KAISER PERMANENTE® Mid-Atlantic States	**Mechanical Stretching Devices** **Medical Coverage Policy**

UTILIZATION *ALERT*

- DME benefit coverage MUST be verified first from the member's Evidence of Coverage (EOC) or other appropriate benefit documents to determine benefit availability and the terms, conditions, and limitations of coverage prior to use of this MCP (Medical Coverage Policy) for evaluation of medical necessity and entering a referral.
- This MCP is applicable to Commercial lines of business in all jurisdictions.
- If after searching the Medicare Coverage Database, no NCD/LCD/LCA is found, please use this KP-MAS (Kaiser Permanente Mid Atlantic States) Medical Coverage Policy for coverage guidelines for Medicare members.
- For Maryland and Virginia Medicaid members, please refer to the appropriate government publications.

I. Procedure: **Mechanical Stretching Device**

II. Specialties: DME, Physical Medicine and Rehabilitation, Orthopedic

III. Scope

A. The policy addresses mechanical stretching devices, particularly Low-Load Prolonged-duration Stretch (LLPS) device, also referred to as dynamic stretching device. See section VII for description of LLPS and other types of mechanical stretching device.

B. The policy does not address Upper Limb Orthoses nor Lower Limb Orthoses

C. Related policies:
- ❖ Orthoses: Upper Extremity and Soft Goods Medical Coverage Policy
- ❖ Orthoses: Lower Extremity, Foot, and Soft Goods Medical Coverage Policy

IV. **Clinical Guidelines**

Low-load prolonged-duration stretch/spring-loaded device or **dynamic splinting device for** the knee, shoulder, elbow, wrist, fingers, or toes is considered medically necessary for **any** of the following indication:

A. Patient is unable to benefit from traditional physical therapy and occupational therapy due to inability to exercise or participate in a rehabilitation treatment program with documentation that the use of the device within a four-month period have resulted in improvement and continue to improve; **or**

B. In the acute post-operative period following a second or subsequent surgery or procedure to improve the range of motion of a previously affected joint(s), with prior documented history of

loss of motion or function /stiffness or spasticity in the joint(s) caused by immobilization; **or**

C. As adjunct to physical therapy and occupational therapy for patients who have documentation of significant stiffness/loss of motion in the joint(s) particularly upper extremity, shoulder. wrist, and finger during:
   1. Sub-acute phase after an injury; or
   2. Post-operative period (at least 3 weeks but less than four (4) months after injury or surgery)

V. Limitations / Exclusions

The use of **dynamic splinting device** is considered not medically necessary for the following:

A. Pediatric use

B. Documentation showing absence of clinical benefit or improvement after LLPS use for the **duration of 4 months** as evidenced by the following:
   1. There is no significant change in motion, in the management of chronic contractures and chronic joint stiffness due to joint trauma, fractures, burns, head and spinal cord injuries, rheumatoid arthritis, multiple sclerosis, muscular dystrophy or cerebral palsy; **or**
   2. Absence of significant improvement after four months of use such as increased range of motion, progression towards goal, advancing ability to perform activities of daily living (ADLs) or return to prior ability to perform ADLs; **or**
   3. Lack of improvement despite use for those who are unable to benefit from standard physical therapy modalities due to inability to exercise or participate in the treatment plan.

C. Dynamic splinting device is **experimental, investigational**, and considered not medically necessary for **any** of the following as its' effectiveness for these intended indications have not been established:
   1. For other indications or use of the device on other joints not listed in section IV.
   2. Prophylactic use in the management of the following
      a. Chronic contractures (no significant change in motion for a 4-month period); or
      b. Joint stiffness due to any of the following:
         i. joint trauma;
         ii. fractures;
         iii. burns;
         iv. head and spinal cord injuries;
         v. rheumatoid arthritis;
         vi. multiple sclerosis;
         vii. muscular dystrophy; or
         viii. cerebral palsy
   3. For treatment of joint injuries of the shoulder, neck, back, ankle and toe; or
   4. Use of LLPS beyond 4 months.
   5. For use on any other joint or other conditions/indications not listed in section IV, including but not limited to the following:

a. Chronic joint stiffness;
b. Chronic or fixed contractures;
c. Carpal tunnel syndrome;
d. Cerebral palsy;
e. Foot drop associated with neuromuscular diseases;
f. Hallux valgus;
g. Head and spinal cord injuries;
h. Improvement of outcomes following botulinum toxin injection for treatment of limb spasticity
i. Injuries of the ankle and shoulder;
j. Multiple sclerosis;
k. Muscular dystrophy;
l. Plantar fasciitis;
m. Rheumatoid arthritis;
n. Stroke; or
o. Trismus

