UnitedHealthcare®

MEDICAL POLICY

MECHANICAL STRETCHING AND CONTINUOUS PASSIVE MOTION DEVICES

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Table of Contents **Page**

Related Policies:
None

INSTRUCTIONS FOR USE

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COVERAGE RATIONALE

The use of continuous passive motion (CPM) devices is proven for the prevention of joint contractures of the upper and lower extremities.

The use of low-load prolonged-duration stretch devices is proven for the treatment of existing joint contractures of the upper and lower extremities.

Information Pertaining to Medical Necessity Review (When Applicable)
Low-load prolonged duration stretch devices are medically necessary for the treatment of existing joint contractures of the upper and lower extremities.

Continuous passive motion devices are medically necessary for patients in the immediate post-operative phase of joint surgery as an adjunct to (and not replacement of) physical therapy to prevent contractures of the joints of the upper and/or lower extremities

The lumbar continuous passive motion device is unproven.
Clinical evidence is limited to manufacturer data. There is no scientific evidence in the published peer-reviewed medical literature that these devices for patient controlled therapy are safe or effective.

Static progressive (SP) stretch splint devices and patient actuated serial stretch (PASS) devices, such as the ERMI Extensionater and Flexionater, for the treatment of joint contractures of the extremities alone or combined with standard physical therapy are unproven.

Clinical evidence is not sufficient to demonstrate that use of static progressive or patient actuated devices improves long-term patient outcomes. Evidence is limited primarily to short term outcomes and lack of comparison to other treatment modalities.

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit 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 claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

Proven HCPCS Code	Description
E0935	Continuous passive motion exercise device for use on knee only
E0936	Continuous passive motion exercise device for use other than knee
E1800	Dynamic adjustable elbow extension/flexion device, includes soft interface material
E1802	Dynamic adjustable forearm pronation/supination device, includes soft interface material
E1805	Dynamic adjustable wrist extension / flexion device, includes soft interface material
E1810	Dynamic adjustable knee extension / flexion device, includes soft interface material
E1812	Dynamic knee, extension/flexion device with active resistance control
E1815	Dynamic adjustable ankle extension/flexion device, includes soft interface material
E1825	Dynamic adjustable finger extension/flexion device, includes soft interface material
E1830	Dynamic adjustable toe extension/flexion device, includes soft interface material
E1840	Dynamic adjustable shoulder flexion / abduction / rotation device, includes soft interface material

Unproven HCPCS Code	Description
E1801	Static progressive stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1806	Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories

Unproven HCPCS Code	Description
E1811	Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
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
E1831	Static progressive stretch toe device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1841	Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories

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 and continuous passive motion (CPM) 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, 2011a; Hayes, 2011b)

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, continuous device-assisted passive motion (CPM), 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)

Continuous Passive Motion (CPM): is used for rehabilitation of joints following injury to or surgery on articular tissues, including cartilage, tendons, and ligaments. CPM involves movement of a joint without active muscle contraction, and is accomplished with motorized devices that move the affected joint through a prescribed arc of motion for an extended period of time. It is generally well accepted that CPM of the joint creates increased synovial fluid movement, intermittent compression, and soft tissue tension, and experimental animal studies suggest that CPM can promote clearing of blood in the joint, stimulate production of new cartilage, and decrease cartilage vascularity.

CPM involves movement of a joint without active muscle contraction, and is accomplished with motorized devices that move the affected joint through a prescribed arc of motion for an extended period of time. (Salter 1989; Salter 1996) While passive motion therapy can be performed by a trained caregiver or therapist, CPM devices allow increased duration of therapy, which can be performed in a controlled, predefined manner. (Salter 1996; O'Driscoll et al., 2000)

Examples for CPM devices include the Artromot® CPM systems (Ormed Inc.), Danniflex CPM devices (Danninger Medical Technology Inc.), Elbow CPM Orthoses (Electrobionics Corp.), Jace CPM device (Jace Systems), Mobilimb and MULTILINK CPM (OrthoLogic Corp.), and Sutter CPM devices (Sutter Corp.).

Mechanical stretch devices include:

- Low-load prolonged-duration stretch devices (LLPS),
- Static progressive (SP) stretch (splint) devices, and
- Patient actuated serial stretch (PASS) devices.

Low-load prolonged-duration stretch devices (LLPS): 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. Dynamic splinting units for both extension as well as flexion are available for elbow, wrist, fingers, knee, ankle and toes. These units are being marketed for the treatment of joint stiffness due to trauma and neurological disorders. Indications included immobilization or limited range of motion (ROM) as a consequence of fractures, dislocations, tendon and ligament repairs, joint arthroplasties, total knee replacements, burns, rheumatoid arthritis, hemophilia, tendon releases, head trauma, spinal cord injuries, cerebral palsy, multiple sclerosis, and other traumatic and non-traumatic disorders.

Available low-load, prolonged-duration stretch (LLPS) devices include:

- Dynasplint System® (Dynasplint Systems, Inc., Severna Park, MD)
- Ultraflex (Ultraflex Systems, Pottstown, PA)
- Pro-glide™ Dynamic ROM devices (DeRoyal®, Powell, TN)
- Advance Dynamic ROM® devices (Empi, St. Paul, MN)

Dynamic splinting is commonly used in the post-operative period for the prevention or treatment of motion stiffness/loss in the knee, elbow, wrist or finger. It is not generally used in other joints such as the hip, ankle or foot.

