

# **Medical Coverage Policy**

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# **Continuous Passive Motion (CPM) Devices**

### **Table of Contents**

# **Related Coverage Resources**

Overview	2
Coverage Policy	
Health Equity Considerations	2
General Background	2
Medicare Coverage Determinations.	10
Coding Information	10
References	10
Revision Details	14

<u>Manipulation Under Anesthesia</u> Physical Therapy

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Page 1 of 14

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

#### Overview

This Coverage Policy addresses the use of continuous passive motion (CPM) devices for rehabilitation after surgery and to treat other conditions.

## **Coverage Policy**

The use of a continuous passive motion (CPM) device is considered not medically necessary for ANY indication.

### **Health Equity Considerations**

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Osteoarthritis (OA) is the most frequent cause of disability for adults in the United States, and the leading indication for joint replacement surgery. Twenty seven million adults had clinical OA in 2005, and in 2009, OA was the fourth most common cause of hospitalization (Weber, et al., 2016). Risk factors for surgical complications after joint replacement and/or impaired healing may include: obesity, diabetes, chronic pain, depression, anxiety, and liver problems. Additionally, people who sustain anterior cruciate ligament (ACL) injuries are at an increased risk for developing arthritis later in life. Approximately 252,000 patients present with ACL injuries every year, and females are two to eight times more likely than males to suffer an ACL injury (Shea and Carey, 2015).

# **General Background**

Continuous passive motion (CPM) is a rehabilitation technique designed to assist in recovery of joint range of motion (ROM). CPM provides progressive passive ROM to an extremity through an externally applied force. The device contains two parts: a carriage for support of the extremity and a controller that can be programmed for ROM, speed, pause, and duration of treatment. During CPM therapy, the joint area is secured in the device, which is programmed to flex and extend the joint passively. CPM use is based on the theory that recovery will be accelerated by decreasing soft tissue stiffness, increasing ROM, promoting healing of joint surfaces in soft tissues, and preventing the development of adhesions. Motion and stress are important for the maintenance of normal connective tissue and the healing of injured connective tissue. Motion enhances blood flow and decreases pain. Passive motion involves movement of a joint without active contraction of muscle groups.

Page 2 of 14

CPM has been used in the rehabilitation period following surgery or injury to synovial joints or associated tissues. It is generally used as an adjunct to active physical therapy (PT). Most of the published literature has evaluated CPM following total knee arthroplasty (TKA). CPM has also been used for other knee indications including rehabilitation following ACL reconstruction or repair, posterior cruciate ligament (PCL) repair, and following manipulation under anesthesia or surgical release of knee arthrofibrosis. Knee arthrofibrosis may occur following surgical procedures performed on the knee, and following an injury or surgical repair of the knee articular cartilage. CPM has been proposed for treatment of various other joints, including the shoulder, elbow, wrist, hand, ankle, hip, and temporomandibular joint.

#### U.S. Food and Drug Administration (FDA)

CPM machines are considered Class I devices and are generally exempt from the FDA premarket notification 510(k) process. CPM devices are most commonly used for the knee, but are available for many joints, including the elbow, hip, ankle, shoulder, and fingers. Examples of CPM devices include the Artromot® CPM systems (Ormed Inc., Concord, CA), Danniflex CPM devices (Danninger Medical Technology Inc., Concord, CA), Elbow CPM Orthosis (Electrobionics Corp., Ankeny, IA), Jace CPM device (Jace Systems, Moorestown, NJ), Mobilimb and Multilink devices (Toronto Medical Corp., Ontario, Canada), and Sutter CPM devices (Sutter Corp., San Diego, CA).

#### **Literature Review—Lower Extremity**

Continuous passive motion (CPM) has been used following total knee arthroplasty (TKA) since the 1980s, despite robust evidence that demonstrates the addition of CPM to standard physical therapy rehabilitation following TKA has no impact on long-term health outcomes. There is some conflicting evidence suggesting the addition of CPM to standard physical therapy may improve range of motion (ROM) during the immediate postoperative time frame and reduce the risk of manipulation under anesthesia. However, final ROM is comparable to that achieved with physical therapy alone (Jia, et al., 2024). There is insufficient evidence in the published peer-reviewed medical literature to demonstrate that CPM when used alone or as a component of standard treatment or rehabilitation for other knee conditions results in improved outcomes.

