

Clinical Policy: Mechanical Stretching Devices for Joint Stiffness and Contracture

Reference Number: CP.MP.144

Date of Last Revision: 12/21

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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 health plans affiliated with Centene Corporation® that the low-load prolonged-duration stretch (LLPS) device/dynamic stretch device is **medically necessary** for the knee, elbow, wrist or finger when meeting both of the following:
 - A. Meets one of the following indications:
 1. In addition to physical therapy in the subacute injury or post-operative period (≥ 3 weeks and ≤ 4 months after injury or operation) in members/enrollees with signs and symptoms of persistent joint stiffness or contracture;
 2. In the subacute injury or post-operative period (≥ 3 weeks and ≤ 4 months after injury or operation) and both 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);
 3. 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 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 health plans affiliated with Centene Corporation 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.

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Background

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. A number of different modalities are used to treat or prevent joint contractures.

Mechanical stretching devices have been investigated 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 devices (LLPS) (also referred to as dynamic splinting), static progressive stretch devices (SPS), 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 extensioners use pneumatic systems while the flexioners 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 investigating 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. 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-VII provides improved functional outcomes at 4 and 12 weeks and 6 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 4, 6, and 8 weeks but not by 6 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. Gallucci and colleagues (2004) 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 2/3 of patients were able to

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achieve at least a 100 degree arc and therefore, improved function after using a dynamic splint for 75 days.³ In a randomized controlled pilot study of 30 patients, Lai and colleagues (2009) found significant improvements in ROM when dynamic splinting was added to the control treatment of botulinum toxin type-A and occupational therapy treatment.⁴ Bhat and colleagues (2010) and Gelinas and colleagues (2000) found similar benefit to SPS at the elbow.^{5,6} In both cases, SPS 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 and 11 out of 22 patients respectively.^{5,6} Doomberg and colleagues (2006) also demonstrated improvements with ROM overall after SPS intervention but noted that early splinting after the initial injury rather than after elbow encapsectomy yielded greater results.⁷ Lindenhovius and colleagues (2012) 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).⁸ No significant difference was found between the two groups prior to treatment or after 3, 6 or 12 month follow-ups. Veltman and colleagues (2015) 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.⁹

At the knee and wrist, dynamic splinting has been identified as beneficial when further progression of range of motion is needed after surgery or an injury. Pace and colleagues (2018) 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.¹⁰ 84% of the patients experienced a significant increase in ROM and 58% were able to avoid further surgical intervention. Willis and colleagues (2016) looked at the treatment of carpal tunnel syndrome using dynamic splinting at the wrist.¹¹ 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 (2011) and Shah and colleagues (2002) looked at the effect of dynamic splinting at the hand and forearm respectively and demonstrated improvements in range of motion after injury in both areas.^{12,13}

Although limited, high-level evidence still exists to address the efficacy of LLPS a current review of the literature supports the medical necessity of the current clinical policy. 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 include the foot, ankle, 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

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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
E1825	Dynamic adjustable finger extension/flexion device, includes soft interface material

HCPCS codes that do not support coverage criteria

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
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
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

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HCPCS Codes	Description
E1841	Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD 10 CM Code	Description
M24.521 - M24.529	Contracture, elbow
M24.531 - M24.539	Contracture, wrist
M24.541 - M24.549	Contracture, hand
M24.561 - M24.569	Contracture, knee
M25.621 - M25.629	Stiffness of elbow, not elsewhere classified
M25.631 - M25.639	Stiffness of wrist, not elsewhere classified
M25.641 - M25.649	Stiffness of hand, not elsewhere classified
M25.661 - M25.669	Stiffness of knee, not elsewhere classified

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed	04/17	04/17
References reviewed and updated. Codes updated.	03/18	03/18
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.	03/19	04/19
Added code E1399 as not medically necessary	06/19	
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.B be met for LPSS. Removed indication of members/enrollees 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.	4/20	04/20
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.	06/20	

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Reviews, Revisions, and Approvals	Revision Date	Approval Date
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.” References reviewed and updated. Codes reviewed.	03/21	04/21
Annual review. Changed “review date” in the header to “date of last revision” and “date” in the revision log header to “revision date.” References reviewed, updated and reformatted. Reviewed by specialist.	12/21	12/21

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Important Reminder

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This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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