Examples of LLPS devices include Dynasplint System® (Dynasplint Systems Inc.); Ultraflex (Ultraflex Systems Inc.); LMB Pro-Glide devices (DeRoyal Industries); Advance Dynamic ROM® and (Empi).

Static progressive (SP) stretch (splinting) devices: 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 motion (passive or active).

An example for this type of device is the Joint Active Systems (JAS) (Thera Tech Equipment Inc.) including: JAS Elbow, JAS Shoulder, JAS Ankle, JAS Knee, JAS Wrist, and JAS Pronation-Supination.

Joint Active Systems (JAS) devices use the principle of stress relaxation in an effort to gradually extend the range of motion 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 systems are designed to simulate manual therapy. The manufacturer claims that JAS devices 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: 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. PASS devices are available for the ankle (ERMI Knee/Ankle Flexionater® Flexionater® fitting. A certified ERMI representative devises a customized treatment protocol and provides training in its correct use. The stretch is provided 4 to 8 times during the day for 15 minutes; during this time, the knee is stretched to full extension from 1 to 5 minutes, followed by a similar time of relaxation until the 15-minute session is completed (ERMI Inc., 2004).

ERMI Shoulder Flexionater® is designed to isolate and treat decreased glenohumeral abduction and external rotation. The device is intended to addresses the needs of patients with excessive scar tissue. This customizable device has biomechanically and anatomically located pads to focus treatment on the glenohumeral joint, without stressing the other shoulder joints. Once customized, the shoulder flexionater can be used by the patient 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 flexionator 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 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.

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 the knee and shoulder extensionators 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 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.

CLINICAL EVIDENCE

The clinical evidence was reviewed on November 7, 2013 with no additional information identified that would change any of the prior conclusions.

Continuous Passive Motion (CPM)

There is conflicting evidence suggesting that continuous passive motion (CPM) as an adjunct to physical therapy may improve range of motion (ROM) during the immediate postoperative time frame following total knee arthroplasty (TKA). However, the final ROM was comparable with that achieved with physical therapy alone. In addition, CPM did not improve knee function, did not decrease pain in most studies, and did not decrease the need for pain medication, further suggesting that the therapeutic benefit may not be clinically meaningful. It is also unclear whether CPM may avoid or reduce the need for additional knee manipulation.

Furthermore, CPM may not reduce the length of hospitalization. There is limited evidence that patients receiving CPM for postsurgical rehabilitation of rotator cuff tendon injury may achieve final optimal ROM faster than those undergoing physical therapy alone, although the ultimate outcome may be the same as physical therapy. There is limited data regarding the effect of CPM on other joints (Hayes, 2011a).

Lower Extremities

Total Knee Arthroplasty: A meta-analysis reviewed 14 studies involving 952 patients who had undergone total knee arthroplasty using Cochrane Collaboration methodology. (Milne et al., 2003; Brosseau et al., 2004) Studies were included in the analysis if they met the following criteria: (a)

patients aged 18 or older with presurgical diagnoses of degenerative joint disease; (b) intervention and control groups of 5 or more individuals per group; (c) evaluations of rehabilitative outcomes, (d) CPM used as an adjunct treatment to physical therapy in the intervention group, and (e) patients in the control group received physical therapy. The analysis found CPM, as an adjunct to physical therapy, was associated with significant improvements in active knee flexion and analgesic use 2 weeks post surgery; as well as decreased HLOS and need for knee manipulations, compared with physical therapy alone. The authors of the meta-analysis concluded that CPM combined with physical therapy provides a short-term therapeutic advantage compared with physical therapy alone and CPM may be an effective substitute for physical therapist-guided session in the immediate postoperative rehabilitation regimen. However, adjunct CPM, if used concurrently with a standard physical therapist-guided rehabilitation regimen, may not provide additional long-term therapeutic benefits and patients undergoing either regimen may have similar long-term outcomes.

Lenssen et al. (2008) conducted a randomized controlled trial to evaluate the effectiveness of prolonged CPM use in the home as an adjunct to standardized physical therapy (PT). A total of 60 patients with knee osteoarthritis undergoing total knee arthroplasty (TKA) and experiencing early post-operative flexion impairment were randomized into 2 treatment groups. The experimental group received CPM and PT for 17 consecutive days after surgery, whereas the usual care group received the same treatment during the in-hospital phase, followed by PT alone in the first 2 weeks after hospital discharge. From 18 days to three months after surgery, both groups received standardized PT. The primary focus of rehabilitation was functional recovery (e.g. ambulation) and regaining range of motion (ROM) in the knee. Prolonged use of CPM slightly improved short-term ROM with patients who had limited ROM at the time of discharge.

Assessment at 6 weeks and three months after surgery found no long-term positive effects of prolonged CPM use. Although results indicate that prolonged CPM use might have a small short-term effect on ROM, routine use of prolonged CPM in patients with limited ROM at hospital discharge should be reassessed, since neither long-term effects nor transfer to better functional performance was detected.

