
Medical Policy



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(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:

- 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). Another type of LLPS that has been developed to correct trismus is the Dynasplint Trismus System (DTS) for patients who were recently diagnosed with trismus following radiation therapy, dental treatment, oral surgery, or following a neural pathology such as a stroke.

- Bi-directional Static progressive (SP) devices (Flexionators and Extensionators): 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. Examples include but are not limited to Joint Active Systems (JAS) splints (e.g., JAS Elbow, JAS Shoulder, JAS Ankle, JAS Knee, JAS Wrist, and JAS Pronation-Supination) and Air Cast®. In addition to these devices, there are also devices to help reduce trismus of the temporomandibular joint (TMJ) due TMJ dysfunction, including, but not limited to, the Therabite® System, a threaded screw-type instrument that is placed between the teeth and turned to gradually open the jaw (much like a car jack).
- Patient-actuated serial stretch (PASS) devices: Patient-actuated stretching devices are mechanical devices that are used at home to increase range of motion (ROM) in patients who experience impairments in functional status due to decreased ROM. 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., Extensionators (ERMI Inc.), or hydraulic, e.g., Flexionators (ERMI Inc.), systems that can be adjusted by the patient. Examples of PASS devices include ERMI Knee Extensionator®, ERMI Elbow Extensionator®, ERMI Knee/Ankle Flexionator® and ERMI Shoulder Flexionator®. Another extensionator device is the Elite Seat®, manufactured by AKT Medical, LLC.

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:

Low-load prolonged duration stretch (LLPS)/Dynamic Splinting Devices: These are mechanical stretching devices, also known as low-load prolonged-duration stretch (**LLPS**) device/dynamic stretch devices (e.g., Advance Dynamic ROM, Dynasplint, EMPI Advance, LMB Pro-glide, Pro-glide Dynamic ROM, SaeboFlex, SaeboReach, and Ultraflex). They are considered established for the treatment of stiffness and/or contractures of the **knee, elbow, wrist or finger** for a period of time up to four months under ANY of the following circumstances:

- As part of a structured rehabilitative program for persistent joint stiffness in a subacute injury or following surgery of the above joints; or
- In the acute postoperative period following surgery to improve the range of motion of a previously affected joint; or

- As a treatment for loss of motion from a contracture when a formal rehabilitative program is not feasible or has failed to provide benefit

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.

Exclusions:

- Low-Load Prolonged Duration Stretch Systems (LLPS) (e.g., Dynasplint systems)
 - The use of LLPS devices/dynamic stretch devices or SP stretch devices for the following conditions (Note: List may not be all-inclusive)
 - * Carpal tunnel (e.g., Dynasplint or CTRAC Carpal Tunnel Treatment System)
 - * Cerebral palsy
 - * Contractures or stiffness of any joint other than the **knee, elbow, wrist or finger.**
 - * Foot drop associated with neuromuscular diseases
 - * Head and spinal cord injuries
 - * Joint trauma (e.g. ankle, shoulder)
 - * Multiple sclerosis
 - * Muscular dystrophy
 - * Plantar fasciitis
 - * Rheumatoid arthritis
 - * Stroke
 - * Trismus (spasm of the jaw muscles, causing the mouth to remain tightly closed)
 - * Temporomandibular joint (TMJ) disorder
 - The 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).
- Bi-directional Static Progressive (SP) Devices (Flexionators and Extensionators)
 - Use of bi-directional static progressive (SP) devices for any indication, including treatment of TMJ disorder (e.g., Therabite® system).
 - Joint Active Systems (JAS) Splints, including but not limited to JAS Elbow, JAS Shoulder, JAS Ankle, JAS Knee, JAS Wrist, and JAS Pronation-Supination
- Patient-Actuated Serial Stretch (PASS) Devices (Flexionators and Extensionators)

Use of patient-actuated serial stretch (PASS) devices for any indication. These devices include, but are not limited to, the ERMI Knee, MPJ, or Elbow Extensionator®, the ERMI Knee/Ankle or Shoulder Flexionator®, the AKT Medical Elite Seat®, etc.)
- CAMO® Ped device (for knee rehabilitation)
- The SaeboMas dynamic mobile arm support system is considered experimental and investigational because of insufficient published evidence of its clinical value.
- 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:

E1800	E1805	E1810	E1812	E1820
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Other codes (investigational, not medically necessary, not a benefit, etc.):

E1399*	E1700	E1701	E1702	E1801	E1802
E1806	E1811	E1815	E1816	E1818	E1825
E1830	E1840	E1841			

**When used to describe the Dynasplint carpal tunnel splint, Elite seat, etc.*

Rationale

Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition.