Total Knee Arthroplasty (TKA): Gil-González et al. (2022) conducted a randomized controlled trial (n=220) to assess the effect of continuous passive motion (CPM) on range of motion (ROM), surgical wound healing, and pain level in patients undergoing total knee arthroplasty (TKA) for the treatment of osteoarthritis. The study excluded individuals with a high degree of deformity; knee contracture; inflammatory arthropathies; or previous surgeries in the same knee. The non-CPM group received a standard rehabilitation program with a physiotherapist beginning the day of surgery, through 10 days post-discharge. The CPM group received the same program, with the addition of CPM therapy until hospital discharge. Six patients were excluded from analysis due to postoperative complications, and four additional patients were lost to follow up. Both the CPM and non-CPM groups demonstrated significant improvement of flexion, extension and ROM between admission and discharge, and over the course of follow-up (all p<0.010). The CPM group showed significantly greater improvement in the operative knee ROM at the earliest follow up points, but by the 24th postoperative week there was no statistically significant difference in ROM between the groups. There was no difference in total surgical wound aspect score (SWAS) or pain level, although significantly more patients in the non-CPM group developed hematoma. Aside from this decreased risk of postoperative hematoma, the study did not find significant clinical improvement in ROM, knee flexion, surgical wound appearance, or pain level when CPM was added to the postoperative treatment of TKA.

Yang et al. (2019) conducted a systematic review and meta-analysis to evaluate the efficacy of CPM after total knee arthroplasty (TKA) and whether the use of CPM is related to improved clinical and functional outcomes. A total of 16 trials with 1224 patients were included. The pooled results revealed that use of CPM did not show a statistically significant improvement of postoperative

Page 3 of 14

knee range of motion (ROM) except for middle-term passive knee extension and long-term active knee flexion ROM. Also, CPM therapy did not show a significant positive effect on functional outcomes. No significant reduction in length of stay (LOS) or incidence of adverse events (AEs) was identified.

Schulz et al. (2018) conducted a randomized controlled trial including 50 patients; 25 allocated to the continuous passive motion (CPM) group and 25 to the controlled active motion (CAM) group. All 50 patients used an identical device, which enabled the performance of active motion and passive motion by different program settings. All patients were postoperative total knee arthroplasty and received an additional physiotherapeutic therapy program. The follow-up period was 30 days. Pain, knee associated problems (Knee Injury and Osteoarthritis Outcome Score [KOOS]), active range of motion (AROM), and adverse events were documented before surgery, during the stationary stay and after an outpatient period. During the postoperative period, KOOS scales improved significantly in both groups, but the CAM group showed a significantly better improvement of pain and quality of life scale. Furthermore, postoperative course of pain intensity and knee flexion was significantly better in the CAM group.

A Cochrane systematic review on continuous passive motion following total knee arthroplasty in people with arthritis (Harvey, et al., 2014) summarized "The findings of 24 RCTs of 1445 participants provide moderate-quality evidence that CPM does not have clinically important short-term effects on active knee flexion ROM or medium-term effects on function or quality of life. There is low-quality evidence to indicate that CPM does not have clinically important short-term effects on pain. The effects of CPM on participants' global assessment of treatment effectiveness, risk of manipulation, risk of adverse events, length of hospital stay, swelling and quadriceps strength remain unclear although there is very low-quality evidence to indicate that CPM reduces the risk of manipulation under anesthesia."

