



MASSACHUSETTS

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Medical Policy

Patient-Controlled End of Range Motion Stretching Devices

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Policy Number: 721

BCBSA Reference Number: 1.03.05

NCD/LCD: N/A

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Patient-controlled end range of motion stretching devices are considered [INVESTIGATIONAL](#).

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service.
Commercial PPO and Indemnity	This is not a covered service.
Medicare HMO BlueSM	This is not a covered service.
Medicare PPO BlueSM	This is not a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following HCPCS codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

HCPCS codes:	Code Description
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

Range of Motion Impairments

Loss of full ROM 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 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. Stephenson et al (2010) 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 85000 per year, and approximately 21000 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).

Static Progressive Stretch Devices

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 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 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 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 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

Patient-controlled serial stretch devices in the home include the ERMI line. Specific ERMI devices are the Shoulder Flexionater, Knee Flexionater, Knee Extensionater, Elbow Extensionater, and the MPJ Extensionater. 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 227 kilograms (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 five to ten 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° 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.² 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.³ 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."⁴ ROM thresholds in joints other than the knee have been less clearly defined.

Summary

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 two 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) 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. The 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 four weeks of treatment, with significant improvements maintained at the two-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.

For individuals who have functional limitations in ROM who receive serial stretch devices and physical therapy, the evidence includes an RCT and observational studies. The 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 a 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.

Date	Action
4/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statement unchanged.
5/2017	BCBSA National medical policy review. Summary section clarified.
9/2016	BCBSA National medical policy review. Policy title changed to "Patient-Controlled End Range of Motion Stretching Devices." References added.
9/2015	New medical policy describing investigational indications. Effective 9/1/2015.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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