Low-Load Prolonged-Duration Stretch (LLPS) Devices/Dynamic Splinting Systems

The SaeboFlex has been promoted for use in rehabilitation in persons with hemiplegia following cerebrovascular accident. However, there is no peer-reviewed published medical literature of the effectiveness of the device for this indication.

In a pilot study, Postans et al investigated the feasibility of applying the combination of dynamic splinting and neuromuscular electrical stimulation (NMES) in order to improve wrist and elbow function, and ROM, in children with upper limb contractures due to CP. Six children aged 7 to 16, with contractures at the wrist or elbow, were recruited. Following a 12-week baseline period all subjects underwent a 12-week treatment period where dynamic splinting was used for 1 hour per day and combined with NMES for the second half of the 1-hr treatment. A 12-week follow-up period then ensued. Upper limb function was assessed with the Melbourne assessment, physical disability with the Pediatric Evaluation of Disability Index and the Activity Scale for Kids, and quality of life with the Pediatric Quality of Life Scale. Passive and active ROM at the wrist and elbow were measured using manual and electrical goniometers. The technique of using combined NMES and dynamic splinting was demonstrated to be feasible and compliance with the intervention was good. There was an increase in passive elbow extension in 2 subjects treated for elbow contractures, although no accompanying change in upper limb function was

reported. Wrist ROM improved in one subject treated for wrist contracture.²⁷ Additional studies are required in order to validate the findings of this pilot study.

In 2011, John and Willis stated that hallux limitus (HL) is a pathology of degenerative arthritis in the first metatarsophalangeal joint (MTJ) of the great toe. Chief complaints of HL include inflammation, edema, pain, and reduced flexibility. The onset of HL commonly occurs after one of the two most common surgical procedures for foot pathologies, a bunionectomy or a cheilectomy. These investigators determined the effectiveness of dynamic splinting in treating patients with post-operative hallux limitus, in a randomized, controlled trial. Fifty patients (aged 29 to 69 years) were enrolled after diagnosis of HL following surgery. The duration of this study was 8 weeks, and all patients received non-steroidal anti-inflammatory drugs, orthotics, and instructions for a home exercise program. Experimental patients were also treated with dynamic splinting for first MTJ extension (60 mins, 3 times per day). The dependent variable was change in active ROM (AROM). A repeated measures analysis of variance was used with independent variables of patient categories, surgical procedure (cheilectomy versus bunionectomy) and duration since surgery. There was a significant difference in change of AROM for experimental versus control patients; there was also a significant difference for patient treated within 2 months of surgery. The authors concluded that the use of dynamic splinting in this pilot study caused no adverse events, and a future randomized, controlled trial would determine if this new modality is effective in separate populations of patients with hallux abducto valgus and hallux varus.¹⁹

Berlet et al 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.¹

Chester et al 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.⁶

Khandwala et al 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.²²

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 or 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.

Shulman et al retrospectively evaluated the effect of the Dynasplint Trismus System (DTS; Dynasplint Systems Inc., Severna Park, MD) for patients who were recently diagnosed with trismus following radiation therapy, dental treatment, oral surgery, or following a neural pathology such as a stroke. These researchers reviewed 48 patient histories (treated in 2006 to 2007), and divided into 4 cohort groups (radiation therapy for head/neck cancer, dental treatment, oral surgery, or stroke), to measure the efficacy of this treatment's modality. Patients were prescribed the DTS after diagnosis of trismus based on examination that showed less than 40 mm maximal interincisal (opening) distance (MID). The DTS uses low-load, prolonged-duration stretch with replicable, dynamic tension to achieve longer time at end range (of motion). Each patient used this device for 20 to 30 minutes, 3 times per day. This cohort case series showed that there was a statistically significant difference within all patient groups ($p < 0.0001$; $t = 10.3289$), but there was not a significant difference between groups ($p = 0.374$). The biomechanical modality of DTS with a low-load, prolonged-duration stretch was attributed to the success in reducing contracture in this study. This improved range of motion, allowing patients to regain the eating, hygiene and speaking patterns they had before developing trismus. The main drawbacks of this study were the lack of a control group and small sample size. The authors stated, "Future studies should include a randomized, controlled, crossover study of this unit to compare the efficacy of treating trismus, and a case/control study could evaluate prevention of trismus with the DTS".²⁹

