Mechanical Stretching Devices

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DESCRIPTION

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.

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.

Several types of mechanical stretching devices (also known as dynamic splinting systems) 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.

- **Low-Load Prolonged-Duration Stretch (LLPS) Devices (Dynamic Splinting) Devices:** LLPS devices permit active and passive motion (elastic traction) within a limited range. LLPS devices maintain a set level of tension by 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. Examples of this type of device include but are not limited to:
    - Dynasplint System® (Dynasplint Systems, Inc., Severna Park, MD)
    - Ultraflex (Ultraflex Systems, Pottstown, PA)
    - Pro-glide™ Dynamic ROM devices (DeRoyal®, Powell, TN)
    - Advance Dynamic ROM® devices (Empi, St. Paul, MN)

Note: *The SaeboMas dynamic mobile arm support system (Saebo, Charlotte, NC) is considered investigational because of insufficient published evidence of its clinical value.*

- **Static Progressive Stretch (SPS) Devices:** SPS stretch devices (also known as bi-directional SPS devices) hold the joint in a set position but allow for manual modification of the joint angle (inelastic traction). This type of device does not exert a stress on the tissue and does not allow for active or passive motion. Examples of this type of device include but are not limited to:
    - Joint Active Systems (JAS) splints (Joint Active Systems, Inc., Effington, IL)
        - JAS Elbow
        - JAS Shoulder
        - JAS Ankle
        - JAS Knee
        - JAS Wrist
        - JAS Pronation/Supination
    - Stat-A-DYNE and Static-Pro® (elbow, knee, wrist) (DeRoyal Industries, Inc.)

- **Patient-Actuated Serial Stretch (PASS) Devices:** PASS devices permit active and passive motion with elastic traction within a limited range, but also provide a low- to high-level load to the joint using pneumatic, hydraulic or tensioning systems that can be adjusted by the individual. Examples of this type of device include but are not limited to:
    - ERMI Knee Extensionator® (ERMI, Inc., Atlanta, GA)
    - ERMI Knee/Ankle Flexionator® (ERMI, Inc., Atlanta, GA)
    - ERMI Shoulder Flexionator® (ERMI, Inc., Atlanta, GA)
    - ERMI MPJ Extensionator® (ERMI, Inc., Atlanta, GA)
    - ERMI Elbow Extensionator® II (ERMI, Inc., Atlanta, GA)

Clinical Contact and Therapy Purpose
The purpose of mechanical stretching devices in patients who have functional limitations in range of motion (ROM) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations
The relevant population of interest is patients with functional limitations in joint range of motion after injury or surgery.

Interventions
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.

Comparators
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).

Outcomes
Improvement in functional outcomes and joint range of motion (ROM).

Review of Evidence
Randomized controlled trials (RCTs), observational studies, case series, and medical community acceptance (Orthopedic and Physical Therapy) confirm the benefits of low-load prolonged-duration stretch (LLPS) (dynamic splinting) devices when used to relieve persistent joint stiffness or contractures that can occur after injury or surgery. However, there is minimal evidence supporting the effectiveness of low-load prolonged-duration stretch (LLPS) (dynamic splinting) devices for the rehabilitation of joints other than finger, wrist, elbow, knee, and toe. There were 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 low-load prolonged-duration stretch (LLPS) (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, low-load prolonged-duration stretch (LLPS) (dynamic splinting) may be considered medically necessary in the clinical settings outlined under the Policy section of this document below.

There is insufficient evidence in the published peer-reviewed literature to support the use of dynamic LLPS devices for the treatment of conditions such as, but not limited to, chronic joint stiffness or chronic fixed contractures caused by chronic medical conditions such as rheumatoid arthritis (RA), cerebral palsy, stroke, long term lack of motion in the joint, neuromuscular disease or plantar fasciitis.

Static Progressive Stretch (SPS) Devices
Research on static progressive stretch (SPS) devices is limited to case reports and small uncontrolled studies. Clinical evidence is not sufficient to demonstrate that use of static progressive devices is an effective treatment option for treating joint contractures.

Patient-Actuated Serial Stretch (PASS) Devices
There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of the use of PASS devices for any indication. Well-designed clinical trials that evaluate these devices are lacking. It is not possible to determine based on the available evidence whether the addition of these devices when used alone or as an adjunct to a PT program provide improved patient outcomes

Regulatory Status
The U.S. Food and Drug Administration (FDA) has determined that devices classified as "Exerciser, Non-Measuring" are considered Class I devices and exempt range of motion 510(k) requirements. This classification does not require submission of clinical data on efficacy, only notification to the FDA prior to marketing.

PRIOR APPROVAL

Not applicable.