In an unblinded, prospective randomized controlled trial, Chiarello et al. (1997) compared short- and long-duration use of CPM devices versus a standard exercise regimen post total knee arthroplasty (n=45). (Chiarello et al., 1997) Postoperatively, patients were randomly assigned to one of five treatment groups. The first group received no CPM; the remaining four groups received either short-duration (3 to 5 hours per day) or long-duration CPM (10 to 12 hours per day) with ROM increased either to patients' level of tolerance or by 5 degrees twice daily. Mean knee ROM was the main outcome measure and was assessed the day prior to hospital discharge or at 14 days post surgery. The results showed that in follow-up ROM did not differ among the five treatment groups although all patients in the CPM groups had increased rates of return of active knee flexion compared with the control group. The small sample size substantially limits the quality of this study and the statistical analysis of the data may not have a sufficient power to detect a treatment effect.

A prospective, investigator-blinded randomized controlled trial by Beaupre et al. (2001) compared three rehabilitation regimens in patients who had undergone primary total knee arthroplasty for osteoarthritis. The sample size required to detect a clinically significant treatment effect was determined a priori using power analysis. All patients were treated using a standard physical therapy rehabilitation regimen. One group of patients received standard physical therapy alone (group 1, n=40); the second group received physical therapy and CPM (group 2, n=40); and the third group received physical therapy and SB therapy (group 3, n=40). Outcomes included knee ROM, WOMAC osteoarthritis index scores, and Short Form-36 (SF-36) health survey scores, assessed preoperatively, at discharge, and at 3 and 6 months post surgery. Results showed that no statistically significant differences were observed among the three treatment groups for any of the outcome variables at any follow-up assessment. At 6 months post surgery, extension had improved from -5 degrees, -8 degrees, and -6 degrees at baseline to -2 degrees, -2 degrees, and

-4 degrees; flexion from 112 degrees, 114 degrees, and 115 degrees at baseline to 94 degrees, 96 degrees, and 98 degrees for groups 1, 2, and 3, respectively. Similarly, no statistically significant differences in the WOMAC osteoarthritis scores were observed among the three treatment groups (group 1, group 2, group 3) for pain (79, 85, 76), stiffness (69, 73, 65), and function (77, 81, 74). SF-36 scores were also similar among all three groups. The results suggest that adjunct CPM and adjunct SB may not provide additional therapeutic benefit in an active mobilization regimen following total knee arthroplasty for osteoarthritis.

In five randomized controlled trials and one nonrandomized, comparative clinical trial the efficacy and safety of the use of CPM devices as an adjunct to physical therapy was evaluated in 51 to 178 patients who had undergone total knee arthroplasty. (Ververeli et al, 1995; Montgomery et al., 1996; Yashar et al., 1997; Chen et al., 2000; Beaupre et al., 2001; Chen et al 2000) In these studies, CPM therapy was started the day following surgery and was administered for 5 to 24 hours per day. CPM was always combined with the same standard physiotherapy regimen that was used in the comparator group. Outcome measures included passive and active knee ROM, Knee Society score, pain severity, analgesic requirements, local swelling, presence of residual contracture, and hospital length of stay (HLOS). While in some studies use of CPM devices was associated with increased knee flexion during the immediate postoperative follow-up period (< 7 days), no statistically significant differences between adjunct CPM and standard physical therapy were observed at follow-up ranging from 4 months to 2 years. From this research, it appears CPM devices may not provide additional therapeutic benefit in a physical therapy rehabilitation regimen following TKA.

A randomized controlled trial by Lau et al. (2001) compared CPM devices to immobilization in 43 patients. One group of patients received postoperative CPM for 6 days (23 hours per day); a second group underwent postoperative immobilization. Seven days post surgery, patients in both groups changed to standard physical therapy including active mobilization and full weight-bearing walking. The main outcome measure was patients' active ROM at 3, 5, 7, 14, 28, and 42 days, and at 3, 6, and 12 months postoperatively. During the acute phase of the study, days 3 to 7, active knee ROM in the CPM group was significantly better (75 degrees on day 7) than in the immobilization group (56 degrees on day 7). However, this difference was not maintained during follow-up and no statistically significant difference in active ROM was observed at any later time (active ROM at 12 months: CPM, 96 degrees; immobilization, 93 degrees). This result suggests that ultimately postoperative CPM may not increase active ROM following total knee arthroplasty, compared with immobilization.

Worland et al. (1998) conducted an investigator-blinded randomized controlled trial of 37 patients (49 knees) who were status post total knee arthroplasty and received treatment with CPM devices as a home therapy program and 43 patients (54 knees) who underwent a standard physical therapy program, also performed at the patients' homes. CPM was performed for 3 hours daily for 10 days; physical therapy was performed for 1 hour, 3 times per week for 14 days. Monitored outcomes included knee scores, knee flexion, presence of knee contracture, and extensor lag, assessed 2 weeks and 6 months following total knee arthroplasty. At 2 weeks, patients in the CPM group had a larger residual flexion contracture (4.2 degrees) than those who underwent physical therapy (2.1 degrees); all other outcomes were similar in both groups. At six months follow-up, CPM patients and those who underwent physical therapy had similar knee scores (95.3, 95.7), flexion (117.6 degrees, 118.1 degrees), flexion contracture (0.3 degrees, 0.4 degrees), and extension lag (0 degrees, 0.06 degrees), respectively. The results of this study suggest postoperative home-based CPM may be as effective as standard physical therapy in the rehabilitation patients following total knee arthroplasty for osteoarthritis.