In a case report, Shulman et al (2009) described the use of dynamic splinting to reduce trismus that occurred in a patient following multiple dental procedures. A 26-year old man was referred for severe trismus and pain following 3 dental procedures on the lower right molars. The patient presented with MID of only 5-mm and mastication muscle spasticity. Following physical therapy (i.e., massage, moist heat, neuromuscular electrical stimulation, and ultrasound) 3 times per week for 2 months and additional treatment of dynamic splinting for 4 weeks (TID), the patient increased his MID to 52 mm and returned to normal eating and speaking. The main drawbacks of this study were that it was a single-case report, and there was a lack of follow-up.³⁰

In a retrospective, cohort study, Stubblefield et al examined the effectiveness of a dynamic jaw opening device as part of a multi-modal treatment strategy for trismus in patients with head and neck cancer (n = 20). All patients underwent assessment by a board-certified physiatrist and

were referred to physical therapy for delivery of the DTS and instructed to progress use of the DTS to 30 minutes 3 times a day. Additional modalities for the treatment of trismus including pain medications and botulinum toxin injections were prescribed as clinically indicated. Main outcome measures included change in MID as documented in the medical record. The use of the DTS as part of multi-modal therapy including physical therapy, pain medications, and botulinum toxin injections as deemed clinically appropriate resulted in an overall improvement of the MID from 16.5 mm to 23.5 mm ($p < 0.001$). Patients who could comply with the treatment recommendations for DTS treatment did better than those who could not, with an improvement of the MID from 16 mm to 27 mm ($p < 0.001$) versus 17 mm to 22 mm ($p = 0.88$). The authors concluded that the DTS is a safe and effective component of a multi-modal strategy for improving trismus associated with head and neck cancer and its treatment. They also stated that further investigation is needed to determine the relative effectiveness of the treatment modalities available for trismus including physical therapy and other jaw stretching devices. This was a retrospective pilot study with a small sample size ($n = 20$); and its finding were confounded by the use of other modalities.³²

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.³

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.¹⁰

Veltman and colleagues performed a search of all studies on nonoperative treatment for elbow stiffness in adults. Eight studies (including 232 patients) met eligibility criteria and were included

for data analysis and pooling. These studies included one randomized controlled trial and seven retrospective cohort studies. Static progressive splinting was evaluated in 160 patients. The average pre-splinting range of motion of all elbows was 72°, which improved by 36° after splinting to an average post-splinting arc of motion of 108°. Dynamic splinting was evaluated in 72 patients with an average pre-splinting range of motion of 63°. The average improvement was 37° to an average post-splinting arc of motion of 100°. The authors concluded that both dynamic orthoses and static progressive splinting show good results for the treatment of elbow stiffness, regardless of etiology. The choice for one treatment over the other is based on the preference of the surgeon and patient.³⁴

Bruner et al 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.³⁸

In a prospective, nonrandomized study, Hewitt and Shakespeare 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.¹⁸

For mandibular hypomobility, preliminary evidence indicates that the Therabite® is more effective than other modalities in maintaining and/or improving mandibular ROM in irradiated patients. There are, however, inadequate outcomes data comparing the Therabite to more

conventional methods to support the use of Therabite for any other condition. Orabite is another brand of jaw stretch device that is no longer on the market.

