Name of Policy:
Stretching and Splinting Devices for the Treatment of Joint Stiffness and Contractures

Policy #: 346
Category: DME

Latest Review Date: August 2014
Policy Grade: Effective 05/1/2013:
Active Policy but no longer scheduled for regular literature reviews and updates.

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
Joint stiffness or contractures may be caused by immobilization following an injury, disease, or surgery. A joint contracture is characterized by persistently reduced range of motion as a result of structural changes in muscles, tendons, ligaments, and skin. This decrease in joint mobility occurs when elastic connective tissue is replaced with inelastic fibrous material, resulting in tissue that is resistant to stretching.

Stretching devices are intended to stretch joints that have reduced range of motion secondary to immobilization, surgery, contracture, fracture, dislocation, or a number of additional non-traumatic disorders. These devices are intended to replace or reduce the number of physical therapist-directed sessions by providing frequent and controlled joint mobilization in a hospital or in a patient’s home. The goal is to cause permanent elongation of the connective tissue in order to increase range of motion. Mechanical stretching devices are not motorized and may be prefabricated or custom fabricated.

Several types of stretching devices are available and may be classified as follows:

1. Dynamic low-load prolonged-duration stretch (LLPS) devices. These devices allow resisted active and passive motion (elastic traction) within a restricted range. LLPS devices sustain a set level of tension using integrated springs. Examples of LLPS devices include but are not limited to: Dynasplint System®, EMPI Advance Dynamic RDM®, LMB Pro-Glide™, Ultraflex®, and Saeboflex®.

2. Bi-directional static progressive (SP) stretch devices. These devices maintain the joint in a set position but permit manual modification of the joint angle and may allow for active motion without resistance (inelastic traction). Examples of this type of device include the Joint Active Systems (JAS) splints: JAS elbow, JAS shoulder, JAS wrist, JAS knee, JAS ankle, and JAS pronation/supination, and JASEZ Systems.

3. Patient-actuated serial stretch (PASS) devices. These devices allow resisted active and passive motion (elastic traction) within a limited range. PASS devices supply a low to high-level load to the joint, using pneumatic or hydraulic systems that can be adjusted by the patient. Examples of PASS devices include the ERMI Knee Extensionater®, ERMI Elbow Extensionater®, ERMI Knee/Ankle Flexionater®, and ERMI Shoulder Flexionater®, and Elite Seat.

Policy:
Effective for dates of service on or after November 18, 2009:
Dynamic low-load prolonged-duration stretch (LLPS) devices for use on the ankle, knee, elbow, wrist, finger or jaw meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for a period of up to 4 months in the following clinical setting:

- As a treatment for loss of motion from a contracture as part of a formal rehabilitation program or when a formal rehabilitative program is not feasible or has failed to provide benefit.
Only one device is covered per affected area, i.e., separate devices for flexion and extension for the same area does not meet Blue Cross and Blue Shield of Alabama’s criteria for coverage.

The use of dynamic LLPS devices for any other joint or condition including, but not limited to toe, foot, shoulder and forearm disorders, chronic joint stiffness, chronic or fixed contractures, rheumatoid arthritis or plantar fasciitis does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational/experimental.

The devices are also non-covered when used as a part of post-operative care.

The use of bi-directional static progressive (SP) stretch devices does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational/experimental.

The use of patient-actuated serial stretch (PASS) devices does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational/experimental.

The use of dynamic, extension/flexion devices with active resistance control does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

The use of carpal tunnel dynamic splinting as a non-surgical rehabilitative modality for the treatment of carpal tunnel syndrome does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

**Key Points:**

**LLPS Devices**

Cetin, et al (2001), conducted a prospective, uncontrolled study of 37 patients (74 digits) with repaired flexor tendon injuries to determine the functional results following a post-operative regimen of early mobilization using LLPS combined with passive and active early mobilization. LLPS was accompanied by the use of a modified Kleinert splint with a palmar pulley. Outcomes were assessed using the TAM system and the Buck-Gramcko system. Follow-up continued for 12.9 ± 5.4 weeks. Results were reported as excellent in 73%, good in 24%, and fair in 1.5% of fingers.
Chester, et al (2002), reported on a prospective, randomized, controlled trial that compared two methods of rehabilitating extensor tendon repairs in zones IV-VIII. Group A patients (n=19, 29 injured digits) followed an early active mobilization regimen and group B patients (n=17, 29 injured digits) followed a dynamic splintage regimen (LLPS, Dynasplint system). They measured extension lag, flexion deficit, and total active motion (TAM). At four weeks, group B patients had a better TAM (87%) compared to group A (77%). At three months follow-up, there was no significant difference in the results of the two groups.