In the first randomized controlled trial conducted by Pope et al. (1997), 53 patients (57 knees) who had undergone primary total knee arthroplasty for osteoarthritis or rheumatoid arthritis were allocated to one of three rehabilitation regimens: group 1 patients (n=19) underwent a standard exercise regimen and had an extension splint placed on the affected knee; group 2 patients (n=18) received low-flexion CPM (0 degrees to 40 degrees); and group 3 patients (n=20) received

high-flexion CPM (0 degrees to 70 degrees) 48 hours following surgery, otherwise following the same exercise regime as group 1. (Pope et al., 1997) The sample size, determined by power analysis, was sufficient to detect a difference in flexion of 16 degrees in flexion with a power of 80%. Outcome measures included mean analgesic requirements, knee ROM, patients' mobility, need for walking aids, and pain severity. The outcomes were assessed at 7 weeks, and 3, 6, and 12 months post surgery. At 12 months follow-up, among groups there were no significant differences in the knee ROM, patients' mobility, and need for walking aids. Patients who had received CPM (groups 2 and 3) required significantly more analgesics compared with those patients who only underwent the standard exercise regimen (group 1= 48.1 mg; group 2= 72.6 mg; group 3= 81.5 mg). The results of this study suggest that high- or low-flexion CPM in the preoperative rehabilitation of total knee arthroplasty may be similar to a standard exercise program. Patients who receive CPM may require fewer analgesics than patients who undergo an exercise program alone.

In a second investigator-blinded randomized controlled trial by MacDonald et al. (2000), 120 patients (120 knees) underwent unilateral total knee arthroplasty for osteoarthritis and were then randomly assigned to one of three physical rehabilitation groups postoperatively: group 1 patients (n=40) underwent standard physical therapy, group 2 patients (n=40) received low-flexion CPM (0 degrees to 50 degrees and increased to highest patient-tolerated level), and group 3 patients (n=40) received adjunct high-flexion CPM (70 degrees to 110 degrees). The sample size required to measure a clinically significant treatment effect was determined a priori using power analysis. Outcomes were assessed prior to surgery and at 12, 26, and 52 weeks postoperatively and included mean knee ROM, Knee Society scores (Insall et al., 1989), analgesic requirements, and hospital length of stay (HLOS). In follow-up, no statistically significant differences among groups were observed for any of the outcome variables: for groups 1, 2, and 3, respectively, mean knee flexion increased from 107, 105, and 107 prior to surgery to 112, 113, and 112 post surgery; mean knee extension improved from 6, 5, and 5 to 2, 2, and 2; Knee Society scores improved from 93, 93, and 90 to 166, 166, and 165, analgesic requirements were 80, 88, and 72 mg and hospital length of stay were 5.1, 5.2, and 5.0 days. The results suggest that adjunct high- or low-flexion CPM does not provide an added therapeutic benefit in physical rehabilitation of patients following total knee arthroplasty for osteoarthritis. Furthermore, adjunct CPM did not appear to reduce HLOS.

In a small randomized controlled trial by Kim et al. (1995), immediate postoperative CPM was compared with a postoperative regimen of static progressive splinting for patients with osteoarthritis or rheumatoid arthritis who had undergone total knee arthroplasty. The final ROM was assessed at a mean follow-up duration of 3.5 years. Patients who underwent the SP splinting protocol had a significantly greater ROM (135 degrees) than patients who received CPM (120 degrees). The results of this study suggest an SP splinting regimen may be more effective than CPM in restoring ROM following TKA.

Anterior Cruciate Ligament (ACL) Surgery: In two randomized controlled trials (Engstrom et al., 1995; McCarthy et al., 1993), adjunct CPM was compared with physical therapy alone, in the rehabilitation of patients (n=30 to 34) who had had ACL surgery. In both studies, patients were randomly assigned to receive a standard physical therapy regimen immediately postoperatively with or without CPM. Outcome measures included ROM, joint swelling, and pain and analgesic use. While patients who received adjunct CPM had less swelling and lower analgesic use than patients who underwent physical therapy alone, adjunct CPM did not improve ROM beyond what was achieved with physical therapy alone. The main study limitations were small sample sizes and lack of blinding.

Tibial Osteotomy: In this retrospective study, Westrich et al. (1998) investigated CPM and internal fixation versus immobilization for the rehabilitation of knees following tibial osteotomy secondary to gonarthrosis (early joint surface damage of the knee). The charts of 65 patients were reviewed; of these, 33 patients (35 knees) had undergone internal fixation and CPM immediately following surgery while 32 patients (34 knees) had been treated with immobilization.

During the mean follow-up of 13 months, patients who had undergone internal fixation/CPM experienced less shortening of patellar tendons and achieved a better positioning of the patella. This result suggests internal fixation/CPM may be more effective than immobilization for the rehabilitation of gonarthrosis patients following tibial osteotomy. The limitations of this study, such as the retrospective design and lack of blinding, preclude any definitive conclusions. Furthermore, CPM was used in combination with internal fixation and a CPM comparative group, using CPM as the sole treatment, was not included. Therefore, the relative contribution of CPM cannot be evaluated.