6. The following devices are considered unproven and not medically necessary as current evidence does not establish its' effectiveness for treating joint contractures of the upper and lower extremities:
   a. Static progressive stretch (SPS) splint devices;
   b. Patient actuated serial stretch (PASS) devices;
   c. Other manual stretching devices
      i. Medi-Dyne Prostretch device;
      ii. The SaeboMas dynamic mobile arm support system, the Kinovo mechanical mobile arm support and similar devices.
      iii. EZ Turnbuckle orthosis (JAS orthosis) after open reduction internal fixation (ORIF) for radial head fracture
      iv. Joint active systems (JAS) splints (e.g., JAS Elbow, JAS Shoulder, JAS Knee, JAS Wrist, and JAS Pronation-Supination)

VI. Required Documentation

The following documentation are required when requesting a dynamic splinting device:

A. Current order or prescription from a qualified physician/practitioner

B. Documentation addressing **all** of the following:
   1. Member's medical condition and affected joint(s); and
   2. Length of time of contracture/joint stiffness; and
   3. Date of surgery or injury; and

4. Current or previous rehabilitation regimen; and
5. Treatment plan and duration of use; and
6. Radiology imaging if applicable

VII. Description

Mechanical stretching devices are non-motorized DME to prevent and treat joint contractures of the extremities, with the goal to maintain or restore range of motion to the joint(s). The use of the device is an adjunct treatment to physical therapy and /or occupational therapy, intended to replace some physical therapist-directed sessions through provision of frequent and consistent joint mobilization under controlled conditions at home or in a facility setting.

Mechanical stretching devices are classified by FDA as Class I medical device, thus having 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 before marketing.

Mechanical stretching devices include the following types:
1. Low-load prolonged-duration stretch (LLPS) devices (referred as Dynamic splinting devices)
2. Patient-actuated serial stretch (PASS) devices and
3. Static progressive stretch (SPS) devices.

Low-load prolonged-duration stretch/spring-loaded devices or **dynamic splinting systems** is a form of mechanical-stretching, spring-loaded DME device, designed to provide a low load, prolonged stretch (LLPS) to joints that have reduced range of motion due to immobilization, dislocation, contracture, fracture, surgery, or other non-traumatic disorders while the patient is asleep or at rest. It is indicated for the following indication:

- Treatment of joint stiffness due to immobilization or limited range of motion after fractures, dislocations, tendon and ligament repairs, joint arthroplasties, tendon releases, head trauma, spinal cord injuries, burns, arthritis, hemophilia, cerebral palsy (CP), multiple sclerosis, and other traumatic and non-traumatic disorders.
- For the prevention or treatment of motion stiffness/loss in the knee, elbow, wrist, or finger during post-operative period
- It is not used for other joints such as the hip, ankle, or foot.

Patient-Actuated Serial Stretch (PASS) device is a type of manual stretching device purported to allow active and passive motion within a limited range, supplying a low- to high-level load to the joint using pneumatic, hydraulic, or tensioning systems which can be adjusted by the individual.

Examples of PASS devices include, but may not be limited to, Elite Seat, ERMI Elbow Extensionater, ERMI Knee Extensionater, ERMI Knee/Ankle Flexionater and ERMI Shoulder Flexionater, JAS EZ Systems (ankle, elbow, finger, knee extension, knee flexion, pronation/supination, shoulder, toe, and wrist) and knee extension devices.

Static progressive stretch (SPS) device holds the joint in a set position but are purported to allow for manual modification of the joint angle without exerting stress on the tissue unless the angle is set to the joint's limitations. While these devices allow for movement (passive or active) within a limited range, the motion is free and does not provide elastic traction.

Examples of SPS devices include, but may not be limited to, Joint Active Systems (JAS) Splints (eg, JAS Ankle, JAS Elbow, JAS Knee, JAS Pronation-Supination, JAS Shoulder, JAS Wrist).

Jaw mobility mechanical stretching devices are suggested for use in the treatment of temporomandibular joint (TMJ) disorders, trismus or other conditions in which jaw movement is limited. Examples of this type of mechanical stretching device include, but may not be limited to, TheraBite Jaw Motion Rehabilitation System, Dynasplint Trismus System or Orastretch.

References

1. Medicare Claims Processing Manual, Ch. 20- Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) §50- Payment for Replacement of Equipment; §110- General Billing Requirements - for DME, Prosthetics, Orthotic Devices, and Supplies https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf
2. Medicare Benefit Policy Manual, Ch. 16- General Exclusions from Coverage, §180- Services Related to and required as a Result of Services Which Are Not Covered Under Medicare https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c16.pdf
3. Medicare Claims Processing Manual, Ch. 20- Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) §50- Payment for Replacement of Equipment; §110- General Billing Requirements - for DME, Prosthetics, Orthotic Devices, and Supplies https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf
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9. Anderson AF, Irrgang JJ, Kocher MS, Mann BJ, Harrast JJ; International Knee Documentation Committee. The International Knee Documentation Committee Subjective Knee Evaluation Form: normative data. Am J Sports Med. 2006 Jan;34(1):128-35. doi: 10.1177/0363546505280214. Epub 2005 Oct 11. PMID: 16219941.

Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC	Date of Implementation
12/21/2023	12/21/2023

*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any set of circumstances for an individual member.