Berlet, et al (2002), reported on a prospective study of 12 patients with plantar fasciitis who were treated with the Ankle Dorsiflexion Dynasplint. The used a modified plantar fasciitis functional assessment scale and a visual analog pain assessment scale for evaluation. At one month follow up, 75% of patients reported improvement of symptoms. At six months post-splinting, there was no deterioration of results. 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.

**SP Devices**

Doornberg et al (2006) reported on a retrospective review (n=37) to evaluate SP elbow splinting using a JAS splint in patients with elbow stiffness after trauma who were no longer achieving gains in motion with a standard exercise program. Three patients were treated following the injury, 14 were treated after 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). The results showed the flexion arc improved from 71 degrees before splinting to 112 degrees after splinting. Also, after splinting, three patients had a flexion contracture > 30 degrees and 10 patients (34%) had fewer than 130 degrees of flexion. Three patients requested an operation to address elbow stiffness.

Bruner et al (2003) reported on 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=58 patients, 87 extensor tendon injuries). The results were graded as excellent and good in more than 94% and as satisfactory in the remainder.

Hewitt and Shakespeare (2001) reported on a prospective, non-randomized study that compared the effectiveness of two post-operative rehabilitation regimens following unilateral total knee arthroplasty (TKA). A total of 160 knees were assigned to two separate post-operative mobilization regimens: a static flexion regimen or an active extension regimen. The results showed that patients subjected to the flexion regimen had a better maximum flexion and range of movement at six weeks and were also discharged earlier. Histograms of results at six weeks showed that the flexion group had a more predictable outcome with smaller standard deviations than the extension group. There were no differences in post-operative wound problems.

Bounetti et al (2008) evaluated the use of static progressive (SP) stretch using the JAS knee device in patients with refractory knee stiffness. They looked at a series of 41 patients who had knee stiffness and had not improved with conventional physical therapy modalities. Patients were treated with a patient-directed orthosis that utilized the principles of static progressive stretch. After a mean of nine weeks of use (range 3-27 weeks) the total arc of motion increased.
by a mean of 33° (range 0-85°). Forty of forty-one patients had increased motion at a mean final follow-up time of one year (range six months-two years) and 93% were satisfied with the results.

PASS Devices
Branch et al (2003) conducted a prospective uncontrolled 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. Patients had developed knee contractures following ACL injury, peripatellar injury, fracture, or other causes. After treatment (range 2-12 weeks), 74% of patients regained full ROM and 91% regained functional knee ROM.

There is insufficient evidence in the published medical literature to support the use of SP stretch devices or LLPS devices/dynamic splinting for rehabilitation of some joints including the toes, ankles and shoulders; or for the treatment of chronic conditions such as rheumatoid arthritis, plantar fasciitis, cerebral palsy or 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 or to determine whether the use of these devices results in outcomes comparable to those achieved with established rehabilitation methods.

Systematic Reviews
Harvey et al (2002) conducted a systematic review to determine whether stretching; either self-administered, administered manually by therapists, or by external devices such as splints, produces lasting increases in the mobility of joints not directly affected by surgery, trauma, or disease process. The 13 studies included studies that evaluated the use of stretching, with a median of 8 stretch sessions, in patients without functionally significant contractures. Four studies were rated as moderate quality and four studies were rated as poor quality. The studies rated as moderate suggested that regular stretching increases joint ROM (mean increase in ROM = 8°, 95% CI 6° - 9°) for at least one day after stretching cessation, and that the effects of stretching may be greater in muscle groups with limited extensibility. The authors stated that these findings require verification with high-quality studies, and that the lasting effects of intensive stretching programs or of stretching in people with functionally significant contracture have not yet been investigated with randomized studies.

In the study by Berner et al 50 patients were enrolled in the study. The study lasted for 60 days with no follow-up to determine the long-term effects of the treatment.

2009 Update
Berner, Willis, and Martinez (2008) reported on a study using dynamic splinting to treat carpal tunnel syndrome (CTS). Dynamic splinting uses low-load prolonged duration stretch to reduce contracture, which contributes to median nerve compression. Fifty patients (mean age 51 ± 12.6 years) were treated for 60 days. There were 25 patients in experimental group and 25 patients in control group. The results showed there was significant improvement in Levine-Katz functional scores, final pain scores, and improved nerve conduction for experimental patients. However, a direct linear correlation between reduced pain scores and frequency of improved nerve conduction was not apparent. The limitations of this study were the short duration, small subject
population, and disproportionate number of women to men. A crossover study with a longitudinal examination should be conducted to measure the lasting effects of this modality. Dr. Willis is an employee of Dynasplint systems.

