Clinical Policy: Mechanical Stretching Devices for Joint Stiffness and Contracture

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Coding Implications
Revision Log

Description
Mechanical stretching devices are used for the prevention and treatment of joint contractures of the extremities, with the goal to maintain or restore range of motion (ROM) to the joint. A variety of mechanical stretching devices are available for extension or flexion of the shoulder, elbow, wrist, fingers, knee, ankle, and toes. These devices are generally used as adjunct treatment to physical therapy and/or exercise.

Policy/Criteria

I. It is the policy of PA Health & Wellness (PHW)® that the low-load prolonged-duration stretch (LLPS) device/dynamic stretch device is **medically necessary** for the knee, elbow, wrist, ankle, or finger when meeting both of the following:
   A. Requested for one of the following indications:
      1. In the subacute injury or post-operative period (≥ three weeks and ≤ four months after injury or operation) in members/enrollees with signs and symptoms of persistent joint stiffness or contracture and all of the following:
         a. Limited range of motion poses a meaningful functional limitation as judged by the physician;
         b. Has not responded to other therapy (including physical therapy);
         c. Provided with or without adjunctive physical therapy;
      2. In the acute post-operative period for members/enrollees who have undergone additional surgery to improve the range of motion of the previously affected joint;
   B. Request is for a rental for one of the following:
      1. An initial four weeks;
      2. A subsequent four week period, and improvement was noted upon reevaluation after the prior four week period.

II. It is the policy of PHW that the current research does not support the use of any of the following over other currently available alternatives**:**
   A. LLPS for any indication not noted in section I;
   B. Bi-directional static progressive stretch (SPS) devices;
   C. Patient-actuated serial stretch (PASS) devices.

Background
A joint contracture is characterized by chronically reduced range of motion (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. A number of different modalities are used to treat or prevent joint contractures.

Mechanical stretching devices have been researched for the treatment of joint contractures. The use of these devices is based on the theory that passive motion early in the healing process can

promote movement of the synovial fluid, and thus promote 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.

Several types of devices exist, including low-load prolonged duration stretch (LLPS) devices (also referred to as dynamic splinting), static progressive stretch (SPS) devices, and patient-actuated serial stretch (PASS) (also known as patient-directed serial stretch) devices.

- 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.
- 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). This type of device itself does not exert a stress on the tissue unless the joint angle is set at the maximum ROM.
- PASS devices permit resisted active and passive motion within a limited range utilizing pneumatic or hydraulic systems that can be adjusted by the patient. The extensionaters use pneumatic systems while the flexionaters use hydraulic systems. These devices require custom fitting.

Mechanical stretching devices are commonly used in the post-operative period, following an injury or when addressing joint stiffness in the knee, ankle, toe, shoulder, elbow, wrist, or finger. Peer reviewed studies researching mechanical stretching devices are limited. The best evidence is available in studies evaluating LLPS when used at the knee, elbow, wrist, and following extensor tendon injuries of the finger and for SPS when used at the elbow.

Several authors have looked at the implementation of dynamic splinting at the finger following an extensor tendon repair.[1,2,3,4,5,6,7] Results from a small, prospective, randomized trial comparing dynamic splinting to static splinting suggest that dynamic splinting of complex lacerations of the extensor tendons in zones V through VII provides improved functional outcomes at four and 12 weeks and six months when compared with static splinting.[1] Another small, prospective, randomized, controlled study comparing postoperative dynamic versus static splinting outcomes of patients following extensor tendon repair reported dynamic splinting of simple, complete lacerations of the extensor tendons in zones V and VI. Dynamic splinting provided improved functional outcomes at four, six, and eight weeks but not by six months when compared with static splinting.[2]

Dynamic splinting and static progressive stretch devices have both been applied at the elbow in isolation and in comparison to one another. In 2004 Gallucci and colleagues looked at a sample of 30 patients who were at least 78 days after surgery or trauma who had a functional arc of movement of less than 100 degrees at the elbow. They found that two thirds of patients were able to achieve at least a 100 degree arc and therefore, improved function after using a dynamic splint for 75 days.[8] In a 2009 randomized controlled pilot study of 30 patients, Lai and colleagues found significant improvements in ROM when dynamic splinting was added to the control treatment of botulinum toxin type-A and occupational therapy treatment.[9] Studies in 2010 by Bhat and colleagues found similar benefits to SPS at the elbow.[10] The SPS device was introduced to the patient approximately 4.5 to 5 months after injury or surgery and once improvements from therapy were stagnant. A functional ROM or arc of movement was achieved in 19 out of 30

patients.[10] In 2006, Doomberg and colleagues also demonstrated improvements with ROM overall after SPS intervention but noted that early splinting after the initial injury rather than after elbow encapselectomy yielded greater results.[11] In 2012, Lindenhovius and colleagues performed a prospective randomized controlled trial looking at the benefit of dynamic splinting versus SPS in improving range of motion and function as measured by the Disabilities of the Arm, Shoulder, and Hand (DASH).[12] No significant difference was found between the two groups prior to treatment or after three, six or 12 month follow-ups.[12] Additionally in 2015, Veltman and colleagues completed a systematic review on the topic that included the results from 232 patients with a similar outcome showing that each device was beneficial but that one was not more effective than the other.[13]

