Mechanical Splinting or Stretching Devices

Policy Number: 1.01.500  Last Review: 8/2014

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for mechanical splinting or stretching devices when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered
Low-load prolonged-duration stretch (LLPS) (Dynamic Splinting) devices:
Examples of LLPS devices include Dynasplint System® (Dynasplint Systems Inc.); Ultraflex (Ultraflex Systems Inc.); LMB Pro-Glide devices (DeRoyal Industries); Advance Dynamic ROM®, Saunders®, Pronex® (Empi).

Dynamic splinting (LLPS devices) devices may be considered medically necessary for use on the knee, elbow, wrist, or finger when any of the following criteria are met:
- As an adjunct to physical therapy in members with documented signs and symptoms of significant motion stiffness/loss in the sub-acute injury or post-operative period (≥ 3 weeks but ≤ 4 months after injury or surgery);
- In the acute post-operative period for members who have a prior documentation of motion stiffness/loss in a joint and are having additional surgery or procedures done to improve motion in that joint;
- As an alternative to manipulation under anesthesia.

When Policy Topic is not covered
Low-load prolonged-duration stretch (LLPS) (Dynamic Splinting) devices:
Examples of LLPS devices include Dynasplint System® (Dynasplint Systems Inc.); Ultraflex (Ultraflex Systems Inc.); LMB Pro-Glide devices (DeRoyal Industries); Advance Dynamic ROM®, Saunders®, Pronex® (Empi).

The use of dynamic splinting (LLPS devices) devices is considered not medically necessary for all other indications including, but not limited to:
- In the management of chronic contractures and joint stiffness due to joint trauma, fractures, burns, head and spinal cord injuries, rheumatoid arthritis, plantar fasciitis, multiple sclerosis, muscular dystrophy, cerebral palsy, or other chronic congenital conditions;
- When conventional methods of treating stiff or contracted joints have not been attempted; or
- If there is no significant improvement after four months of use; or
- If initiated more than four months post-operatively (unless it is to be used as an alternative to manipulation under anesthesia)
- The use on any other joint not mentioned above.

Bi-directional static progressive (SP) stretch devices:
An example for this type of device is the Joint Active Systems (JAS) (Joint Active Systems).

Bi-directional static progressive (SP) stretch devices are considered investigational.
PASS devices:
Examples of PASS devices include ERMI Knee Extensionater®, ERMI Elbow Extensionater®, ERMI Knee/Ankle Flexionater®, and ERMI Shoulder Flexionater® (ERMI).

Patient-actuated serial stretch (PASS) devices are considered investigational.

Accessories and supplies such as soft pads would not be eligible for coverage when the device itself is investigational.

Considerations
Covered devices should only be approved for monthly rental.

These devices should not be confused with Continuous Passive Motion devices designed for use in the immediate post-operative period.

Description of Procedure or Service
A joint contracture is characterized by a chronically reduced range of motion (ROM) secondary to structural changes in non-bony tissues, including muscle, tendons, ligaments, and skin. This joint dysfunction occurs when elastic connective tissue is replaced with inelastic fibrous material, making the tissue resistant to stretching.

Prolonged immobilization of joints following surgery or trauma is the most common cause of joint contractures. While immobilization may prevent excess tension to the joint and prevent disruption of the healing of repaired tissues, it can also cause pathological conditions that contribute to the development of joint contractures. For example, the tensile strength of collagen decreases, while the randomness of collagen increases; simultaneously, cross-linking of collagen can occur, with subsequent joint adhesion formation. Permanent degenerative changes can occur if the synovial fluid, the lubricating fluid produced by the connective tissue, and chondroblasts and fibroblasts do not move freely throughout the joint.

Other causes of joint contractures include conditions such as spasticity secondary to nerve damage, such as stroke or spinal cord injury; and muscle weakness due to muscle, tendon, or ligament disease, including paralysis. In spasticity, contractures are formed as a result of continuous muscle contraction, which causes a shortening of myofibrils due to a loss of sarcomeres. It has also been suggested that the muscle’s resting length may be shortened. In a healthy muscle, muscle contraction occurs by a coordinated attaching and detaching of actin and myosin. In spasticity, an ordered interaction of myosin and actin is inhibited. Myosin and actin may attach prematurely or fail to detach, leading to increased overlap that significantly reduces the ROM of the affected muscle and joint. Contractures secondary to muscle weakness form when muscle fibers are replaced with collagen and fatty tissue. In addition, the remaining muscle fibers are chronically shortened. In paralysis, the affected muscle lacks normal innervation, which reduces the size of muscle fibers, induces necrosis of some fibers, and slows voluntary or induced muscle contraction.