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®
- AKT Medical's Elite Seat®

The knee/ankle flexionator (ERMI Knee/Ankle Flexionator) is a self-contained device that facilitates recovery from decreased range of motion of the knee and/or ankle joints. The knee flexionator is designed to address the needs of patients with arthrofibrosis (excessive scar tissue within and around a joint). The knee/ankle flexionator is a variable load/variable position device that uses a hydraulic pump and quick-release mechanism to allow patients to perform dynamic stretching exercises in the home without assistance, alternately stretching and relaxing the scar tissue surrounding affected joints. The knee/ankle flexionator includes a frame to house hydraulic components, a pump handle and quick release valve for patient control, supporting footplate and specially incorporated padded chair. The frame attaches to a folding chair and is adjustable to accommodate treatment of either extremity, or both extremities simultaneously. The load potential ranges from a few ounces up to 500 foot-pounds. The knee/ankle flexionator was listed with the FDA in 2002, and is Class 1 exempt.

The knee extensionator (ERMI Knee Extensionator) and elbow extensionator (ERMI Shoulder Extensionator) provide serial stretching, using a patient-controlled pneumatic device that can deliver variable loads to the affected joint. The manufacturer claims that the knee and shoulder extensionators are the only devices on the market that can “consistently stretch scar tissue, without causing vascular re-injury and thereby significantly reduce the need for additional surgery” (ERMI, 2002). The extensionator telescopes to the appropriate length, and is applied to the leg with Velcro straps. During a typical training session, the joint is stretched from 1 to 5 minutes, and then is allowed to recover for an equal length of time, and is then stretched again. A typical training session lasts 15 minutes, and the usual prescription is to perform 4 to 8 training sessions per day. There are no controlled published peer-reviewed studies on the effectiveness of the knee/ankle flexionator, the shoulder flexionator, the knee extensionator, or the elbow extensionator. There is insufficient scientific evidence to support the manufacturer's claims that these home-based stretching devices can consistently stretch scar tissues without causing vascular re-injury and thus significantly reduce the need for additional surgery (e.g., surgery for arthrofibrosis after knee surgery). Furthermore, there is a lack of published data to support the claim that these devices can reduce the need for surgery manipulation under anesthesia. Therefore, extensionator and flexionator devices are considered experimental and investigational.

The Elite Seat is a portable knee hyper-extension rehabilitation device that is used to correct the loss of knee extension, increase ROM, decrease knee pain and improve function. In May

2007, Shelbourne et al. wrote an article called “Deconditioned Knee: The Effectiveness of a Rehabilitation Program that Restores Normal Knee Motion to Improve Symptoms and Function.” This article discussed a study of 50 patients (mean age 53.9 years) who had “deconditioned” knees. The patients were given a rehabilitation program to increase knee extension (including hyperextension) and flexion equal to the normal knee, after which patients were instructed in leg strengthening exercises. The conclusion was reached that a rehabilitation program that improved knee range of motion can relieve pain and improve function for patients with deconditioned knees. The use of the Elite Seat was included in the regimen of physical therapy that the patients went through. The author of the article is a consultant to the company that manufactures the elite seat. However, there is insufficient evidence to support the use of the Elite Seat.³⁵

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.⁵

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.³⁶

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.³⁷

SUMMARY OF EVIDENCE

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 have fees assigned to them.

(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)
- Temporomandibular Joint Dysfunction (TMD) Testing and Treatment

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through June 2023, 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
2/19/14	Routine update; added information regarding the “Elite Seat.” No change in policy status.
7/16/14	Added information regarding TMJ rehabilitation systems, including codes, description, rationale and references.
8/19/15	Routine maintenance; references and rationale updated. No change in policy status
8/17/16	Routine policy maintenance; references and rationale updated. No change to policy status.
8/23/17	Routine policy maintenance. No change in policy status.
7/18/18	Routine policy maintenance. No change in policy status.
7/17/19	Removed Medicaid section. Routine policy maintenance, no change in policy status.
7/9/20	Routine policy maintenance, no change in policy status.
7/15/21	Routine policy maintenance, no change in policy status.
7/7/22	Routine policy maintenance, no change in policy status.
7/13/23	Routine policy maintenance. Policy retired to follow Medicare coverage. Vendor managed: Northwood. (ds)

Next Review: No further reviews. Policy retired to follow Medicare coverage.

**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 established HCPCS codes are covered. Any device coded as an NOC code (e.g., E1399) because there is no established code for the device should be reviewed following commercial guidelines. Note that Medicare also covers jaw rehabilitation systems, such as Therabite (E1700-E1701 and E1702).
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

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.