative years, with only 8% demonstrating lasting residual motion restriction. On the contrary, 58% of patients with more severe motion restriction (≥10°) were reported to have residual loss of knee extension two years after TKA. Losses of knee extension after TKA led to poorer outcomes related to pain, walking, stair-climbing, and function. Conservative treatments including physical therapy and home exercise programs are often used to treat flexion contractures. While generally successful, as many as 48% of patients treated with these protocols may still require surgical intervention. Surgical procedures, such as arthroscopic lysis of adhesions, may successfully improve the range of knee extension (Dempsey et al., 2010).

Randomized Controlled Trials

A small RCT conducted by Papotto and Mills (2012) compared a high-intensity serial stretch device with lower intensity static progressive stretch device for home therapy in patients who had undergone total knee arthroplasty and were experiencing arthrofibrosis. High-intensity stretch was performed with the End Range of Motion Improvement (ERMI) Knee/Ankle Flexionater. Patients in the high-intensity stretch group (n=11) 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. Patients in the lower intensity stretch group (n=9) used a static progressive stretch device (StaticPro 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 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 =0.048). A significantly greater number of patients in the HIS group (91%) were able to achieve a functional range of motion >110° than those in the LIS group (22%, p < .001).

Uncontrolled studies

Branch et al., 2003 reported results of 34 patients who did not have full knee range of motion after 6 weeks of physical therapy and were prescribed a serial stretch device (ERMI Knee/Ankle Flexionater). 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. Only 2 patients in this study required surgical manipulation. With functional range of motion defined as 115° or more, 31 (91%) of the 34 patients met this goal after 6.7 weeks. Stephenson et al., 2010 reported results of 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 subsequent knee event within 6 months after the index surgery compared with high-intensity (24.5%) or low-intensity (22.2%) stretch patients.

Dempsey et al., 2010, reported results of a retrospective review of adjunctive high-intensity stretch (HIS) mechanical therapy to treat flexion contractures in 56 patients (19 women, 37 men, age = 51.5 ± 17.0 years). Patient information including sex, age, and the diagnosis or surgical procedure that immediately preceded the prescription of mechanical therapy was recorded. In addition, whether or not each patient was being treated as part of a worker's compensation claim was recorded. Sixteen of the 56 patients were worker's compensation cases. Mechanical therapy was only prescribed for those patients whose motion had reached a plateau when treated with physical therapy alone. As an adjunct to outpatient physical therapy, patients were asked to perform six, 10-minute bouts of end-range stretching per day with the ERMI Knee Extensionater (ERMI, Inc., Atlanta, GA). Passive knee extension was recorded during the postoperative visit that mechanical therapy was prescribed, 3 months after beginning mechanical therapy, and at the most recent follow-up. The mean follow-up for the sample was 13.7 ± 11.5 months (mean ± standard deviation). Regardless of group (worker's compensation versus non-worker's compensation), the use of adjunctive HIS mechanical therapy resulted in passive knee extension deficits that significantly improved from 10.5° ± 5.2° at the initial visit to 2.6° ± 3.5° at the 3 month visit ($p < 0.001$). The degree of extension was maintained at the most recent follow-up (2.0° ± 2.9°), which was significantly greater than the initial visit ($p < 0.001$) but did not differ from the 3 month visit ($p = 0.23$). The gains in knee extension did not differ between worker's compensation and non-compensation patients ($p = 0.56$).

