Medical Policy

Blue Care Network of Michigan

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BCN Policy Effective Date: 8/15/12
(See policy history boxes for previous effective dates)

Title: Stretch Devices for the Treatment of Joint Stiffness or Contracture

Description / Background

Joint contractures are caused by changes in tendon, muscle, ligament and skin tissues and can result in a reduced range of motion (ROM) of the affected joint. The elastic connective tissue is slowly replaced with fibrous material, which makes the tissue resistant to stretching. Joint contractures are usually caused by a lengthy immobilization of a joint following surgery or trauma to the joint. Joint contractures can also be caused by spasticity secondary to nerve damage, such as stroke or spinal cord injury. They can also result from muscle weakness due to muscle, ligament and/or tendon disease and neurological conditions such as paralysis.

Dynamic splinting systems are devices that create a spring-tension, low-load, prolonged stretch (LLPS) designed to improve range of motion (ROM) and reduce joint contractures while patients are asleep or at rest. Dynamic splinting systems include, but are not limited to, such products as Dynasplint®, Ultraflex®, LMB Pro-glide®, EMPI Advance® and SaeboFlex®.

It has been theorized that mechanical stretching devices can provide passive motion after joint surgery in order to assist in the movement of synovial fluid to better lubricate the affected joint, prevent adhesions, eliminate joint stiffness, reduce swelling and help heal articular surfaces of the joint. These stretching devices are supposed to provide these benefits without disrupting the healing of the surgical site. The devices were developed to replace some of the physical therapy needed after surgery by providing frequent and constant mobilization of the joint following a prescribed regimen in order to restore the patient's range of motion.

There are three categories of mechanical stretching devices:

- Static progressive (SP) devices: These 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 range of motion. An example for this type of device is the Joint Active Systems (JAS) (TheraTech Equipment Inc.).
- Low-load prolonged duration stretch (LLPS): LLPS devices permit resisted active and passive motion (elastic traction) within a limited range. They maintain a prescribed level of tension by means of incorporated springs. Examples of LLPS devices include Dynasplint System® (Dynasplint Systems Inc.); Ultraflex (Ultraflex Systems Inc.); LMB Pro-Glide devices (DeRoyal Industries); Advance Dynamic ROM®, Saunders®, Pronex® (Empi)
- Patient-actuated serial stretch (PASS) devices: They permit resisted active and passive motion (elastic traction) within a limited range. PASS devices provide a low- to high-level load to the joint using pneumatic, e.g., Extensionaters (ERMI Inc.), or hydraulic, e.g., Flexionaters (ERMI Inc.), systems that can be adjusted by the patient. Examples of PASS devices include ERMI Knee Extensionater®, ERMI Elbow Extensionater®, ERMI Knee/Ankle Flexionater® and ERMI Shoulder Flexionater®.

Medical Policy Statement

The safety and effectiveness of specified stretch splinting systems have been established. They may be considered useful therapeutic options for selected patients.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Inclusions:
Stretch splinting systems are considered established when used with in patients with documented signs and symptoms of significant joint stiffness or loss of motion in the sub-acute injury or post-operative period following major open surgery or trauma to the finger, wrist, elbow or knee joints only.

They should be used in combination with an active treatment plan that includes physical or occupational therapy in members with documented signs and symptoms of significant motion stiffness or loss in the sub-acute injury or post-operative period. Use of these systems should begin at least three weeks after injury or surgery when one of the following criteria is met:
- In the acute post-operative period for patients who have a prior documented history of motion stiffness or loss of joint motion and who will be having additional surgery or procedures done to improve the motion in that joint.
- As a treatment for loss of motion from a contracture when a formal rehabilitative program is not feasible or has failed to provide benefit

Exclusions:
- Use of LLPS devices/dynamic stretch devices or SP stretch devices for any other joint or condition including but not limited to foot, toe, shoulder and ankle disorders, cerebral palsy,

rheumatoid arthritis or plantar fasciitis because they are considered experimental and investigational.