Periosteal Transplantation: A retrospective study by Alfredson and Lorentzon (1999) compared the efficacy of adjunct CPM (n=38) with active physical therapy (APT) alone (APT; n=19) for rehabilitation after autologous periosteal transplantation for isolated full-thickness cartilage defects of the patella and disabling knee pain. The main outcome measure was the reduction in knee pain graded as excellent/good, fair, and poor. At a mean follow-up of 51 months, 76% of patients in the CPM group had excellent/good results, 19% had fair results and 5% had poor outcome. The mean follow-up in the group with APT alone was 21 months; 53% of patients in this group achieved excellent/good results, 32% had fair and 15% had poor results. The study results suggest adjunct CPM may provide an added therapeutic benefit for the postoperative rehabilitation of patients with periosteal transplantation for patellar full-thickness cartilage defects and disabling knee pain. The substantial limitations of this study including retrospective design; variable length of follow-up; and small sample size, particularly in the APT group; preclude any definitive conclusions regarding the efficacy and safety of adjunct CPM for this indication.

Upper Extremities
Rotator Cuff Repair: Adjunct CPM for rehabilitation following surgical rotator cuff repair was evaluated the following studies. The main outcome measures were combined shoulder scores for function, pain, muscle strength, and ROM. In addition, postoperative pain severity was assessed using a visual analogue scale (VAS).

Garofalo et al. (2010) conducted a randomized controlled trial (n=100) to evaluate the use of CPM following arthroscopic rotator cuff repair. Immediately postoperatively, patients were randomized to one of two different postoperative physiotherapy regimens: passive self-assisted range of motion exercise (n=46) versus passive self-assisted range of motion exercise associated with use of continuous passive motion (CPM) for a total of 2 hours per day (n=54). After 4 weeks, all patients underwent the same physical therapy protocol. Patients were assessed for pain and range of motion (ROM) at 2.5, 6 and 12 months. The authors concluded that postoperative treatment of an arthroscopic rotator cuff repair with passive self-assisted exercises associated with 2-hour CPM a day provides a significant advantage in terms of ROM improvement and pain relief when compared to passive self-assisted exercise alone over the short term. However, No significant differences between the two groups were observed at 1 year postoperatively.

The first study, an investigator-blinded randomized controlled trial by Raab et al. (1996), compared a standard physiotherapy protocol (n=12) with the adjunct use of a 3-week course of CPM (n=14) following surgical rotator cuff repair. Three months post surgery there was no statistically significant difference in the overall shoulder score between the two groups. However, women aged 60 years or older who received adjunct CPM experienced better pain relief and ROM than younger women who received the same therapy.

The second study, an unblinded randomized controlled trial by Lastayo et al. (1998) compared a manual passive mobilization regimen to a regimen involving CPM plus standard passive mobilization in 31 patients who had undergone rotator cuff repair. Patients receiving the standard mobilization regimen (n=15) underwent therapy 3 times per week for 6 weeks under the supervision of a caregiver who had been trained in the correct use of the CPM device. Patients in the CPM group (n=17) received 4 weeks of CPM for 4 hours per day as well as standard passive mobilization following the same schedule as the standard treatment group for an additional 2 to 5 months. The mean duration of follow-up was 22 months (range 6 to 45 months). Outcome

measures included Shoulder Pain and Disability Index scores that were used to grade overall treatment outcomes as excellent, good, fair, and poor; in addition, ROM and isometric strength were assessed. The overall outcomes for both groups combined were excellent in 84% of shoulders, good in 6%, fair in 7% and poor in 3% of shoulders. While no statistically significant difference was observed between the two groups, patients who had undergone CPM had less pain during the first week following surgery than those who had received standard passive mobilization therapy.

The results of these two studies (Raab et al., 1996; Lastayo et al., 1998) indicate that adjunct CPM may decrease postoperative pain and increase ROM in some patients. CPM, if used concurrently with standard physical therapy, may not provide an additional therapeutic benefit. However, CPM may be an effective substitute for standard physical therapy during the immediate postoperative rehabilitation of rotator cuff repair.

Adhesive Capsulitis (frozen shoulder): A prospective, randomized controlled trial by Dunbar et al. (2008) compared CPM to conventional physiotherapy treatment (CPT) in 57 patients with adhesive capsulitis. The CPM group (n = 29) received CPM treatments 1 hour/day for 20 days during a 4 week period (5 days per week). The CPT group (n = 28) had a daily physiotherapy treatment protocol which included active stretching and pendulum exercises for 1 hour/day for 20 days during a 4 week period (5 days per week). All patients were also given a standardized home exercise program consisting of passive ROM and pendulum exercises to be performed every day until week 12. Outcomes were measured at baseline, 4 weeks and 12 weeks by visual analog scale (VAS), range of motion, constant functional shoulder score and the shoulder pain and disability index (SPADI). Both groups had improvement in all outcome measures however the CPM group had greater pain relief. The authors concluded that CPM treatment provides better pain control than the CPT protocol in the early phase of treatment in adhesive capsulitis. However, the results do not suggest superiority of CPM over conventional physiotherapy. In addition, conclusions that can be drawn from this study are limited by small sample size.