At the knee and wrist, dynamic splinting has been identified as beneficial when further progression of ROM is needed after surgery or an injury. In 2018, Pace and colleagues performed a Level IV retrospective study, looking at the implementation of dynamic splinting following knee surgery in 74 adolescents and children who had ROM deficits in flexion, extension, or both directions.[14] 84% of the patients experienced a significant increase in ROM, and 58% were able to avoid further surgical intervention. In 2016, Willis and colleagues looked at the treatment of carpal tunnel syndrome using dynamic splinting at the wrist.[15] They performed a randomized control trial where the experimental group was provided with dynamic splinting in addition to anti-inflammatories and a stretching program. Those patients who received dynamic splinting in addition to the other treatments had a significant decline in the need for surgical intervention after conservative management was complete. Similarly, Glasgow and colleagues in 2011 looked at the effect of dynamic splinting at the hand and forearm respectively and demonstrated improvements in ROM after injury in both areas.[16]

A variety of randomized control trials, observational studies, case series, and medical community acceptance confirms the benefits of dynamic LLPS devices at the knee, elbow, wrist, and fingers when used to relieve persistent joint stiffness that can occur after injury or surgery.

While additional evidence is emerging, there is insufficient evidence in the published peer-reviewed literature to support the use of dynamic LLPS at other joints to including the foot and shoulder. There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes on the use of patient-actuated serial stretch (PASS) devices.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS codes that support coverage criteria

HCPCS Codes	Description
E1800	Dynamic adjustable elbow extension/flexion device, includes soft interface material
E1802	Dynamic adjustable forearm pronation/supination device, includes soft interface
E1805	Dynamic adjustable wrist extension/flexion device, includes soft interface material
E1810	Dynamic adjustable knee extension/flexion device, includes soft interface material
E1812	Dynamic knee, extension/flexion device with active resistance control
E1815	Dynamic adjustable ankle extension/flexion device, includes soft interface material
E1825	Dynamic adjustable finger extension/flexion device, includes soft interface material

HCPCS codes that do not support coverage criteria -To be reviewed on case by case basis

HCPCS Codes	Description
E1399	Durable medical equipment, miscellaneous
E1801	Static progressive stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1806	Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
E1811	Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
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
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

Reviews, Revisions, and Approvals	Date	Approval Date
Policy developed	09/18	
Removed the following codes from being not medically necessary: E1800, E1801, E1802, E1805, E1810, E1812. Clarified in policy/criteria the joints for which devices are not medically necessary.	10/19	

Reviews, Revisions, and Approvals	Date	Approval Date
References reviewed and updated. Codes updated. Added code E1399 as not medically necessary	10/19	
Adapted criteria from WellCare's Dynamic Stretching Devices for Treatment of Joint Stiffness and Contracture HS164. For LPSS, added knee, elbow, and wrist injuries as medically necessary indications. Specified that criteria I.A-I.D be met for LPSS. Removed indication of members unable to benefit from standard physical therapy modalities because of inability to exercise, from original HS164 criteria. Changed the not medically necessary statements regarding LPSS for other indications, PASS and SPS devices to experimental/investigational. Added the following HCPCS codes as supporting coverage criteria: E1800, E1802, E1805, E1810, E1812. Removed HCPCS table of codes not supporting medical necessity. Replaced existing ICD-10 codes with the following: M24.521 - M24.529, M24.531 - M24.539, M24.541 - M24.549, M24.561 - M24.569, M25.621 - M25.629, M25.631 - M25.639, M25.641 - M25.649, M25.661 - M25.669.	6/2020	7/21/2020
Added a table of HCPCS codes not supporting medical necessity, including the following codes: E1399, E1801, E1806, E1811, E1815, E1816, E1818, E1830, E1831, E1840, E1841. **To be reviewed on case by case basis.**		
Annual review. Combined sections II-IV into II and replaced "Experimental/investigational" verbiage with descriptive language. Minor updates to background with no impact on criteria. Replaced all instances of "member" with "member/enrollee." Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." Background updated with no impact on criteria. Removed ICD-10 codes. References reviewed and updated. Reviewed by specialist.	12/8/2022	
Annual review. Added ankle to Criteria I. Rearranged Criteria I.A. for clarification and added Criteria I.A.1.c. stating that low-load prolonged-duration stretch (LLPS) device/dynamic stretch device is provided with or without adjunctive physical therapy. Minor rewording in Background section with no impact on policy criteria. Removed code E1815 from HCPCS codes that do not support coverage and added to HCPCS codes that do support coverage. References reviewed and updated. Reviewed by internal specialist.	11/2023	02/2024
Annual review. Background updated with no impact on criteria. References reviewed and updated. Reviewed by internal specialist.	11/2024	

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