A number of different modalities are used to treat or prevent joint contractures, including manual joint mobilization by a physical therapist, serial plastering, static splinting, mechanical stretching devices, continuous device-assisted passive motion (CPM), massage, exercise, electrical stimulation, botulinum toxin, and surgery. There is no single technique that has been identified as being superior to others, and often a combination of treatments is used to restore ROM.

The use of mechanical stretching devices is based on the theory that passive motion early in the healing process can provide movement of the synovial fluid, and thus promotes lubrication of the joint, stimulate the healing of articular tissues, prevent adhesions and joint stiffness, and reduce edema, without interfering with the healing of incisions or wounds over the moving joint. These devices are
intended to replace or complement some physical therapist-directed sessions by providing frequent and consistent application of joint mobilization under controlled conditions in a hospital or in the patient’s home. The goal of these modalities is to restore ROM.

A variety of mechanical stretching devices are available for extension or flexion of shoulder, elbow, wrist, fingers, knee, ankle, and toes. This category includes static progressive (SP) stretch, low-load prolonged-duration stretch (LLPS) (also referred to as dynamic splinting), and patient-actuated serial stretch (PASS) (also known as patient-directed serial stretch) devices. In most cases, mechanical stretching devices are used as an adjunct treatment to physical therapy and/or exercise.

- **Bi-directional static progressive (SP) stretch devices:**
  An example for this type of device is the Joint Active Systems (JAS) (Joint Active Systems).

  SP stretch devices hold the joint in a set position but allow for manual modification of the joint angle and may allow for active motion without resistance (inelastic traction). This type of device itself does not exert a stress on the tissue unless the joint angle is set at the maximum range of motion. The bi-directional static progressive stretch device concept of static progressive stretching applies a different biomechanical principle than the spring loaded dynamic splinting devices, which use low load, prolonged stress technique. The static progressive stretch technique, coupled with stress relaxation, is a series of incremental increasing displacements applied to a joint over a period of time, which theoretically causes plastic deformation of the soft tissues, which the brace can maintain. The stretch or force applied is typically increased every few minutes by the patient in order to increase range of motion during the period of brace utilization, thus the area never has time to recover. The period of brace utilization is typically 30 minutes, used 2-3 times a day.

- **Low-load prolonged-duration stretch (LLPS) (Dynamic Splinting) devices:**
  Examples of LLPS devices include Dynasplint System® (Dynasplint Systems Inc.); Ultraflex (Ultraflex Systems Inc.); LMB Pro-Glide devices (DeRoyal Industries); Advance Dynamic ROM®, Saunders®, Pronex® (Empi).

  LLPS devices permit resisted active and passive motion (elastic traction) within a limited range. LLPS devices maintain a set level of tension by means of incorporated springs. Most spring loaded 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. Most of these devices are adjustable-tension controlled units that provide a continuous dynamic stretch while patients are asleep or at rest. Commonly time of use is continuously for 6 – 12 hours, which can be at night or can be two three-hour sessions during the day for less than four months. The objective of stretch therapy is to improve range of motion without compromising the stability and quality of the connective tissue and joint. Currently, dynamic splinting devices are available for but not limited to the elbow, wrist, knee, ankle, and toes.

- **PASS devices:**
  Examples of PASS devices include ERMI Knee Extensionater®, ERMI Elbow Extensionater®, ERMI Knee/Ankle Flexionater®, and ERMI Shoulder Flexionater® (ERMI).

  PASS devices permit resisted active and passive motion (elastic traction) within a limited range. PASS devices provide a low- to high-level load to the joint using pneumatic, e.g., Extensionaters (ERMI Inc.); or hydraulic, e.g., Flexionaters (ERMI Inc.), systems that can be adjusted by the patient. These devices are custom fitted. Typically a certified ERMI representative develops an individualized treatment protocol and provides training regarding its correct usage.

