MECHANICAL STRETCHING DEVICES

Policy Number: 2017T0481N
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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

The use of low-load prolonged-duration stretch devices is proven and medically necessary for the treatment of existing joint contractures of the upper and lower extremities as an adjunct to therapy in patients with symptoms of significant joint motion stiffness.

The use of static progressive (SP) stretch splint devices and patient actuated serial stretch (PASS) devices, for the treatment of joint contractures of the upper and lower extremities alone or combined with standard physical therapy are unproven and not medically necessary.
Clinical evidence is not sufficient to demonstrate that use of static progressive or patient actuated devices is a safe or effective treatment option. Studies are limited to small sample sizes.

**APPLICABLE CODES**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>E1800</td>
<td>Dynamic adjustable elbow extension/flexion device, includes soft interface material</td>
</tr>
<tr>
<td>E1801</td>
<td>Static progressive stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories</td>
</tr>
<tr>
<td>E1802</td>
<td>Dynamic adjustable forearm pronation/supination device, includes soft interface material</td>
</tr>
<tr>
<td>E1805</td>
<td>Dynamic adjustable wrist extension/flexion device, includes soft interface material</td>
</tr>
<tr>
<td>E1806</td>
<td>Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories</td>
</tr>
<tr>
<td>E1810</td>
<td>Dynamic adjustable knee extension/flexion device, includes soft interface material</td>
</tr>
<tr>
<td>E1811</td>
<td>Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories</td>
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<td>Dynamic knee, extension/flexion device with active resistance control</td>
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<td>E1815</td>
<td>Dynamic adjustable ankle extension/flexion device, includes soft interface material</td>
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<td>Static progressive stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories</td>
</tr>
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<td>E1818</td>
<td>Static progressive stretch forearm pronation/supination device, with or without range of motion adjustment, includes all components and accessories</td>
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<td>E1825</td>
<td>Dynamic adjustable finger extension/flexion device, includes soft interface material</td>
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<td>Dynamic adjustable toe extension/flexion device, includes soft interface material</td>
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<td>E1831</td>
<td>Static progressive stretch toe device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories</td>
</tr>
<tr>
<td>E1840</td>
<td>Dynamic adjustable shoulder flexion/abduction/rotation device, includes soft interface material</td>
</tr>
<tr>
<td>E1841</td>
<td>Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories</td>
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**DESCRIPTION OF SERVICES**

Joint stiffness or contracture may be caused by immobilization following surgery, disease, or trauma. Joint contracture is associated with reduced range of motion (ROM) due to structural changes in non-bony tissues, including muscles, tendons, ligaments and skin.

Mechanical stretching devices are used for the prevention and treatment of joint contractures of the extremities, with the goal to maintain or restore range of motion (ROM) to the joint. These devices are intended to replace some physical therapist-directed sessions by providing frequent and consistent joint mobilization under controlled conditions in a hospital setting or in the patient's home. (Hayes, 2013; updated 2016)

A number of different physical therapy modalities are used to treat or prevent joint contractures, including manual joint mobilization by a physical therapist, static splinting, mechanical stretch devices, massage, and exercise. There is no single technique that has been identified as being superior to others, and often a combination of treatments is used to restore ROM. (Farmer et al., 2001; Thien et al., 2004)

**Mechanical stretch devices** include:
- Low-load prolonged-duration stretch devices (LLPS),
- Static progressive (SP) stretch (splint) devices, and
Dynamic splinting systems are adjustable spring-loaded devices designed to provide low-load prolonged stretch while patients are asleep or at rest. Units for both extension and flexion are available for elbow, wrist, fingers, knee, ankle and toes. These units are marketed for the treatment of joint stiffness due to immobilization or limited range of motion (ROM).

**Dynamic low-load prolonged-duration stretch (LLPS) devices** permit resisted active and passive motion (elastic traction) within a limited range. LLPS devices maintain a set level of tension by means of incorporated springs.

**Static progressive (SP) stretch (splinting) devices** hold the joint in a set position but allow for manual modification of the joint angle (inelastic traction). This type of device does not exert a stress on the tissue and does not allow for active or passive motion.

**Joint active systems (JAS)** use the principle of stress relaxation in an effort to gradually extend the ROM of an injured joint. The patient adjusts the device to apply a low level of tension to the affected joint. As the joint stretches and relaxes, the joint accommodates to this new position. According to the manufacturer, JAS are designed to simulate manual therapy, eliminate the risk of joint compression, provide soft tissue distraction, and "achieve permanent soft tissue lengthening in a short amount of time."