- Use of patient-actuated serial stretch (PASS) devices (e.g., ERMI Knee, MPJ, or Elbow Extensionator ®, ERMI Knee/Ankle or Shoulder Flexionator®) for *any* indication because they are considered experimental and investigational.
- Prophylactic use of dynamic splinting systems the management of chronic contractures (chronic means that there has been no significant change in motion in a four-month period).
- The use of a carpal tunnel stretch system (e.g., Dynasplint or CTRAC Carpal Tunnel Treatment System) is considered experimental and investigational in the management of carpal tunnel syndrome.
- Joint Active Stretch devices (JAS Splints)
- Pronators/Supinators
- CAMO® Ped device (for knee rehabilitation)
- The use of dynamic splinting systems, for all other conditions not listed in the inclusions section.
- Use of any stretch device for more than four months.

CPT / HCPCS Level II Codes (*Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

E1815	E1816	E1818	E1820	E1821	E1825
E1830	E1831	E1840	E1841		

Other codes (investigational, not medically necessary, not a benefit, etc.):

E1399*

**When used to describe the Dynasplint carpal tunnel splint*

Rationale

Static Progressive (SP) Stretch Devices

In 2008, Bonutti et al. evaluated the use of SP stretch using the JAS Knee device in a series of 41 consecutive patients with refractory knee stiffness (e.g., a total range of motion of less than 90 degrees or a flexion contracture that impaired the patient's activities of daily living and quality of life). All of the patients had a history of physical therapy ranging from six to 26 weeks. The therapy programs included the following components: stretching, range of motion therapy, strengthening exercises, gait training and ultrasound. After the patients were instructed on how to use the devices, the appropriate stretch was maintained for five minutes, after which time the device was adjusted to maintain a gentle stretch. This process was repeated every five minutes for 30 minutes. If both flexion and extension exercises were required, 30 minutes were allocated for each movement for a total of one hour per session. Patients underwent one treatment session per day for the first five days, and increased up to three sessions per day if

tolerated. After nine weeks of this therapy, the range of motion was increased in all patients. However, these results were not compared to the use of traditional physical therapy.

In 2006, Doornberg et al. conducted a retrospective review of 37 patients for the purpose of evaluating SP elbow splinting using a JAS splint in patients who had developed chronic elbow stiffness following a trauma who were no longer achieving gains in motion with a standard physical therapy program. Three patients were treated following the injury, 14 were treated following operative treatment of the injury and 12 were treated after a secondary operative release. Splinting was started on an average of 55 days after injury or operative treatment (range 15–200 days). Patients used the splints for an average of four months. The splinting protocol was customized for each patient. In general, the treatment consisted of 30 minutes of splinting in each direction (flexion and extension), three times per day. The authors reported statistically significant improvement in flexion, flexion contracture and arc of motion at an average follow-up of 11 months. Further follow-up is needed to determine if the increase flexibility remained after therapy was stopped.

Bruner et al. (2003) conducted a retrospective review to evaluate the efficacy of SP splinting as an adjunct to active mobilization following extensor tendon repair in Verdan's zones V to VII (n= 85 patients, 87 extensor tendon injuries). Splinting therapy commenced on the second post-operative day to hold the wrist in 30-degree extension and the metacarpophalangeal (MCP) joints in 10-degree hyperextension. Range of motion was increased to 90 degrees over the course of five weeks. Active extension of the distal interphalangeal and proximal interphalangeal joints began in the fourth week, and the splint was removed at five weeks. Results were assessed at a mean follow-up of 21 months Results were considered excellent or good in 94 percent of the patients, and fair in the remainder of patients. There was no control group.