Stinton et al., 2022, reported results of an industry-funded retrospective review of records of 9,482 patients with knee arthrofibrosis who were prescribed high-intensity home mechanical stretch therapy using a high-intensity stretch (HIS) device (the Ermi Knee Flexionater) to recover knee flexion loss between 2008 and 2018. Patients were prescribed an HIS device after reaching a plateau in their motion recovery after at least 4 weeks of treatment with a standard protocol of physical therapy. Patients used the HIS device to assist flexion stretching of their knee during three treatment sessions per day. During each session, the patient advanced the stretch to the maximum tolerable flexion, maintained the stretch for 10 min, and then released the stretch for 10 min. This was followed by another identical 10 min period of end-range stretch. Patients were instructed to stretch the joint to a level of discomfort just below the pain threshold. A subset of 966 patients taken from the larger dataset. These 966 patients were selected for the subset, because in addition to the records from the internal database, these patients also had more rigorous ROM data that were available from physical therapy notes. Mean ROM for the 9,842

patients at baseline was 79.5 ± 20.0 (95% CI 79.1-79.9). The last recorded flexion was significantly greater than the initial flexion (108.4 ± 15.3 (95% CI, 108.1-108.7), $p < 0.01$). For the 9, 842 patients, there were 8,259 patients who had a date for both delivery of the HIS device and the end of device use. The time between device delivery and end of use averaged 75.4 days. The vast majority (91.9%) of these patients used the device for a period of 4 months or less (3.8% treated for < 30 days, 16.6% treated for 30–59 days, 43.1% treated for 60–89 days, and 28.4% treated for 90–119 days). Mean ROM for the subset of 966 patients taken from the internal database at baseline was 80.7 ± 19.8, and mean ROM from physical therapy notes at baseline was 85.3 ± 19.5. The last recorded flexion was significantly greater than the initial flexion for both data sources ($p < 0.01$), at 109.8 ± 14.7 and 110.7 ± 14.7, respectively. For the subset data for the 966 patients taken from physical therapy notes, the time between the first and last flexion measurement averaged 55.9 days and the time between device delivery and the last recorded measurement averaged 45.1 days. This means the initial measurement was taken an average of 10.8 days prior to device delivery. The average initial flexion for the subset of 966 patients in both the internal database and from physical therapy notes was below the expected clinical level that would likely require a motion restoring surgery. When comparing males and females, there was not a statistically significant difference in initial flexion, flexion gain, or days of use. There was a statistically significant difference in the last recorded flexion with 2.0° higher flexion in males. The most important finding in this study is that regardless of sex or age, patients with severe motion loss who were treated with high-intensity home mechanical stretch therapy achieved excellent gains in their range of motion (> 25° on average). These gains were achieved over a relatively short period of time (6–10 weeks). As described by Keating et al., 2007, at least 90° of knee flexion is required to perform basic daily activities and the goal of an MUA after knee arthroplasty is to increase flexion in patients who have failed to reach 90° of flexion postoperatively.

Shoulder

Randomized Controlled Trials

Teytelbaum et al., 2024 reported results of a randomized controlled trial (NCT05384093) that compared the effectiveness of an at-home high-intensity stretch (HIS) device to traditional physical therapy (PT) and to PT in combination with the HIS device. Thirty-four patients between the ages of 38–74 diagnosed with idiopathic adhesive capsulitis and a minimum of 12 months follow-up were included in this study. Adhesive capsulitis was defined as shoulder pain with limited ROM for more than one month with ≤130 degrees of passive forward flexion and ≤30 degrees of passive external rotation. A minimum one-month criterion was selected to exclude all patients with short-term, temporary loss of motion which could have been attributed to causes unrelated to adhesive capsulitis. Patients were randomized into one of the three groups: HIS device (n=13), PT alone (n=10), or combined HIS device plus PT (n=11). Passive range of motion (ROM), American Shoulder and Elbow Surgeons (ASES), and Simple Shoulder Test (SST) scores were measured. Additionally, patient satisfaction, compliance and complications were recorded. A goniometer was used to measure and record passive ROM of both the non-affected and affected shoulder in forward flexion (FF), abduction (ABD), and external rotation (ER). The PT protocol consisted of shoulder range of motion exercises, including joint mobilization and scapular stabilization as deemed appropriate by the treating physical therapist according to a standardized protocol. Physical therapists instructed patients on proper techniques and specific stretches and exercises. The patients were scheduled for three 60-minute PT sessions per week. Patients continued physical therapy until the affected shoulder achieved external rotation and forward flexion ROM equal to or greater than 90% of the contralateral unaffected side. Patients randomized to the HIS stretch device group (Flexionater Chair, Ermi, Atlanta, GA) were instructed to stretch at a high intensity for 60 min per day divided into 3 time periods by the representative of the company. Patients were asked to use the HIS for 10 min, followed by 10 min of rest and another 10 min of stretch. This cycle was repeated two more times each day to achieve the goal of 60 min of stretching per day. The chair was initially adjusted for ER. Once 90% of contralateral motion was completed, the HIS stretch device was then changed to perform abduction. The patient continued use until they reached ER and FF of at least 90% of the contralateral side. Patients in the combined therapy group were instructed to perform the daily HIS stretching exercises while attending PT for 2–3 sessions per week using the exact protocols followed by the