**Patient-actuated serial stretch (PASS) devices** provide a low- to high-level load to the joint using pneumatic (Extensionaters, ERMI Inc.) or hydraulic (Flexionaters, ERMI Inc.) systems that can be adjusted by the patient. Different PASS devices are available for use depending on the joint being treated (knee/ankle, knee, and shoulder). Protocols for use include a customized treatment plan and individualized patient education (ERMI Inc.).

ERMI Shoulder Flexionater® is intended to address the needs of patients with decreased glenohumeral abduction and external rotation secondary to excessive scar tissue. It biomechanically and anatomically focuses treatment on the glenohumeral joint without stressing the other shoulder joints. Once customized, the Shoulder Flexionater can be used at home without assistance to perform serial stretching exercises, alternately stretching and relaxing the scar tissue surrounding the glenohumeral joint. The device has three sections, the main frame, arm unit and pump unit. The shoulder flexionater was listed with the FDA in 2001 and is Class I exempt.

ERMI Knee/Ankle Flexionater® is a self-contained device that facilitates recovery from decreased ROM 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.

ERMI Knee Extensionater® and ERMI Shoulder Extensionater® provide serial stretching, using a patient-controlled pneumatic device that can deliver variable loads to the affected joint. The manufacturer claims that these are the only devices on the market that can "consistently stretch scar tissue, without causing vascular reinjury and thereby significantly reduce the need for additional surgery." 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 for 1-5 minutes, is allowed to recover for an equal length of time, and then is stretched again. A typical training session lasts 15 minutes, and the usual prescription is to perform 4-8 training sessions per day.

**CLINICAL EVIDENCE**

**Mechanical Stretch Devices**

Evidence suggests that low-load prolonged-duration stretch (LLPS) for finger contractures following surgical extensor injury repair may increase ROM faster than static splinting. However, the treatment benefit is small and the final outcome is similar to that achieved with static splinting. Furthermore, LLPS did not significantly improve hand function and grip strength, indicating that the small short-term gains in ROM may not be clinically meaningful and that LLPS may not improve final outcomes. There was a paucity of studies investigating mechanical stretching devices for other applications, including contracture of the fingers following flexor injury or trauma, the hand, wrist, elbow, shoulder, and the knee. Factors reducing the quality of these studies were small sample sizes, no or short-term follow-up, lack of intention-to-treat analysis, lack of blinding, large dropout rates, or failure to use recommended methods of randomization. Because there were only one or two studies available for each device type, a systematic analysis of the
Low-Load Prolonged-Duration Stretch Devices (LLPS)

Dynamic splinting systems also known as low-load prolonged-duration stretch (LLPS) are spring-loaded, adjustable mechanical stretching devices designed to provide low-load prolonged stretch while patients are asleep or at rest. They permit resisted active and passive motion (elastic traction) within a limited range while maintaining a set level of tension by means of incorporated springs. These units are being marketed for the treatment of joint stiffness due to trauma and neurological disorders.

Randomized controlled studies, observational studies, case series, and medical community acceptance confirm the benefits of dynamic LLPS devices when used to relieve persistent joint stiffness that can occur after injury or surgery. However, there is minimal evidence supporting the effectiveness of dynamic LLPS devices for the rehabilitation of joints other than finger, wrist, elbow, knee, and toe. There is insufficient evidence in the published peer-reviewed literature to support the use of dynamic LLPS devices for the treatment of conditions such as, but not limited to, chronic joint stiffness or chronic fixed contractures caused by chronic medical conditions such as RA, cerebral palsy, or plantar fasciitis.

Treatment of Lower Extremity Contractures

A systematic review was performed by Furia et al. to evaluate the safety and efficacy of dynamic splinting as it is used to treat joint contracture in lower extremities, and to determine if duration on total hours of stretching had an effect on outcomes. A total of 354 abstracts were screened and eight studies with 487 subjects met the inclusion criteria. The primary outcome measure was change in active range of motion (AROM). The mean aggregate change in AROM was 23.5º in the collective studies. Dynamic splinting with prolonged, passive stretching as home therapy treatment showed a significant direct, linear correlation between the total number of hours in stretching and restored AROM. The authors concluded that dynamic splinting is a safe and efficacious treatment for lower extremity joint contractures (2013).

Professional Societies

American Academy of Neurology (AAN)

In its evidence-based guideline summary on diagnosis and treatment of limb-girdle and distal dystrophies, the AAN directs clinicians to prescribe physical and occupational therapy, as well as bracing and assistive devices that are adapted specifically to the patient's deficiencies and contractures, in order to preserve mobility and function and prevent contractures (Narayanaswami, et al. 2014).