In a prospective, nonrandomized study, Hewitt and Shakespeare (2001) compared the effectiveness of two postoperative rehabilitation programs following unilateral total knee arthroplasty (TKA). A total of 160 knees were allocated to different regimens following the surgery. All of the patients were operated on by the same physician. Patients were assigned to either the use of SP flexion (Group 1, n=86) or to a regimen of static extension splinting combined with physical therapist-guided flexion exercises (Group 2, n=74).

- In Group 1, the operative knee was placed in a 90-degree splint that remained in place overnight. On the first postoperative day, the knee was placed on the 90° splint for ten minutes every two hours, followed by ten minutes of passive extension combined with leg exercises.
- In Group 2, the operative knee was placed in an immobilizer splint that remained in place overnight. On the first postoperative day, patients participated in three physical therapy treatments in which the knee was flexed as far as possible, and leg exercises were encouraged.

At six weeks, the patients in group I had more flexion and better range of motion than the patients in Group II. The authors stated, "We believe a static flexion regime is as good as reported results with CPM, better than an extension regime and does not result in an increase in wound problems." However, they note that there is little evidence in medical literature that the patients in group I maintained this superior function at one year and beyond.

Low-Load Prolonged-Duration Stretch (LLPS) Devices/Dynamic Splinting Systems
Berlet et al. (2002) conducted a prospective study of 13 patients with plantar fasciitis to evaluate the effectiveness of the Ankle Dorsiflexion Dynasplint. All patients had plantar fasciitis recalcitrant to first-line treatment of anti-inflammatory medication, Achilles stretching program, and a viscoelastic heel orthoses. The patients used the splint for an average of 95 percent of weekly sleeping hours. The difference in pre- and post-treatment pain scores did not reach levels of significance (p=0.12). At one month, 75 percent of patients reported improvement in symptoms. At six months, all patients who had achieved improvement continued to be satisfied with the night splint. The authors stated that a randomized study with a comparison between different dorsiflexion splint designs is warranted to determine if patient compliance and clinical results are related to specific design modifications.

Chester et al. (2002) conducted a prospective, randomized controlled trial to compare the post-surgical impact of two rehabilitation regimens in 54 patients with finger extensor tendon division in zones IV–VIII. The patients were placed into two different groups. Group I consisted of 19 patients with 29 injured digits. They received early active mobilization combined with static splinting. Group II consisted of 17 patients (29 injured digits) and received LLPS therapy using the Dynasplint system. At four weeks, total active motion (TAM) was significantly improved for Group II compared to Group I. However, these differences were not maintained in the long term. Both groups exhibited the same level of improvement.

Khandwala et al. (2000) conducted a randomized controlled trial to evaluate postoperative rehabilitation techniques in patients with complete divisions of the extensor tendons in Verdan's zones five and six. Patients were randomly assigned to two different rehabilitation program using LLPS and active mobilization (Group 1, n=50) or to palmar block SP splinting and active mobilization (Group II, n=50). Outcomes were assessed using two evaluation tools. At eight weeks, there was no significant difference in outcomes between the two groups.

SP stretch devices and LLPS devices/dynamic splinting are frequently employed and have gained acceptance as a part of the rehabilitation of fingers, wrists, elbows and knees in the postoperative period, although there is a lack of evidence from well designed clinical trials on their use. However, the use of these devices may shorten the need for prolonged joint rehabilitation in selected patients.

There is insufficient evidence in the published medical literature, however, to support the use of SP of LLPS devices/dynamic splinting for the rehabilitation of other joints (i.e., toes, ankles, shoulders). In addition, there is insufficient evidence to support the use of these devices for the treatment of neurological conditions (e.g., cerebral palsy, multiple sclerosis) or chronic conditions such as rheumatoid arthritis and plantar fasciitis.