Larson and Jerosch-Herold (2008) reported on a systematic review of the literature to evaluate the quantity and quality of evidence regarding the effectiveness of splinting in the post-surgical management of Dupuytren’s contractures. They identified only four studies which provided low level evidence on the effects of static and dynamic post-operative splinting. Patients were not allocated to interventions randomly, so results may be biased. The quality of reporting was poor due to the heterogeneity in splint types, duration of wear, outcomes and follow-up period. One study indicated that splinting resulted in fewer contractures in compliant patients, but another study did not support this. One study looked at composite finger flexion and hand function outcomes, but the results indicated that patients who wore a splint had lower total finger flexion and greater disability at three months. There were no results at six months or one year. The clinical effectiveness of long-term static night splinting on finger movement and hand function remains unproven and a properly randomized controlled trial is needed with a sufficient sample size to confer adequate power for detecting clinically important differences. Future trials need to be factor in the effect of different types of splints, duration and patient adherence.

Lai, Jones and Willis (2008) published the results of a controlled cross-over study that lasted six months and examined the efficacy of low-load, prolonged duration stretch with dynamic splinting in reducing ankle contracture for stroke (CVA) and traumatic brain injury (TBI) patients. There were 50 patients (30 CVA, 20 TBI), one year or more post-incident, with a pre-existing plantar flexion contracture. Patients were treated with a standardized PT protocol two times a week for six months. At three months, selected patients crossed over (25 CVA, 15 TBI) and received additional treatment with an ankle dorsiflexion Dynasplint (AFD). The results showed that after wearing the AFD for 180 days, there was a statistically significant change in PROM for crossover patients. The limitations of the study were that the patients were not randomly assigned to the different groups, so there may be bias. Dr. Willis works for Dynasplint Systems, Inc.

Finger and Willis (2008) published a single case report of a 61 year old male who presented with knee flexion contracture following total knee arthroplasty. After 28 PT sessions, the AROM improved from -20° to -12°. After eight additional weeks with nightly wear of a knee extension dynamic splint, the active extension improved from -12° to 0°. Dr. Willis is employed by Dynasplint Systems, Inc.

Kalish and Willis (2009) reported on a retrospective study to examine dynamic splinting for treating hallux limitus (HL). They looked at 61 cases to measure the difference between HL from contusion, bunionectomy, or cheilectomy. The metatarsal Dynasplint (MDS) was used for treatment for a mean duration of 4.2 weeks. There was significant change for all patients, with a mean 73% gain in dorsiflexion at the metatarsal joint. Dr. Kalish and Dr. Willis both work for Dynasplint Systems, Inc.

John, Willis and Portillo (2009) published a single case report of a 47 year old male competitive runner who had hallux limitus and had a cheilectomy with removal of exostoses and osteophytes.
The patient had continued pain when running and had a contracture. After four months of treatment with Dynasplint splinting, the patient regained 45° in active range of motion. The post-treatment gait analysis showed significant and beneficial changes. Dr. Willis is employed by Dynasplint Systems.

Lundequan and Willis (2009) published a single case report of a five year old girl with right hemi-paresis, below average motor skills, and a gait pattern of right toe contact and left heel strike (without shoes). The patient was treated with PT plus six hours/night of ankle dorsiflexion Dynasplint. After four months, the patient gained 14° in passive dorsiflexion, 9° in active dorsiflexion, and returned to flat foot contact in ambulation without ankle foot orthosis. Dr. Willis is employed with Dynasplint systems.

2010 Update
Plantar Fasciitis
There has been some discussion in the literature on the treatment of heel pain, plantar fasciitis, with orthotic devices and night splints. Some of the pertinent information is summarized below.

Porter et al (2002) reported on a prospective, randomized, blinded study to evaluate and compare the effectiveness of sustained and intermittent Achilles tendon stretching for the relief of pain associated with painful heel syndrome. A total of 94 patients (122 feet) were randomized into two stretching groups. One group performed sustained Achilles tendon stretches (three minutes TID) and the other performed intermittent stretches (five sets, 20 seconds each, BID). Patients were evaluated once a month for four months. At each visit, patients completed pain questionnaires and PT measured Achilles tendon flexibility. The results showed that both sustained and intermittent Achilles tendon stretching exercises increase Achilles tendon flexibility and this correlated with a decrease in pain. There was no significant difference between the two groups.