Rehabilitation of Extensor/Flexor Injuries of the Hand

Sameem et al. (2011) evaluated which rehabilitation protocol yields the best outcomes with respect to ROM and grip strength in extensor zones of the hand. A comprehensive literature review and assessment was undertaken by 2 independent reviewers. Methodological quality of randomized controlled trials (RCTs) and cohort studies was assessed using the Scottish Intercollegiate Guidelines Network scale. A total of 17 articles were included in the final analysis. The authors concluded that the available level 3 evidence suggested better outcomes when using dynamic splinting over static splinting. Moreover, they stated that additional studies comparing dynamic and early active motion protocols are needed before a conclusive recommendation can be made.

Khandwala et al., (2000) conducted the largest randomized controlled trial of 100 patients with complete divisions of the extensor tendons in Verdan's zones 5 and 6 of the hand. Patients were randomly assigned to be rehabilitated postoperatively through use of LLPS and active mobilization (group 1, n=50) or palmar block static splinting and active mobilization (group 2, n=50). TAM and Miller's assessment of tendon repair (Miller et al.1942) were the main outcome measures, assessed 4 and 8 weeks postsurgery. At 8 weeks, there was no statistically significant difference between the two groups: 50% of patients assigned to group 1 achieved excellent TAM versus 49% of those assigned to group 2; and good TAM was achieved by 48% and 46% of patients in groups 1 and 2, respectively. Miller's assessment demonstrated good or excellent results in 95% of group 1 and 93% of group 2 patients. The results suggest the efficacy and safety of LLPS and active mobilization regimen may be similar to that of static splinting combined with active mobilization program.

A randomized controlled trial by Chester et al. (2002) evaluated 54 patients with simple finger extension division in Verdan's zones 4-8. Patients were randomly assigned to one of two rehabilitation regimens; however 18 patients were lost to follow-up leaving only 36 patients included in the data analysis. These patients had been assigned to receive early active mobilization combined with static splinting (group 1; n=19 patients with 29 injured digits) or LLPS (group 2; n=17 patients with 29 injured digits). The main outcome measures were metacarpophalangeal joint TAM, median extension lag, and median flexion deficit, assessed at 4 weeks and at 3 months postsurgery. At 4 weeks postsurgery, TAM was significantly improved for group 2 (87%) compared with group 1 patients (77%). However, this difference...
was not maintained with follow-up TAM at 3 months being similar for both groups (group 1= 100%; group 2= 98%). While the median flexion deficit at 4 weeks postsurgery was significantly lower for group 2 (25 degrees) compared with group 1 (45 degrees), this difference was also not maintained at 3 months follow-up with the value being 0 degrees for both groups. No significant difference in median extensor lag was observed at both times. The authors concluded that, while LLPS combined with active mobilization results in better TAM at 4 weeks postsurgery than static splinting combined with active mobilization, the long-term efficacy and safety is similar for both rehabilitation regimens.

A prospective uncontrolled study by Cetin et al. evaluated 37 patients (74 digits) with repaired flexor tendon injuries using a regimen of LLPS combined with passive and active early mobilization exercises. Based on the Buck-Gramcko system and TAM results, this regimen achieved excellent results in 73% of fingers, good results in 24% and fair in 1.5%. The authors concluded that LLPS combined with passive and active early mobilization exercises may be an effective treatment for repaired flexor tendon injuries (2001).

**Static Progressive (SP) Stretch (Splinting) Devices**

A meta-analysis by Katalinic et al. (2010) reviewed 35 studies (n=1391 patients) to determine the effects of stretch (sustained passive stretching, positioning, splinting and serial casting) on contractures in people with, or at risk of, contractures. Primary outcomes measured were joint mobility and QOL. Secondary outcomes were pain, spasticity, limitations in activity and participation restriction. Outcomes were measured immediately after treatment, at 1 week post treatment and greater than 1 week with no study performed for more than 7 months. The authors found that for all conditions, there is little or no effect of stretch on pain, spasticity, activity limitation, participation restriction or QOL if performed for less than seven months. The effects of stretch performed for periods longer than seven months has not been investigated.