Metacarpophalangeal (MCP) Joint Arthroplasty: A randomized controlled trial by Ring et al. (2005) compared adjunct CPM with a standard rehabilitation protocol in patients with disabling hand deformities secondary to rheumatic arthritis who had silicone interposition arthroplasty of the metacarpophalangeal joints. The study involved 12 patients (15 hands) who underwent a 12-week modified Madden protocol involving static and dynamic splints combined with intermittent active flexion and extension exercises, and 10 patients (10 hands) who were treated with CPM devices and the modified Madden protocol. Range of motion, ulnar deviation, grip strength, and lateral pinch strength were the main outcome measures, assessed prior to surgery and 6 months post surgery. The mean change in postoperative ROM compared with baseline values was significantly greater for patients who had undergone the modified Madden protocol (22 degrees) compared with patients who had been treated using CPM (5 degrees). No statistically significant differences in the remaining outcome measures were observed between the two groups. These results suggest that use of CPM devices may not provide an added therapeutic advantage in the rehabilitation of rheumatoid arthritis patients following metacarpophalangeal interposition arthroplasty for the treatment of disabling hand deformities. In this study the sample size was very small, therefore the power of the statistical analysis may have been too small to measure a treatment effect. Furthermore, the modified Madden protocol for the CPM group was only performed 3 times a day during the first 2 postoperative weeks while it was performed every 2 hours in the comparator group.

Mechanical Stretch Devices

Evidence suggests that low-load prolonged-duration stretch (LLPS) for finger contractures following surgical extensor injury repair may increase range of motion (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. Because there were only one or two studies available for each device type, a systematic analysis of the evidence was not possible. No safety issues associated with mechanical stretching devices were identified in the reviewed studies. (Hayes, 2011b)

Low-load Prolonged-Duration Stretch Devices (LLPS)
Dynamic splinting systems also known as low-load prolonged-duration stretch are spring-loaded, adjustable mechanical stretching devices designed to provide low-load prolonged stretch while patients are asleep or at rest. 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. Dynamic splinting units for both extension as well as flexion are available for elbow, wrist, fingers, knee, ankle and toes. These units are being marketed for the treatment of joint stiffness due to trauma and neurological disorders. Indications included immobilization or limited range of motion (ROM) as a consequence of fractures, dislocations, tendon and ligament repairs, joint arthroplasties, total knee replacements, burns, rheumatoid arthritis, hemophilia, tendon releases, head trauma, spinal cord injuries, cerebral palsy, multiple sclerosis, and other traumatic and non-traumatic disorders.

A search of the peer-reviewed literature identified eight studies that met the criteria for detailed review. Six of the studies evaluated the efficacy and safety of low-load prolonged-duration stretch (LLPS) for the rehabilitation of extensor and flexor tendon injuries of the hand: two randomized controlled trials (Khandwala et al.., 2000; Chester et al., 2002) two prospective, uncontrolled studies (Cetin et al., 2001; Ip et al., 1997) and two retrospective studies. (Crosby et. al., 1999; Bruner et al., 2003) The remaining two studies included for detailed review evaluated mechanical stretch devices in the rehabilitation of knee contractures. Of these, one nonrandomized comparative clinical trial by Hewitt et al. (2001) evaluated SP splinting devices in the rehabilitation of total knee arthroplasty. In addition, one nonrandomized study by Steffen et al. (1995) evaluated LLPS for bilateral knee flexion contractures, using the patients' contralateral knee as a comparator group. No studies were identified that evaluated patient actuated serial stretch (PASS) devices.

Treatment of Knee Contractures: In a small, nonrandomized, comparative study involving 28 patients, Steffen and Mollinger (1995) compared LLPS with a standard program of passive ROM exercises and manual stretching for the treatment of knee flexion contractures in nursing home residents. Residents with bilateral knee contractures of 10 degrees or greater were invited to participate in the study. Only 18 of the 28 patients completed the study. For each patient, both legs received passive ROM and manual stretching twice a week; in addition, one leg of each patient received LLPS for 3 hours per day, 5 days per week. ROM and torque measurements were assessed once a month for 6 months to assess changes in knee extension. At 6 months follow-up, there was no difference in any of the outcomes between the legs receiving LLPS and those receiving passive ROM and manual stretching as the sole treatment. In conclusion, it appears LLPS as an adjunct therapy may not increase knee extension beyond what can be achieved with a standard regimen of passive ROM exercises and manual stretching. Small sample size, large dropout rate, the use of patients' contralateral leg as a comparator, and the short follow-up limit the quality of this study.

Rehabilitation of Extensor/Flexor Injuries of the Hand: 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 second randomized controlled trial by Chester et al. (2002) evaluated 54 patients with simple finger extension division in Verdan's zones 4 to 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 (MCP) joint TAM, median extension lag, and median flexion deficit, assessed at 4 weeks and at a median follow-up of 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 and at 3 months follow-up TAM was similar for both groups (group 1= 100%; group 2= 98%). While 4 weeks postsurgery the median flexion deficit was significantly lower for group 2 patients (25 degrees) compared with group 1 patients (45 degrees), this difference was also not maintained at 3 months follow-up as this value was 0 degrees for both groups. No significant difference in median extensor lag was observed at both times. The results suggest, 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.

In addition, one prospective uncontrolled study by Cetin et al. (2001) of 37 patients (74 digits) with repaired flexor tendon injuries and one retrospective study by Crosby et al. (1999) of 30 hands (50 extensor lacerations) reported on the use of LLPS as adjunct therapy.

A prospective uncontrolled study by Cetin et al. (2001) used 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 results indicate that LLPS combined with passive and active early mobilization exercises may be an effective treatment for repaired flexor tendon injuries.