Sheridan L et al (2010) reported on a randomized controlled trial of plantar fasciopathy or plantar fasciitis treated with dynamic splinting. There were 60 patients (76 feet) enrolled in this 12 week study. Patients were randomized into experimental and control groups. All patients received NSAIDs, orthoses, and steroid injections if needed. Thirty experimental patients also received the Ankle Dorsiflexion Dynasplint to wear for six to eight hours each night while sleeping. Pain was measured using the Plantar Fasciopathy Pain/Disability Scale which was administered on enrollment and again after 12 weeks. The results showed that the mean change in pain/symptom scores for experimental patients was -33 points and for control patients was -2 points, a significant difference. The authors concluded that dynamic splinting was effective for reducing the pain of plantar fasciopathy. One of the authors of the study is employed by Dynasplint Systems Inc., the maker of the Ankle Dorsiflexion Dynasplint.

In 2008, the Orthopedic Section of the American Physical Therapy Association issued clinical practice guidelines for the treatment of heel pain – plantar fasciitis. One of the interventions discussed was night splints. They stated that night splints should be considered for patients with symptoms greater than six months in duration. The desired length of time for wearing night splints is one to three months. The type of night splint used (i.e., posterior, anterior, sock-type) does not appear to affect the outcome.
In 2010, Thomas et al published a revision to the clinical practice guideline on the diagnosis and treatment of heel pain. This guideline was based on a consensus of current clinical practice and review of the clinical literature. The guideline was developed by the CPG Heal Pain Committee of the American College of Foot and Ankle Surgeons (ACFAS). They discussed initial or Tier 1 treatment options which included stretching exercises, oral anti-inflammatory medicines, corticosteroid injections, and others. If there was unsatisfactory improvement, Tier 2 treatment options were added. These included orthotic devices, night splints to maintain an extended length of the plantar fascia and gastroc-soleus complex during sleep, and others. The evidence-based medicine (EBM) conclusions regarding Tier 2 therapies included prefabricated and custom orthotic devices and night splints. All of these were Grade B recommendations.

There is insufficient evidence in the published medical literature to support the use of orthotic devices or night splints for the treatment of plantar fasciitis.

**Key Words:**
Joint stiffness, contracture, dynamic low-load prolonged-duration stretch (LLPS) devices, bi-directional static progressive (SP) stretch devices, patient-actuated serial stretch (PASS) devices, plantar fasciitis, FlexPro Knee Flexor

**Approved by Governing Bodies:**
Mechanical stretching devices are classified by the FDA as Class 1 medical devices. Class 1 devices have 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 prior to marketing. Numerous mechanical stretch devices have been developed and are generally categorized as static progressive (SP) stretch devices, low-load, prolonged-duration stretch (LLPS) devices, and patient-actuated serial stretch (PASS) devices.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.

**Coding:**

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1700</td>
<td>Jaw motion rehabilitation system</td>
</tr>
<tr>
<td>E1701</td>
<td>Replacement cushions for jaw motion rehabilitation system, pkg. of 6</td>
</tr>
<tr>
<td>E1702</td>
<td>Replacement measuring scales for jaw motion rehabilitation system, pkg. of 200</td>
</tr>
</tbody>
</table>
E1800 Dynamic adjustable elbow extension/flexion device, includes soft interface material
E1801 Static progressive stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1802 Dynamic adjustable forearm pronation/supination device, includes soft interface material
E1805 Dynamic adjustable wrist extension / flexion device, includes soft interface material
E1806 Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
E1810 Dynamic adjustable knee extension / flexion device, includes soft interface material
E1811 Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1812 Dynamic knee, extension/flexion device with active resistance control
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
E1820 Replacement soft interface material, dynamic adjustable extension/flexion device
E1821 Replacement soft interface material/cuffs for bi-directional static progressive stretch device
E1825 Dynamic adjustable finger extension/flexion device, includes soft interface material
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 (Effective 01/01/11)
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
References:

Proprietary Information of Blue Cross and Blue Shield of Alabama
Medical Policy #346

Policy History:
Medical Policy Group, January 2009 (3)
Medical Policy Administration Committee, July 2009
Medical Policy Group, September 2009 (3)
Medical Policy Administration Committee, October 2009
Available for comment October 3-November 17, 2009
Medical Policy Group, December 2009 (3)
Medical Policy Group, December 2010 – Add CPT Code effective Jan 1, 2011
Medical Policy Group, April 2011 – Added Key Points, Key Word, and References
Medical Policy Group, February 2012 (3): Added new devices in Policy Section.
Medical Policy Administration Committee, February 2012
Medical Policy Group, May 2013: Effective 05/1/2013: Active Policy but no longer scheduled for regular literature reviews and updates.
Medical Policy Group, September 2013 (2): Added new Key Word ‘FlexPro Knee Flexor’
Medical Policy Group, August 2014 (5): Added References; no change to policy statement.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.
This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.