MECHANICAL STRETCHING AND CONTINUOUS PASSIVE MOTION DEVICES

Policy Number: 2013M0012A  Effective Date: January 1, 2014

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee's specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual 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. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:

This policy describes the use of mechanical stretching devices (also known as dynamic splinting devices) and continuous passive motion (CPM) devices for the prevention and treatment of joint contracture or stiffness, commonly caused by immobilization or limited range of motion (ROM), following injury, disease, or surgery. The goal is to restore and maintain range of motion (ROM) and flexibility to the joint in the early postoperative period or immediately following an injury. CPM allows passive movement to be performed for long periods and while the patient and caregivers are sleeping. These devices are available for many joints of the body. They are intended to complement physical therapist-directed sessions by providing frequent and consistent joint mobilization under controlled conditions in a hospital setting or in the patient’s home.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

Continuous Passive Motion (CPM) Devices:

A CPM device may be considered MEDICALLY NECESSARY durable medical equipment (DME) for use postoperatively, as an adjunct to conventional rehabilitation (e.g., physical therapy, home exercise program), in individuals who have undergone total arthroplasty (knee replacement), revision of total knee replacement, or revision of a worn component. Use of the CPM device must begin within 48 hours of the surgical procedure (or on discharge from facility following the procedure) and may continue for ONLY up to 21 days postoperatively.

The use of CPM device is NOT MEDICALLY NECESSARY for the rehabilitation or treatment of any other knee indication, including but not limited to:

- following treatment of knee arthrofibrosis by manipulation under anesthesia and/or surgical release
- following anterior or posterior cruciate ligament (ACL, PCL) repair/reconstruction
- following an injury or surgical repair of the articular cartilage of the knee

The use of a CPM device for rehabilitation or treatment of ANY other joint, including but not limited to the shoulder, elbow, wrist, hand, or hip, or for any other indication, is considered EXPERIMENTAL AND/OR INVESTIGATIONAL, including but not limited to the following:

- Low back pain (lumbar continuous passive motion device)
- Postoperative rehabilitation for:
  - Shoulder, elbow, or hand surgery (e.g., rotator cuff repair)
  - Total hip replacement (THR)
  - Temporomandibular joint (TMJ) surgery
  - Ankle or toe surgery (e.g., bunionectomy)
- Treatment of osteoarthritis in the shoulder, hip, or any other major joint;
- Aiding in the clearance of infection from a septic joint;
- Treatment of hemarthrosis in hemophiliac patients;
- Treatment of contractures caused by burns, trauma, and Dupuytren’s contractures;
- Treatment of any other conditions not listed above.

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.
**Mechanical Stretching Devices:**
The use of low-load prolonged-duration stretch (LLPS) devices, also referred to as dynamic splinting (e.g., Dynasplint System®, Ultraflex, Pro-glide™ Dynamic ROM, Advance Dynamic ROM®), may be considered **MEDICALLY NECESSARY** durable medical equipment (DME), as an adjunct to (and not replacement of) physical therapy, in individuals who have undergone major open joint surgery of the finger, wrist, elbow or knee joints, and have a prior history of joint contractures or loss of joint motion. **Use of these systems should begin in the acute postoperative period following surgery to improve the range of motion of a previously affected joint (≥ 3 weeks but ≤ 4 months after surgery).** The use of any stretching device for more than four months is considered **EXPERIMENTAL AND/OR INVESTIGATIONAL**.

Use of LLPS dynamic splinting devices for the rehabilitation or treatment of any other joint or condition not listed above, including but not limited to foot, toe, shoulder, jaw and ankle disorders, plantar fasciitis, fractures, burns, rheumatoid arthritis, head and spinal cord injuries, carpal tunnel, multiple sclerosis, muscular dystrophy, or cerebral palsy are considered **EXPERIMENTAL AND/OR INVESTIGATIONAL**. There is insufficient evidence in the published medical literature to permit conclusions on safety, efficacy and long-term outcomes.

Static progressive (SP) stretch splint devices, such as JAS Static Progressive Stretch, and patient actuated serial stretch (PASS) devices, such as the ERMI Extensionater and Flexionater, are considered **EXPERIMENTAL AND/OR INVESTIGATIONAL** for the treatment of joint contractures or any other indication, alone or combined with standard physical therapy. 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.

