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

Policy #: 346
Category: DME

Latest Review Date: January 2015
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.

Dynamic low-load prolonged-duration stretch (LLPS) 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 ROM®, and LMB Pro-Glide™.

For Bi-directional static progressive (SP) stretch devices and patient-actuated serial stretch (PASS) devices, please refer to Medical Policy 578-Patient-actuated End Range Motion Stretching Devices.

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 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.

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, bunionection, 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.

Lundequian 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.

**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, plantar fasciitis

**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 and will be reviewed for medical necessity.
## Coding:

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
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<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>
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<td>E1800</td>
<td>Dynamic adjustable elbow extension/flexion device, includes soft interface material</td>
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<td>E1802</td>
<td>Dynamic adjustable forearm pronation/supination device, includes soft interface material</td>
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<td>E1805</td>
<td>Dynamic adjustable wrist extension/ flexion device, includes soft interface material</td>
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<td>E1810</td>
<td>Dynamic adjustable knee extension/ flexion device, includes soft interface material</td>
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<td>E1812</td>
<td>Dynamic knee, extension/flexion device with active resistance control</td>
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<td>Dynamic adjustable ankle extension/flexion device, includes soft interface material</td>
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<td>E1830</td>
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<tr>
<td>E1840</td>
<td>Dynamic adjustable shoulder flexion / abduction / rotation device, includes soft interface material</td>
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## References:


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.
Medical Policy Group, January 2015 (6): Removed information on bi-directional static
progressive (SP) stretch devices and Patient-actuated serial stretch (PASS) devices – these
devices are addressed in Medical Policy 578.

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.