Medical Policy

Patient-Controlled End of Range Motion Stretching Devices

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Policy Number: 721
BCBSA Reference Number: 1.03.05 (For Plan internal use only)
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 (static progressive and serial) 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.

<table>
<thead>
<tr>
<th></th>
<th>Outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>This is not a covered service.</td>
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<tr>
<td>Medicare HMO BlueSM</td>
<td>This is not a covered service.</td>
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<tr>
<td>Medicare PPO BlueSM</td>
<td>This is not a covered service.</td>
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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

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>E1801</td>
<td>Static progressive stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories</td>
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<tr>
<td>E1806</td>
<td>Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories</td>
</tr>
<tr>
<td>E1811</td>
<td>Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories</td>
</tr>
<tr>
<td>E1816</td>
<td>Static progressive stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories</td>
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<tr>
<td>E1818</td>
<td>Static progressive stretch forearm pronation/supination device, with or without range of motion adjustment, includes all components and accessories</td>
</tr>
<tr>
<td>E1831</td>
<td>Static progressive stretch toe device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories</td>
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<tr>
<td>E1841</td>
<td>Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories.</td>
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### 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 from 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 to 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, 1 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 from a low chair or commode, entering or exiting a car, or tying one’s shoes. 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. 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.”

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.

Summary of Evidence
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. 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 that the technology results in an improvement in the net health outcome.

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 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 that the technology results in an improvement in the net health outcome.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>5/2023</td>
<td>Annual policy review. Minor editorial refinement to policy statement; intent unchanged.</td>
</tr>
<tr>
<td>4/2021</td>
<td>Annual policy review. Description, summary, and references updated. Policy statements unchanged.</td>
</tr>
<tr>
<td>5/2020</td>
<td>Annual policy review. Description, summary, and references updated. Policy statements unchanged.</td>
</tr>
<tr>
<td>5/2017</td>
<td>Annual policy review. Summary section clarified.</td>
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<tr>
<td>9/2016</td>
<td>Annual policy review. Policy title changed to “Patient-Controlled End Range of Motion Stretching Devices.” References added.</td>
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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