other two groups. Final ROM in all planes improved for all groups compared to baseline ($p < 0.001$), with only HIS device group able to restore >95% of contralateral ROM in all planes at final follow-up. Patients with PT alone were on average slowest to improve ROM from baseline, at 3 months, 6 months, and 1 year in all planes except internal rotation. ASES and SST scores improved for all groups when compared to baseline ($p < 0.001$). Use of HIS-device resulted in greater improvement in SST and ASES Total scores compared to PT alone ($p=0.045$, and $p=0.048$, respectively).

Uncontrolled Studies
Dempsey et al., 2011, reported results of an industry-funded retrospective series in 36 patients. This study evaluated the use of a patient-activated serial stretch device (ERMI Shoulder Flexionater) in combination with continued physical therapy in patients with adhesive capsulitis who had failed 6 weeks of physical therapy alone (glenohumeral abduction and external rotation not equal to the opposite uninvolved limb). 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 ($p <0.05$), 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).

Analysis of Evidence (Rationale for Determination)

Joint stiffness and joint contractures are relatively common disorders that can result in significant, long-term morbidity. Initial treatment is non-operative and often entails the use of mechanical modalities such as dynamic and static splints. Although widely utilized, there is a paucity of data that support the use of such measures.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Low-load prolonged-duration stretch devices/dynamic splinting devices are described by HCPCS codes E1800, E1802, E1805, E1810, E1812, E1815, E1825, E1830, and E1840.

Static progressive stretch devices and patient-actuated stretch devices are described by HCPCS codes E1801, E1806, E1811, E1816, E1818, E1821, E1831, and E1841.

With the exception of E1820 and E1821, these items are capped rental DME. E1820 and E1821 are purchased items.

Code	Description
E1800	Dynamic adjustable elbow extension/flexion device, includes soft interface material
E1801	Static progressive stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1802	Dynamic adjustable forearm pronation/supination device, includes soft interface material
E1805	Dynamic adjustable wrist extension/flexion device, includes soft interface material
E1806	Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
E1810	Dynamic adjustable knee extension/flexion device, includes soft interface material
E1811	Static progressive stretch knee device, extension and/or flexion, with or

	without range of motion adjustment, includes all components and accessories
E1812	Dynamic knee, extension/flexion device with active resistance control
E1815	Dynamic adjustable ankle extension/flexion device, includes soft interface material
E1816	Static progressive stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
E1818	Static progressive stretch forearm pronation/supination device, with or without range of motion adjustment, includes all components and accessories
E1820	Replacement soft interface material/cuffs for dynamic adjustable extension/flexion device
E1821	Replacement soft interface material/cuffs for bi-directional static progressive stretch device
E1825	Dynamic adjustable finger extension/flexion device, includes soft interface material
E1830	Dynamic adjustable toe extension/flexion device, includes soft interface material
E1831	Static progressive stretch toe device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1840	Dynamic adjustable shoulder flexion/abduction/rotation device, includes soft interface material
E1841	Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories

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Policy history

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Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.