In a retrospective study by Crosby et al. (1999), 50 extensor tendon lacerations in 30 hands were surgically repaired and treated by immediate mobilization and LLPS. At mean follow-up of 7 months (range, 8 weeks to 2 years), patients regained full ROM in 45 of the 50 tendons. All patients returned to their previous levels of activity in a mean of 10 weeks and regained at least 93% of their predicted strength prior to the injury. The results of this study suggest that LLPS may be effective and safe for the rehabilitation of repaired extensor tendon lacerations.

Overall, an active mobilization regimen combined with LLPS may not improve joint mobility beyond what can be achieved with a regimen of static splinting combined with active mobilization. Adjunct LLPS may, however, achieve the rehabilitation goal sooner than static splinting.

Lumbar Passive Motion Devices

Lumbar CPM devices were designed to aid the healing process of injuries to the spine. The gentle motion is designed to encourage the damaged soft tissues to heal in a normal striated fashion instead of conglomerated scarring. Soft tissues are postulated to reform to more elastic fibers and the formation of scar tissue is reduced. Lumbar CPM manufacturers state that this device will help decrease scarring, edema, and loss of range of motion. The device is prescribed for use at home following established protocols and physician's orders. There is no scientific evidence in the published peer-reviewed medical literature that these devices for patient controlled therapy are safe or effective.

Clinical data are only available at the manufacturer's web pages. These are short summaries of

case series which have not been published in peer- reviewed journals.

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 quality of life. 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 quality of life 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 two postoperative total knee arthroplasty (TKA) mobilization regimens. All 160 patients underwent unilateral total knee arthroplasty 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 patients had better ROM and improved maximum knee flexion compared with Group 2. Blood loss and analgesic requirements were similar for both groups (exact values were not reported). The results of this study suggest 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 total knee arthroplasty. 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 (APT) or passive mobilization, can be achieved. A regimen of APT and SP was superior to APT combined with static splinting.

A retrospective study by Bret et al. (2003) involved 85 patients with 87 extensor tendon injuries who underwent regimens of SP stretch splinting and active mobilization following extensor tendon repair in Verdan's zones 5 to 7. At a mean follow-up of 21 months (range, 5 to 39), results were deemed to be excellent and good in more than 94% of cases and fair in the remainder. From this study, it appears that SP stretch splinting may be effective for rehabilitation after surgery for extensor tendon injuries of the hand.

The lack of a control or comparator group was the main factor limiting the quality of these studies; therefore, it is not clear whether SP stretch splinting would provide an additional therapeutic benefit if used in combination with standard early mobilization.

While more studies were available for static progressive 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 preliminary evidence suggests that overall an active mobilization regimen combined with static progressive may not improve joint mobility beyond what can be achieved with a standard PT program. Adjunct static progressive may, however, achieve the rehabilitation goal sooner than static splinting and PT.

Although proponents of static progressive 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 static progressive stretch to any other type of device. Instead, there were 7 seven uncontrolled case studies or case series identified in which devices using static progressive stretch were used to treat injured elbow Kazmareck and McMahon, 2004; Bonutti et

al., 1994; Ring et al., 1994), and knee (Jansen et al., 1996) joints. Although all of the studies reported improved range of motion, in the absence of any comparison groups the actual effects of treatment cannot be determined. Factors other than static progressive stretch may be responsible for patient improvement.

Published reports of the effectiveness of joint active system splints are limited to case reports and small uncontrolled case series. There is limited evidence demonstrating that the addition of the use of JAS devices to the physical therapy management of patients with joint injury or surgery significantly improves the patient's clinical outcomes.

Upper Extremities

Rehabilitation of Extensor Tendon Injuries of the Hand: A retrospective study by Ip et al. (1997) involved 84 patients with 101 extensor tendon injuries. All patients underwent surgical tendon repair. Two days post surgery, a palmar wrist slab was applied with the patients' wrists in 30 degrees extension; thumbs and index fingers could be extended individually; all other digits were fully extended. The rehabilitation program included a combination of physical therapist-guided exercises and active flexion. The static progressive (SP) splints were progressively adjusted from 30 degrees as the beginning flexion setting; 45 degrees as the second setting; and 60 degrees as the third setting. The angle was then further increased until full active flexion was achieved. Outcomes for the thumb were assessed with the Dargan system, Buck-Gramcko system, and total active motion (TAM) score. Outcomes were assessed at baseline, and 8 weeks and 6 months post surgery. For the fingers, the Dargan system, TAM score, and power grip were assessed. Buck-Gramcko evaluation results for thumbs were excellent, good, and fair in 67%, 30%, and 3% of tendons, respectively. Results as assessed using the Dargan score for thumbs and fingers were excellent in 97% and 83%, good in 0 and 9%, fair in 3% and 6%, and poor in 0 and 2% of patients, respectively. Mean TAM was 107 degrees for thumbs and 246 degrees for fingers. No treatment-related complications were observed.