Patient-Actuated Serial Stretch (PASS) Devices
This category includes the following devices:
- ERMI Knee Extensionator®,
- ERMI Knee/Ankle Flexionator®
- ERMI Shoulder Flexionator®
- ERMI MPJ Extensionator®

- ERMI Elbow Extensionator®

Branch et al. (2003) conducted an uncontrolled, prospective study to determine the effectiveness of a PASS rehab regimen using an ERMI Knee/Ankle Flexionator® in 34 patients who had failed a six-week regimen of conventional physical therapy. These patients had developed knee contractures following anterior cruciate ligament injury (n=14), peripatellar injury (n=7), fracture (n=4) and unspecified causes (n=9). PASS was administered four to eight times each day for 15 minutes. The treatment period ranged from two to twelve weeks. The authors reported that 74 percent of the patients regained full range of motion and 91.2 percent regained functional knee range of motion.

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of the use of patient-actuated serial stretch (PASS) for the treatment of joint stiffness or contractures. There is no evidence that these devices are comparable to established treatment methods.

Crawford et al. (2003) conducted a Cochrane meta-analysis of the literature to determine the effectiveness of conservative treatment on plantar heel pain. As a result of this review, the researchers determined that there is limited evidence upon which to base clinical practice of prescribing dorsiflexion night splints or any other adjunctive modality of pain relief. There were no significant decreases in pain demonstrated with the use of these splints.

In 2001, Germann et al. conducted a prospective study on 20 patients to determine the efficacy of using dynamic motion protocols in the early post-operative phase following thumb surgery versus immobilization. Ten patients were randomized in each group with group one having their thumb immobilized in an extensor spica cast for three weeks after surgery and group two began using dynamic motion immediately post-operative. After three weeks, the range of motion in the dynamic group was almost twice as good as that of the immobilized group (59 degrees versus 31 degrees). Grip strength and pinch grip were also found to be better in the dynamic group versus the immobilized group. At six weeks there was no significant difference noted between the two groups. The researchers showed that the use of early dynamic motion allowed patients to recover their hand function quicker than when the hand is immobilized after surgery.

Although evidence from well-designed clinical trials on the use of mechanical stretch devices is lacking, SP stretch devices and LLPS devices/dynamic splinting are frequently employed and have gained acceptance as components of the rehabilitation of fingers, wrists, elbows and knees in the postoperative period. Although an active mobilization program combined with LLPS or SP stretch devices may not improve joint mobility beyond what would be achieved with a standard physical therapy program, the use of these devices may positively influence and possibly shorten the need for prolonged joint rehabilitation in selected patients.

There is insufficient evidence in the published medical literature, however, to support the use of or SP stretch devices or LLPS devices/dynamic splinting for the rehabilitation of other joints (i.e., toes, ankles, shoulders); or for the treatment of chronic conditions (e.g., rheumatoid arthritis, plantar fasciitis) or the treatment of neurological conditions (e.g., cerebral palsy,

multiple sclerosis). There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of the use of patient-actuated serial stretch (PASS) for the treatment of joint stiffness or contractures. There is no evidence that these devices are comparable to established treatment methods.

There are no published professional society positions that specifically address the use of SP stretch devices, LLPS devices or PASS devices.

Government Regulations

National / Local:

There are no local or national coverage determinations on the use of these devices. All of the codes are payable by Medicare.

Michigan Department of Community Health:

All codes are payable by Medicaid.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Continuous Passive Motion Machines (CPM)-Joint policy
- Durable Medical Equipment (Joint policy)

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 7/12/12, the date the research was completed.

BCN Medical Policy History

Date	Rationale
5/18/11	BCN policy established
8/15/12	Routine maintenance; references updated. No change in policy statement

Next Review: 3rd Qtr, 2012

MEDICAL POLICY TITLE: STRETCH DEVICES FOR THE TREATMENT OF JOINT STIFFNESS OR CONTRACTURE
BCN BENEFIT ADMINISTRATION

I. Coverage Determination

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply.
BCNA (Medicare Advantage)	All codes are covered; no review required
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.
Blue Cross Complete of Michigan	All codes are covered; no review required

II. Administrative Guidelines

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate benefits and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.