Medical Coverage Policy | Patient-Controlled End of Range Motion Stretching Devices

EFFECTIVE DATE: 10|01|2015
POLICY LAST REVIEWED: 03|19|2025

OVERVIEW
Patient-controlled stretching devices are used in the home to increase range of motion (ROM) in patients who have impaired functional status due to ROM. There are 2 commercially available types of devices. Static progressive stretch (SPS) 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)) devices use hydraulics to alternate between periods of higher intensity stretch and relaxation.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Patient-controlled end range of motion stretching devices are not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
Patient-controlled end range of motion stretching devices are considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND
Range of Motion Impairments
Loss of full ROM occurs in a significant proportion of patients following surgical procedures around the 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 range of motion compared with the normal contralateral side. Loss of ROM of the knee can lead to impairments in walking, sitting down and rising from a chair, and navigating stairs. A 2010 publication estimated that based on the annual rates of total knee arthroplasty (TKA) and anterior cruciate ligament (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.

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.

Static Progressive Stretch Devices
This policy focuses on patient-controlled mechanical devices that provide either moderate- to high-intensity stretch or static progressive stretch 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 session per day, and number of days per week that stretching is performed. SPS 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 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. Individuals are typically instructed to use the devices for 30 minutes, 3 times a day. During each session, individuals 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).

Serial Stretch Devices
The purpose of serial stretch devices in individuals 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.Serial stretch devices (eg, ERMI) use hydraulics to alternate between periods of higher intensity stretch and relaxation.

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. 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." One small study (2000) correlated knee ROM with functional parameters and concluded that 110° 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. This threshold of ROM is therefore used as a measure of treatment success for individual patients. Loss of knee ROM 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. 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." ROM thresholds in joints other than the knee have been less clearly defined.

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. Four ~~Three~~ RCTs have evaluated static progressive stretch devices but comparators in each differed (physical therapy, a dynamic splint, and a 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. One RCT found greater improvements in range of motion and Western Ontario and McMaster University Osteoarthritis Index (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. A trial reported results of 34 participants with adhesive capsulitis that compared static progressive stretch to physical therapy alone or the combination of stretch and physical therapy. Although significant improvements with static stretching were found compared with placebo in terms of range of motion, differences between groups were generally similar. A fourth 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 is higher with static progressive stretch devices. 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 an 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 range of motion. One small RCT and a larger retrospective comparative study have reported that high-intensity stretching with 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 that have demonstrated improved range of motion in patients whose range 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.

CODING

Medicare Advantage Plans and Commercial Products

The following HCPCS codes are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

E1801 Static progressive stretch/patient actualized serial stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories (Text Revised Effective 4/1/2025)

E1806 Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, inclurange motdes all components and accessories

E1811 Static progressive stretch/patient actualized serial stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories (Text Revised Effective 4/1/2025)

E1816 Static progressive stretch/patient actualized serial stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories (Text Revised Effective 4/1/2025)

E1818 Static progressive stretch/patient actualized serial stretch forearm pronation / supination device, with or without range of motion adjustment, includes all components and accessories (Text Revised Effective 4/1/2025)

E1831 Static progressive stretch toe device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories

E1832 Static progressive stretch finger device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories (New Code Effective 4/1/2025)

E1841 Static progressive stretch/patient actualized serial stretch shoulder device, with or without range of motion adjustment, includes all components and accessories (Text Revised Effective 4/1/2025)

RELATED POLICIES

None

PUBLISHED

Provider Update, May 2025
Provider Update, June 2024
Provider Update, June 2023
Provider Update, July 2022
Provider Update, July 2021

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