**Clinical Considerations:**

**Initial Management/Treatment:**
Possible Complications: The use of mechanical stretching devices was not associated with a significant increase in complication rates. In one retrospective study, investigating SP for contractures of the elbow, several possibly device-related complications occurred, including: pin-track infection (5), pin-track osteomyelitis (1), broken screws (2), ulnar nerve irritation (2), and fracture related to pin (1) (Ring et al., 2005).

No specific credentials beyond a license to practice medicine are required to prescribe a mechanical stretching device. A physical therapist or nurse may be required to instruct patients in the correct use of the device or to assist with the use of the device; however, some of these devices can be used by the patient at home.

**BACKGROUND:**

A joint contracture is characterized by a chronically reduced range of motion (ROM) secondary to structural changes in non-bony tissues, including muscles, tendons, ligaments, and skin. This joint dysfunction occurs when elastic connective tissue is replaced with inelastic fibrous material, making the tissue resistant to stretching. Joint contractures may be the result of immobilization following an injury, surgery, or disease; nerve damage, such as stroke or spinal cord injury; or muscle, tendon, or ligament disease.

A number of different modalities are used to treat or prevent joint contractures, including manual joint mobilization by a physical therapist, serial plastering, static splinting, mechanical stretching devices,
continuous device-assisted passive motion (CPM), massage, exercise, electrical stimulation, botulinum toxin, and surgery. 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 and James, 2001).

This medical policy focuses on the use of mechanical stretching and CPM devices for the treatment of joint contractures of the extremities, either alone or as an adjunct to active physical therapy or passive therapist-guided joint mobilization with or without static splinting.

The use of mechanical stretching and CPM devices is based on the theory that passive motion early in the healing process can provide movement of the synovial fluid, and thus promote lubrication of the joint, stimulate the healing of articular tissues, prevent adhesions and joint stiffness, and reduce edema, without interfering with the healing of incisions or wounds over the moving joint. These devices are intended to replace or complement some physical therapist-directed sessions by providing frequent and consistent application of joint mobilization under controlled conditions in a hospital or in the patient’s home. The goal of these modalities is to restore ROM (Farmer and James, 2001).

Continuous passive motion (CPM) devices are available for many joints of the body, including the knee, ankle, jaw, hip, elbow, shoulder, and finger joints (Adams and Thompson, 1996; ERMI, 2011; Nextag.com, 2011). During CPM therapy, the joint area is secured in the CPM device and the device is programmed to passively flex and extend the joint through a preselected range of motion (ROM) and duration. The CPM device normally attaches to the extremity above and below the joint in such a way that it will not interfere with blood circulation or other aspects of healing. The clinician sets and adapts the extent of motion and speed individually to the patient. Movement is slow and controlled, and the patient does not actively exert muscle force to move the joint (Salter, 1996). Different CPM protocols exist and there is currently no consensus on standard parameters. For surgical applications, CPM is usually initiated either in the recovery room immediately after surgery or during the early postoperative period. CPM therapy may involve from 1 to 24 hours of treatment per day. It is often used as an adjunct to physical therapy regimens and may continue for 1 to 6 weeks; duration can vary significantly, depending on the diagnosis and goals of the therapy (Salter, 1996).

A variety of mechanical stretching devices are available for extension or flexion of shoulder, elbow, wrist, fingers, knee, ankle, and toes. This category includes static progressive (SP) stretch, low-load prolonged-duration stretch (LLPS) (also referred to as dynamic splinting), and patient-actuated serial stretch (PASS) (also known as patient-directed serial stretch) devices. In most cases, mechanical stretching devices are used as an adjunct treatment to physical therapy and/or exercise.

