MASSACHUSETTS

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Medical Policy

Patient-Controlled End of Range Motion Stretching Devices

Table of Contents

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 Blue℠ and Medicare PPO Blue℠ 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 Blue℠	This is **not** a covered service.
Medicare PPO Blue℠	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 <u>Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:</u>

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

Treatment

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

This evidence review focuses on patient-controlled mechanical devices that provide either moderate- to high-intensity stretch or static progressive stretch in the home. Patient-controlled stretching devices are used at home to increase range of motion in patients who have impaired functional status due to decreased range of motion. We address 2 types of commercially available devices. Static progressive stretch devices (eg, 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 (eg, End Range of Motion Improvement (ERMI)) use hydraulics to alternate between periods of higher intensity stretch and relaxation.

Improvement in functional outcomes, such as the ability to perform activities of daily living, is the primary goal of this intervention. Joint range of motion is an intermediate outcome. In 2000, one small study by Rowe et al. correlated knee range of motion with functional parameters and concluded that 110° is considered the functional range of motion necessary to allow patients to perform common activities of daily living such as navigating stairs, rising range of motion a low chair or commode, entering or exiting range of motion a car, or tying one's shoes.[3,] This threshold of range of motion is therefore used as a measure of treatment success for individual patients. Loss of knee range of motion of more than 15°, which occurs in about 1% to 2% of patients after anterior cruciate ligament reconstruction, has been associated with loss of quadriceps muscle strength and the development of osteoarthritis.[4,] According to the knee examination form developed by the International Knee Documentation Committee (2000), an extension deficit of 6° to 10° or a flexion deficit of 16° to 25° when compared with the noninvolved knee is categorized "abnormal," and an extension deficit of more than 10° or a flexion deficit of more than 25° when compared with the noninvolved knee is categorized "severely abnormal."[5,] Range of motion thresholds in joints other than the knee have been less clearly defined.

Summary

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

For individuals who have functional limitations in range of motion who receive static progressive stretch 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 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 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 third RCT found comparable improvements in most outcomes for the static progressive stretch device compared with dynamic splinting, and a systematic review of case reports and series found similar clinical efficacy for increasing elbow range of motion between static progressive stretch devices and dynamic splints. 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 range of motion 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 of motion 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.

Policy History

Date	Action
5/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statement unchanged.
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

References

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