Only one prospective, nonrandomized, comparative clinical study investigated static progressive (SP) devices for joint contractures of the lower extremities (n=160). Hewitt and Shakespeare (2001) compared 2 postoperative TKA mobilization regimens. All 160 patients underwent unilateral TKA and were then assigned to one of two rehabilitation regimens: Group 1 (n=86) had a static progressive flexion regimen which involved the patient's knee being placed on a 90° splint for 10 minutes followed by 10 minutes of passive extension combined with exercises every 2 hours. Group 2 (n=74) had a regimen of static extension splinting combined with physical therapist-guided flexion exercises. Outcome measures included knee joint ROM, stability, and alignment; extensor lag; pain and mobility aids used. These outcomes were assessed 1 day prior to surgery and at 6 weeks post-surgery. Six weeks after surgery, Group 1 had better ROM and improved maximum knee flexion compared with Group 2. Blood loss and analgesic requirements were similar for both groups. The authors concluded that, as an adjunct treatment to physical therapist-guided exercises, a static progressive flexion regimen may be superior to a static extension regimen in the rehabilitation of unilateral TKA. Short follow-up and lack of blinding were the main limitations of this study. While the preliminary evidence suggests that this technique may be beneficial, it is unclear whether a therapeutic benefit, beyond that achieved with active PT or passive mobilization, can be achieved. A regimen of active PT and SP was superior to active PT combined with static splinting.

While more studies were available for SP treatment of joint contractures of the upper extremities, mainly for finger joints following finger extensor or flexor injuries, the evidence was insufficient to draw definitive conclusions. The evidence suggests that while adjunct SP treatment may achieve the rehabilitation goal sooner than static splinting and PT, an active mobilization regimen combined with SP treatment may not improve joint mobility beyond what can be achieved with a standard PT program.

Although proponents of SP stretch claim that the technique leads to faster recovery and has greater patient compliance than dynamic splints, there were no studies identified that compared devices using SP stretch to any other type of device. In the absence of any comparison groups, the actual effects of treatment cannot be determined.

Published reports of the effectiveness of joint active system (JAS) splints are limited to case reports and small uncontrolled case series limited by lack of randomization, lack of controls, and small sample size. There is limited evidence demonstrating that the addition of the use of JAS devices to the PT management of patients with joint injury or surgery significantly improves the patient's clinical outcomes.

**Patient-Actuated Serial Stretch (PASS)**

PASS devices supply a low to high-level load to the joint using pneumatic or hydraulic systems that can be adjusted by the patient. PASS devices are available for the knee/ankle, shoulder, or knee. There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of the use of PASS devices for any indication. There are no well-designed clinical trials that evaluate these devices. It is not possible to determine based on the available evidence whether the addition of these devices when used alone or as an adjunct to a physical therapy program provide improved patient outcomes.
Mechanical stretching devices are classified by the FDA as Class I medical devices. Class I 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.

Mechanical stretching devices are categorized under product code ION and are Class I, 510(k) exempt devices. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed September 30, 2016)

Patient-controlled stretch devices such as Dynasplint, Ultraflex, Pro-glide Knee, Elbow, Wrist (DeRoyal® Advance Dynamic ROM® are approved as Class I devices and exempt from testing.

Joint Active System devices are Class I, 510(k) exempt devices. The JAS devices were listed in 1999 by Bonutti Research, Inc. (Note: Bonutti developed the device which is now marketed by Thera Tech Inc.)

Medicare does not have a National Coverage Determination for mechanical stretching devices. LCDs do not exist at this time. (Accessed September 30, 2016)

REFERENCES


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<tr>
<td>03/01/2017</td>
<td>• Updated list of related policies to reflect title change for Community Plan policy titled <em>Mechanical Stretching Devices</em> (previously titled <em>Mechanical Stretching and Continuous Passive Motion Devices</em>)</td>
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| 02/01/2017 | • Changed policy title; previously titled *Mechanical Stretching and Continuous Passive Motion Devices*  
• Updated benefit considerations; added instruction to check the member specific benefit plan document and any federal or state mandates, if applicable, before using this policy  
• Revised coverage rationale:  
  o Removed content/language pertaining to use of continuous passive motion (CPM) devices  
  o Replaced language indicating:  
    ▪ "The use of low-load prolonged-duration stretch devices is proven and medically necessary for the treatment of existing joint contractures of the upper and lower extremities as an adjunct to therapy in patients with symptoms of significant joint motion stiffness in the immediate post-operative period" with "the use of low-load prolonged-duration stretch devices is proven and medically necessary for the treatment of existing joint contractures of the upper and lower extremities as an adjunct to therapy in patients with symptoms of significant joint motion stiffness"  
    ▪ "The use of static progressive (SP) stretch splint devices and patient actuated serial stretch (PASS) devices, for the treatment of joint contractures of the extremities alone or combined with standard physical therapy is unproven and not medically necessary" with "the use of static progressive (SP) stretch splint devices and patient actuated serial stretch (PASS) devices for the treatment of joint contractures of the upper and lower extremities alone or combined with standard physical therapy is unproven and not medically necessary"  
• Updated list of applicable HCPCS codes:  
  o Removed E0935 and E0936  
  o Modified table headings; removed descriptors classifying codes as “proven” and “unproven”  
• Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information, and references  
• Archived previous policy version 2016T0481M |