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**Rationale**

Low-load prolonged-duration stretch (LLPS) (Dynamic Splinting) devices
Evidence from five randomized controlled trials (RCTs) and two uncontrolled studies suggests that low-load prolonged-duration stretch (LLPS) for finger contractures following surgical extensor injury repair may increase range of motion (ROM) faster than static splinting. However, the treatment benefit is small and the final outcome is similar to that achieved with static splinting. Furthermore, LLPS did not significantly improve hand function and grip strength, indicating that the small short-term gains in ROM may not be clinically meaningful and that LLPS may not improve final outcomes. There was a paucity of studies investigating mechanical stretching devices for other applications, including contracture of the fingers following flexor injury or trauma, the hand, wrist, elbow, shoulder, and the knee. Because there were only one or two studies available for each device type, a systematic analysis of the evidence was not possible. No safety issues associated with mechanical stretching devices were identified in the reviewed studies.

Although there is inadequate data in the published peer reviewed literature to validate the effectiveness of dynamic splinting in improving joint range of motion, this technology is widely used in the Orthopedic and Physical Therapy communities for selected patient populations. On the basis of national community standards, dynamic splinting may be considered medically necessary in the clinical settings outlined under the Policy section of this document.

PASS devices
There are no controlled published peer-reviewed studies on the effectiveness of the knee/ankle flexionator, the shoulder flexionator, the knee extensor, or the elbow extensionator. There is insufficient scientific evidence to support the manufacturer's claims that these home-based stretching devices can consistently stretch scar tissues without causing vascular re-injury and thus significantly reduce the need for additional surgery (e.g., surgery for arthrofibrosis after knee surgery). Furthermore, there is a lack of published data to support the claim that these devices can reduce the need for surgery manipulation under anesthesia. Therefore, extensionator and flexionator devices are considered investigational.

Bi-directional static progressive (SP) stretch devices
Published reports of the effectiveness of SP stretch devices are limited to case reports and small uncontrolled observational studies. There are no prospective randomized studies demonstrating that the addition of the use of JAS devices to the physical therapy management of patients with joint injury or surgery significantly improves patient's clinical outcomes. Thus, Bi-directional static progressive (SP) stretch devices are considered investigational.

References:
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>E1801</td>
<td>Bi-directional static progressive stretch elbow device with range of motion adjustment, includes cuffs</td>
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<tr>
<td>E1802</td>
<td>Dynamic adjustable forearm pronation/supination device, includes soft interface material</td>
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<tr>
<td>E1805</td>
<td>Dynamic adjustable wrist extension/flexion device, includes soft interface material</td>
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<tr>
<td>E1806</td>
<td>Bi-directional static progressive stretch wrist device with range of motion adjustment, includes cuffs</td>
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<td>E1810</td>
<td>Dynamic adjustable knee extension/flexion device, includes soft interface material</td>
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<td>E1811</td>
<td>Bi-directional progressive stretch knee device with range of motion adjustment, includes cuffs</td>
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<td>E1812</td>
<td>Dynamic knee, extension/flexion device with active resistance control</td>
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<td>E1815</td>
<td>Dynamic adjustable ankle extension/flexion, includes soft interface material</td>
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<td>Bi-directional static progressive stretch ankle device with range of motion adjustment, includes cuffs</td>
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<td>E1818</td>
<td>Bi-directional static progressive stretch forearm pronation/supination device with range of motion adjustment, includes cuffs</td>
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<td>E1820</td>
<td>Replacement soft interface material, dynamic adjustable extension/flexion device</td>
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<td>Replacement soft interface material/cuffs for bi-directional static progressive stretch device</td>
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<td>Dynamic adjustable finger extension/flexion device, includes soft interface material</td>
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<td>Dynamic adjustable toe extension/flexion device, includes soft interface material</td>
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<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>E1840</td>
<td>Dynamic adjustable shoulder flexion/abduction/rotation device, includes soft interface material</td>
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<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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**Additional Policy Key Words**
- Flexionator
- Extensionator

**Policy Implementation/Update Information**

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<th>Update Description</th>
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<td>8/1/03</td>
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<td>3/1/12</td>
<td>Coding updated. Terminology of the various devices updated. Post operative period extended to four months for LLPS devices.</td>
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