Medica Coverage Policy

Policy Name:	**Mechanical Stretching Devices for the Treatment of Joint Contractures of the Extremities**
Effective Date:	**8/21/2023**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Mechanical stretching devices for the treatment of joint contractures of the extremities are considered investigative and unproven and therefore **NOT COVERED** for all indications, including but not limited to:

1. Low-load prolonged-duration stretch (LLPS) devices, also known as dynamic splinting systems
2. Static progressive stretch (SPS) devices, also known as bi-directional SPS devices
3. Patient actuated serial stretch (PASS) devices, also known as patient-controlled serial stretch devices or high intensity stretch devices.

There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Description

A joint contracture is characterized by chronically reduced ROM secondary to structural changes in non-bony tissues including muscle, tendons, ligaments, and skin. 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 pathologic conditions that contribute to the development of joint contractures. Other causes of joint contractures include spasticity secondary to nerve damage, such as stroke or spinal cord injury, and muscle weakness due to muscle, tendon, or ligament disease including paralysis.

A variety of outpatient mechanical stretch devices intended for home use have been developed to restore functioning range of motion to a joint with stiffness and limited range of motion. These the devices are intended for used in addition to conventional physical therapy (PT) in a hospital setting or in the individual's home.

Mechanical stretching devices may be classified into one of the following three categories:

- **Low-load prolonged-duration stretch devices (LLPS):** These devices, also known as dynamic splinting systems, are spring/elastic-loaded devices designed to maintain a set level of tension, which provide resisted active and passive motion (spring/elastic traction) within a limited range while individuals are asleep or at rest. Units for both extension and flexion are available for ankle, knee, elbow, wrist, finger, or toe.
- **Static progressive stretch (SPS) devices**: SPS devices (also known as bi-directional SPS 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). SPS devices are used for multiple short treatment sessions per day with the joint angle progressively advanced at each session. SPS devices essentially allow the individual to duplicate physical therapy by therapists who apply a new positional stretch multiple times throughout the session.
- **Patient-actuated serial stretch (PASS) devices**: PASS devices are also known as patient-controlled serial stretch devices or high intensity stretch devices, are used in the home primarily to address excessive scar tissue around the joint. PASS devices provide a low- to high-level load to the joint using pneumatic or hydraulic systems that can be adjusted by the patient to permit resisted active and passive motion within a limited range. Different PASS devices are available for use depending on the joint being treated (ankle, elbow, finger, knee extension, knee flexion, pronation/supination, shoulder, toe, and wrist).

FDA Approval

Food and Drug Administration (FDA) classifies mechanical stretching devices as class I devices. Class I devices have the least amount of regulatory control; manufacturers of these devices are exempt from premarket notification procedures and are not required to provide safety and effectiveness data prior to marketing.

- **Low-load prolonged-duration stretch (LLPS) devices:** These products are considered by the FDA as Class I limb orthosis devices and are exempt from 510(k) requirements.

  Examples of LLPS devices (e.g., shoulder, elbow, pro/sup, wrist, thumb, knee, ankle, and toe) include:
  1. Disappoint® System (Dynasplint Systems Inc.)
  2. JAS® Dynamic (Kinex Medical Co.)
  3. Ultraflex (Ultraflex Systems Inc.)
  4. Pro-Glide™ devices (DeRoyal Industries)
  5. SaeboFlex (Saebo)
  6. SaeboReach
  7. Stat-A-Dyne and
  8. Advance Dynamic ROM, Saunders, and Pronex (Empi Inc., acquired by JAS).

- **Static progressive stretch (SPS) devices:** These devices are classified by the FDA as "Exerciser, NonMeasuring," and are exempt from 510(k) requirements as Class I devices.

  Examples of this type of devices (e.g., shoulder, elbow, pro/sup, wrist, thumb, knee, ankle, and toe) include:
  1. Joint Active Systems (JAS) splints and Air Cast® products:
     - JAS EZ (extension, flexion, pronation, supination)
     - JAS SPS ((extension, flexion, pronation, supination)
  2. Stat-A-Dyne®
  3. AliMed® Turnbuckle Orthosis,
  4. Static-Pro®.

- **Patient-actuated serial stretch (PASS) devices:** These devices are also classified by the FDA as "Exerciser, NonMeasuring" and are exempt from 510(k) requirements as Class I devices.

  Examples of PASS devices (e.g., shoulder, elbow, pro/sup, wrist, thumb, knee, ankle, and toe) include:
  1. ERMI (ERMI, Inc.) line of PASS devices:
     - ERMI Knee Extensionater®

- ERMI Elbow Extensionater®
- ERMI Knee/Ankle Flexionater®
- ERMI Shoulder Flexionater®

2. Elite Seat®

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement. (denial)

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met. (split)

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes

- **E1399 -** Durable medical equipment, miscellaneous
- **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
- **E1820 -** Replacement soft interface material, dynamic adjustable extension/flexion device
- **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
- **L4396 -** Static or dynamic ankle foot orthosis, including soft interface material, adjustable for fit, for positioning,

may be used for minimal ambulation, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise.

Original Effective Date: 8/21/2023

Re-Review Date(s):