POLICY

Low-Load Prolonged-Duration Stretch (LLPS) Devices (Dynamic Splinting) (E1800, E1802, E1805, E1810, E1812, E1815, E1825, E1830, E1840)
Low-load prolonged-duration stretch (LLPS) devices (dynamic splinting) may be considered **medically necessary** for use on the knee, elbow, wrist or finger in any of the following clinical settings:

A. As an addition to physical or occupational therapy in the subacute injury or post-operative period (greater than or equal to 3 weeks but less than or equal to 4 months after injury or operation) in individuals with signs and symptoms of persistent joint stiffness or contracture:

    a. For an initial period of up to 4 months; **and**

    b. If the individual shows improvement after the initial period, thereafter for as long as improvement can continue to be demonstrated; **or**

B. In the subacute injury or post-operative period (greater than or equal to 3 weeks but less than or equal to 4 months after injury or operation) in an individual whose limited range of motion poses a meaningful (as judged by the physician) functional limitation, **AND** who has not responded to other therapy (including physical or occupational therapy);

    a. For an initial period of up to 4 months; **and**

    b. If the individual shows improvement after the initial period, thereafter for as long as improvement can continue to be demonstrated; **or**

C. In the acute post-operative period for individuals who have undergone additional surgery to improve the range of motion of a previously affected joint:

    a. For an initial period of up to 4 months; **and**

    b. If the individual shows improvement after the initial period, thereafter for as long as improvement can continue to be demonstrated; **or**

D. For individuals unable to benefit from standard physical or occupational therapy modalities because of an inability to exercise:

    a. For an initial period of up to 4 months; **and**

    b. If the individual shows improvement after the initial period, thereafter for as long as improvement can continue to be demonstrated.

Persistent Joint Stiffness of the Hallux Limitus (Great Toe)
Low-load prolonged-duration stretch (LLPS) devices (dynamic splinting) may be considered **medically necessary** for the treatment of persistent joint stiffness of the hallux limitus (i.e., degenerative pathology in the first metatarsophalangeal joint or the great toe) following bunionectomy or cheilectomy when provided within two months after surgery.

No Improvement after 4 Months of Use
If there is no significant improvement after 4 months of use, low-load prolonged-duration stretch (LLPS) devices (dynamic splinting) for the above medically necessary indications, this will be considered **not medically necessary** under any circumstance, including but not limited to individuals unable to benefit from standard physical or occupational therapy modalities because of an inability to exercise.

Low-load prolonged-duration stretch (LLPS) devices (dynamic splinting) including but not limited to the following is considered **investigational** because their safety and/or effectiveness cannot be established by review of the available published peer reviewed literature:

- Knee, elbow, wrist, or finger not meeting the above criteria
- persistent joint stiffness of the hallux limitus (i.e., degenerative pathology in the first metatarsophalangeal joint or the great toe) not meeting the above criteria
- For the treatment of the shoulder (E1840) and ankle (E1815)
- For the treatment of conditions related to chronic joint stiffness or chronic fixed contractures caused by the following:
    - Cerebral palsy
    - Long term lack of motion in the joint
    - Neuromuscular disease
    - Plantar fasciitis
    - Rheumatoid arthritis
    - Stroke

Static Progressive Stretch (SPS) Devices (Also Known as Bi-Directional SPS Devices) (E1801, E1806, E1811, E1816, E1818, E1821, E1831, E1841)
Static progressive stretch (SPS) devices including but not limited to the following, are considered **investigational** because their safety and/or effectiveness cannot be established by review of the available published peer reviewed literature:

- Joint Active Systems (JAS) Splints
  - JAS Elbow
  - JAS Shoulder
  - JAS Ankle
  - JAS Knee
  - JAS Wrist
  - JAS Pronation/Supination

- Stat-A-Dyne and Static-Pro (elbow, knee, wrist)

Patient-Actuated Serial Stretch (PASS) Devices (E1399)
Patient-actuated serial stretch (PASS) devices including but not limited to the following are considered **investigational** for all indications because their safety and/or effectiveness cannot be established by review of the available published peer reviewed literature:

- ERMI Knee Extensionator
- ERMI Knee/Ankle Flexionator
- ERMI Shoulder Flexionator
- ERMI MPJ Extensionator
- ERMI Elbow Extensionator II

SaeboMas Support System (E1399)
The SaeboMas dynamic mobile arm support system is considered **investigational** because of insufficient published evidence of its clinical value.

Policy Guidelines

Required Documentation
Medical records documenting the following, when applicable:

- Current prescription from physician
- Physician office notes that indicate the following:
  - The affected joint
  - The date of injury/surgery
  - Previous treatment attempted
  - Treatment plan, including proposed duration of use

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- E1800 Dynamic adjustable elbow extension/flexion device includes soft interface material
- E1801 Static progressive stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
- E1802 Dynamic adjustable forearm pronation/supination device, includes soft interface material
- E1805 Dynamic adjustable wrist extension/flexion device, includes soft interface material
- E1806 Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
- E1810 Dynamic adjustable knee extension/flexion device, includes soft interface material
- E1811 Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
- E1812 Dynamic knee, extension/flexion device with active resistance control
- E1815 Dynamic adjustable ankle extension/flexion device, includes soft interface material
- 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
- E1821 Replacement soft interface material/cuffs for bi-directional static progressive stretch device
- E1825 Dynamic adjustable finger extension/flexion device, includes soft interface material
- E1830 Dynamic adjustable toe extension/flexion device, includes soft interface material
- E1831 Static progressive stretch toe device, extension and/or flexion with or without range of motion adjustment, includes all components and accessories
- E1840 Dynamic adjustable shoulder flexion/abduction/rotation device, includes soft interface material
- E1841 Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories
- E1399 Durable medical equipment, miscellaneous (Patient actuated serial stretch (PASS) device)

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POLICY HISTORY

Date	Reason	Action
January 2022	Annual Review	Policy Revised
January 2021	Annual Review	Policy Revised
January 2020	Annual Review	Policy Revised
January 2019	Annual Review	Policy Revised
January 2018	Annual Review	Policy Revised
January 2017	Annual Review	Policy Revised
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February 2012	Annual Review	Policy Revised
October 2011	Annual Review	Policy Renewed
August 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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