A retrospective study by Bruner et al. (2003) involved 85 patients with 87 extensor tendon injuries who underwent regimens of SP stretch splinting and active mobilization following extensor tendon repair in Verdan's zones 5 to 7. The functional results were evaluated with three systems: the Geldmacher's, (Geldmacher et al., 1986) the Kleinert and Verdan system, (Kleinert et al., 1983) and the Miller's system (Miller 1942); all three systems provided a grading of excellent, good, fair, and poor. At a mean follow-up of 21 months (range, 5 to 39), results were deemed to be excellent and good in more than 94% of cases, and fair in the remainder. From this study, it appears SP stretch splinting may be effective for rehabilitation after surgery for extensor tendon injuries of the hand. The lack of a control or comparator group was the main factor limiting the quality of these studies and it is therefore not clear whether SP stretch splinting would provide an additional therapeutic benefit if used in combination with standard early mobilization.

Lower extremities

Rehabilitation Post Total Knee Arthroplasty: A clinical trial by Bonutti et al. (2008) evaluated the use of static progressive stretch, using the JAS knee device, as a treatment modality in 41 consecutive patients with knee stiffness. Patients received treatment for a mean of 9 weeks (range 3 to 27 weeks) with follow-up at a mean of 1 year (range, 6 months to 2 years). Range of motion was the primary outcome measurement. All patients had an increase in range of motion. The mean increase was 33° (range, 0 to 85°), with a mean pretreatment total arc of motion of 69° (range, 21 to 96°), and a mean follow-up total arc of motion of 102° (range, 55 to 130°). Patients gained a mean of 9° of extension (range, −14 to 30°) and a mean of 24° of flexion (range, 1 to 80°). The authors concluded that the use of static progressive stretch devices may be useful in treating knee stiffness. The study is limited by small sample size and lack of a comparison group.

In a prospective, nonrandomized, comparative clinical study, Hewitt and Shakespeare (2001) compared two postoperative TKA mobilization regimens. All 160 patients underwent unilateral TKA and were then assigned to one of two rehabilitation regimens: a static progressive flexion regimen (group 1, n=86) during which the patient's knee was, every 2 hours, placed on a 90

degrees splint for 10 minutes followed by 10 minutes of passive extension combined with exercises; or a regimen of static extension splinting combined with physical therapist-guided flexion exercises (group 2, n=74). 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 patients had better range of motion (ROM) (group 1= 99.94 degrees; group 2= 92.04 degrees) and improved maximum knee flexion (group 1= 104.82 degrees; group 2= 98.18 degrees) compared with group 2. Blood loss and analgesic requirements were similar for both groups (exact values were not reported). The results of this study suggest 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.

Patient-Actuated Serial Stretch PASS

There is a lack of data in the published, peer-reviewed, scientific literature demonstrating long-term improved patient outcomes through the use of patient actuated stretch such as ERMI extensionators® or ERMI flexionators® for the treatment of joint stiffness or post-surgical rehabilitation.

There is no published peer-reviewed clinical data 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 reinjury 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.

Branch et al. (2003) conducted a prospective study to determine the effectiveness of using patient-controlled home mechanical therapy to increase knee ROM in patients with knee contracture. The sample size included 34 patients who had failed to reach full ROM with a 6-week regimen of conventional physical therapy. Patients included those who developed knee contractures following anterior cruciate ligament (ACL) injury (n=14), peripatellar injury (n=7), fracture (n=4), and other, unspecified causes (n=9). These patients used a patient-controlled device (the ERMI Knee/Ankle Flexionater®times daily for 15 minutes. The duration of the treatment ranged from two to 12 weeks. Thirty-one (91.2%) of these patients regained functional flexion after 6.7 weeks. Full ROM was regained by 74% of the patients and mean knee flexion progressed from 70.8 degrees to 130.6 degrees. Two patients in this study required surgical manipulation. Conclusions regarding this study are limited by the small sample size and lack of a control group. Furthermore, due to the overall lack of published studies investigating PASS devices, no conclusion can be drawn regarding their efficacy in treating joint stiffness or contractures for any other indication.

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 ankle (ERMI Knee/Ankle Flexionater®Extensionater®Extensionater® Flexionater® (ERMI Shoulder Flexionater®custom fitted. Typically a certified ERMI representative develops an individualized treatment protocol and provides training regarding its correct usage.

No studies on ERMI products have been published. (Washington State Department of Labor and Industries, 2003)

There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of the use patient-actuated serial stretch (PASS) 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

Additional Search Terms
Acetabular joint, Dupuytren's contracture

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

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.

Continuous passive motion devices, under product code BXB, are 510(k) class I exempt devices. A large number of bed-mounted, stationary, and portable CPM units have been approved by the FDA over the past 15 years. Examples for FDA approved CPM devices include the Artromot® CPM systems, Danniflex CPM devices, Elbow CPM Orthoses, Jace CPM device, Mobilimb and MULTILINK CPM, and Sutter CPM devices. Additional information is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accesses November 7, 2013

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. Accesses November 7, 2013

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.).

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare covers the use of Continuous Passive Motion Devices (CPM) when criteria are met. See the National Coverage Determination (NCD) for Durable Medical Equipment Reference List (280.1) for coverage criteria. Local Coverage Determinations (LCDs) do not exist at this time. (Accessed November 7, 2013)

Medicare does not have a National Coverage Determination for Mechanical Stretching Devices. LCDs do not exist at this time. (Accessed November 7, 2013)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
02/01/2014	• Reorganized policy content • Updated description of services to reflect most current clinical evidence and references; no change to coverage rationale or list of applicable codes • Archived previous policy version 2013T0481I