- Bi-directional static progressive (SP) stretch devices: SP stretch devices hold the joint in a set position but allow for manual modification of the joint angle and may allow for active motion without resistance (inelastic traction). This type of device itself does not exert a stress on the tissue unless the joint angle is set at the maximum range of motion. An example for this type of device is the Joint Active Systems (JAS) (Joint Active Systems, 2011).
- Low-load prolonged-duration stretch (LLPS) devices: 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. Examples of LLPS devices include Dynasplint System® (Dynasplint Systems Inc.); Ultraflex (Ultraflex Systems Inc.); LMB Pro-Glide devices (DeRoyal Industries); Advance Dynamic ROM®, Saunders®, Pronex® (Empi).
- Patient-actuated serial stretch (PASS) devices: PASS devices permit resisted active and passive motion (elastic traction) within a limited range. PASS devices provide a low- to high-level load to the joint using pneumatic, e.g., Extensionaters (ERMI Inc.), or hydraulic, e.g., Flexionaters (ERMI Inc.), systems that can
be adjusted by the patient. Examples of PASS devices include ERMI Knee Extensionater®, ERMI Elbow Extensionater®, ERMI Knee/Ankle Flexionater®, and ERMI Shoulder Flexionater® (ERMI, 2011).

REGULATORY STATUS:

1. U.S. FOOD AND DRUG ADMINISTRATION (FDA):

   Numerous mechanical stretch and continuous passive motion devices are available in the United States (CDRH, 2011).

   Continuous passive motion devices, under product code BXB, are classified as powered exercise equipment and 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. Accessed February 18, 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.).

   Note: 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.

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):

   CPM devices are covered in patients who have undergone total knee replacement/arthroplasty (ICD-9 diagnosis code V43.65 or CPT code 27447), or revision of a total knee replacement/arthroplasty (CPT code 27486 or 27487) if CPM is commenced within 2 days post surgery. Coverage is limited to a 3-week time frame following surgery, during which the device is used in the patient’s home. There is insufficient evidence to justify coverage of these devices for longer periods of time or for other applications (E0935-E0936) and will be denied as not medically necessary.

   See the National Coverage Determination (NCD) for Durable Medical Equipment reference list (280.1). See Local Coverage Article for CPM Devices (A2613).

   CMS has not established a National Coverage Determination (NCD) for the use of mechanical stretching devices for the treatment of joint contractures (CMS, 2011). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):

   Minnesota DHS does not have a policy statement regarding CPM or MSD devices in its Provider Manual or other specific provider references.
**CLINICAL EVIDENCE:**

There was no restriction to patient age and etiology, and included were adult and pediatric patients with joint contractures of the extremities secondary to surgery, trauma, stroke, and joint degeneration. The studies had to report on the effect of mechanical stretching on range of motion (ROM) or function of the affected joint. Excluded were case reports, studies older than 20 years, and preclinical and cadaver studies.

**SUMMARY**

**MECHANICAL STRETCHING DEVICES:**

Although evidence from well designed clinical trials on the use of mechanical stretch devices is lacking, SP stretch devices and LLPS devices/dynamic splinting are frequently employed and have gained acceptance as components of the postoperative rehabilitation of fingers, wrists, elbows and knees. These devices may also be considered in the rehabilitation of these joints following subacute injury, or for contracture when a formal rehabilitation program is not feasible or has failed to provide benefit.

Evidence from five randomized controlled trials and two uncontrolled studies 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 is insufficient evidence in the published medical literature to support the use of SP stretch devices or LLPS/dynamic splinting devices for other joints applications (e.g., shoulder and ankle), for chronic conditions (e.g., rheumatoid arthritis, plantar fasciitis) or in the treatment of cerebral palsy. There is insufficient evidence to demonstrate the safety, efficacy, and long-term outcomes of the use patient-actuated serial stretch (PASS) for any indication. 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. There are very few published studies that evaluate the use of jaw stretch devices or of passive rehabilitation of the TMJ using any device, as compared to traditional methods of treating jaw hypomobility.

**CONTINUOUS PASSIVE MOTION (CPM):**

The published studies provide evidence that continuous passive motion (CPM) can improve health outcomes in the early postoperative phase (21 days post-operation) in patients who have undergone total knee arthroplasty (TKA) or anterior cruciate ligament (ACL) repair/reconstruction. There is adequate evidence that CPM used as an adjunct to active physical therapy may decrease knee swelling, improve flexion and decrease the need for knee manipulation following these procedures. CPM may also be used following posterior cruciate ligament (PCL) repair, following injury or surgical repair of the articular cartilage of the knee, or to treat knee arthrofibrosis that may occur following surgical procedures performed on the knee. CPM has also been proposed for rehabilitation of other joints such as the shoulder, elbow, wrist, hand, ankle, knee, or hip, and for treatment of numerous conditions, including degenerative joint conditions and diseases (e.g., rheumatoid arthritis, Dupuytren’s contracture). There is insufficient evidence in the medical literature evaluating the use of CPM for these conditions or for rehabilitation of joints other than the knee. Evidence published to date has failed to demonstrate that the use of CPM results in improved outcomes (i.e., decreased
pain or improved range of motion) when applied to other joints/conditions, compared to an active physical therapy program.

**APPLICABLE CODES:**

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>E0935</td>
<td>Continuous passive motion exercise device for use on knee only</td>
</tr>
<tr>
<td>E1800</td>
<td>Dynamic adjustable elbow extension/flexion device, includes soft interface material</td>
</tr>
<tr>
<td>E1802</td>
<td>Dynamic adjustable forearm pronation/supination device, includes soft interface material [not covered for carpal tunnel syndrome]</td>
</tr>
<tr>
<td>E1805</td>
<td>Dynamic adjustable wrist extension/flexion device, includes soft interface material [not covered for carpal tunnel syndrome]</td>
</tr>
<tr>
<td>E1810</td>
<td>Dynamic adjustable knee extension/flexion device, includes soft interface material</td>
</tr>
<tr>
<td>E1825</td>
<td>Dynamic adjustable finger extension/flexion device, includes soft interface material</td>
</tr>
<tr>
<td>E1830</td>
<td>Dynamic adjustable toe extension/flexion device, includes soft interface material</td>
</tr>
<tr>
<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>
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<th>ICD-9-CM Diagnosis Codes</th>
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<tr>
<td>714.0</td>
<td>Rheumatoid arthritis</td>
</tr>
<tr>
<td>714.30</td>
<td>Polyarticular juvenile rheumatoid arthritis, chronic or unspecified</td>
</tr>
<tr>
<td>715.x</td>
<td>Osteoarthritis and allied disorders</td>
</tr>
<tr>
<td>717.83</td>
<td>Old disruption of anterior cruciate ligament</td>
</tr>
<tr>
<td>718.0</td>
<td>Articular cartilage disorder</td>
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<tr>
<td>727.00</td>
<td>Synovitis and tenosynovitis</td>
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<tr>
<td>727.61</td>
<td>Complete rupture of rotator cuff</td>
</tr>
<tr>
<td>727.9</td>
<td>Tendon injury</td>
</tr>
<tr>
<td>728.6</td>
<td>Contracture of palmar fascia (Dupuytren’s contracture)</td>
</tr>
<tr>
<td>754.5-754.7</td>
<td>Clubfoot not specified as acquired</td>
</tr>
<tr>
<td>869.1</td>
<td>Severe multiple injuries</td>
</tr>
<tr>
<td>V43.60</td>
<td>Autologous chondrocyte transplantation (unspecified joint replacement by other means)</td>
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<tr>
<td>M15-M19</td>
<td>Arthrosis</td>
</tr>
<tr>
<td>M06.9</td>
<td>Rheumatoid arthritis, unspecified</td>
</tr>
<tr>
<td>M08.0</td>
<td>Juvenile rheumatoid arthritis</td>
</tr>
<tr>
<td>M65</td>
<td>Synovitis and tenosynovitis</td>
</tr>
<tr>
<td>M72.0</td>
<td>Palmar fascial fibromatosis [Dupuytren]</td>
</tr>
<tr>
<td>S46.0</td>
<td>Injury of tendon of the rotator cuff of shoulder</td>
</tr>
<tr>
<td>S83.5</td>
<td>Sprain and strain involving anterior or posterior cruciate ligament of knee</td>
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<tr>
<td>29126</td>
<td>Application of short arm splint (forearm to hand); dynamic</td>
</tr>
<tr>
<td>29131</td>
<td>Application of finger splint; dynamic</td>
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</table>
Application of long arm splint (shoulder to hand)

Application of long leg splint (thigh to ankle or toes)

Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(s), lower extremity(s) and/or trunk, each 15 min

CPT® is a registered trademark of the American Medical Association

REFERENCES:


POLICY HISTORY:

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