A Cochrane systematic review by He et al. (2014) evaluated the use of continuous passive motion for preventing thrombosis after total knee arthroplasty. Eleven randomized controlled trials involving 808 patients met the inclusion criteria. Five studies (405 patients) reported the incidence of deep vein thrombosis (DVT). In the CPM group (205 patients) 36 developed DVT (18%) compared to 29 (15%) in the control group of 200 patients. The meta-analysis showed no evidence that CPM had any effect on preventing venous thromboembolism after TKA (RR 1.22, 95% CI 0.84 to 1.79). No deaths were reported. The authors concluded that there is not enough evidence from the available randomized controlled trials to conclude that CPM reduces venous thromboembolism after TKA.

Postel et al. (2007) performed a systematic review of the literature regarding the use of CPM after TKA in order to develop clinical practice guidelines. After analysis of 21 studies included in the review, the authors determined that CPM after TKA could have short-term beneficial influence on the speed of recovery of motion, early flexion, postoperative pain, knee swelling and length of hospital stay but found no long-term confirmation of the early benefit of CPM. The authors concluded that, although there is insufficient evidence to recommend substituting CPM for other modalities of rehabilitation following TKA, it can be used as an adjunctive option to accelerate short-term results.

**Anterior Cruciate Ligament (ACL) Reconstruction**: Friemert et al. (2006) studied 60 patients following ACL rupture with reconstruction, to compare continuous active motion (CAM) to continuous passive motion (CPM). Patients were randomized, and an angle reproduction test was used to assess the proprioceptive deficit. No preoperative difference was found between the two groups. The angle examinations were performed before surgery and after the seventh postoperative day. After postoperative treatment, the deficit was reduced in both groups. Significantly better results were obtained in the CAM group (CPM, 4.2+/-1.6 degrees; CAM, 1.9+/-

Page 4 of 14

1.2 degrees; p<0.001). The authors noted that during the first postoperative week, a CAM device produced a significantly greater reduction in the proprioceptive deficit. It is unknown if this advantage is sustained past the first week after surgical ACL repair.

Engstrom et al. (1995) reported on a prospective randomized study of 34 patients with unilateral anterior cruciate ligament ruptures randomized to either the early active motion group (n=17) or the active motion with CPM group (n=17). Outcome measurements included ROM and joint swelling, evaluated preoperatively and at six weeks post-operation. At six weeks follow-up, there was no difference in ROM between the two groups, and joint swelling was more pronounced in the early active motion group. The data suggests that CPM did not improve ROM.

McCarthy et al. (1993) evaluated the effect on pain when CPM is used immediately following ACL reconstruction. Thirty patients were randomized to a rehabilitation program with CPM (n=15) or without CPM (n=15). The CPM group used significantly less (p<0.05) narcotics within the first postoperative 24 hours and used patient-controlled analgesia (PCA) less frequently (p<0.05) compared to the no-CPM group. The CPM group also received significantly less (p<0.05) oral medication on postoperative days two and three. There was no significant difference between the two groups regarding perceived pain. The study did not address whether these results affected functional outcome.

Rosen et al. (1992) conducted a prospective study to examine the effects of CPM and supervised active ROM following ACL repair (n=75). Patients with ACL deficiencies treated with arthroscopic ACL autograft reconstruction were randomized into one of three groups. Group A (n=25), the active motion group, received PT three times a week. Group B (n=25) received PT and CPM. Group C (n=25) received CPM but no formal PT. Evaluations occurred at specific intervals for six months. The authors reported no statistically significant differences among the three groups in drain output, medication usage, hospital length of stay, or in any other outcome measures. The authors concluded that effects of CPM on ROM were similar to that of active motion and that neither protocol had deleterious effects on stability.

**Knee Arthrofibrosis**: Arthrofibrosis and associated stiffness may occur following total knee arthroplasty (TKA), and other surgical procedures, including ACL reconstruction or total knee arthroplasty, and is associated with inflammation and scar tissue proliferation. Arthrofibrosis may also occur following traumatic injury of the knee. Treatment options for knee arthrofibrosis include physical therapy, manipulation under anesthesia (MUA), arthroscopic debridement, and open debridement. Open release of adhesions or revision surgery may be considered for refractory arthrofibrosis or in cases of component malposition or damage following TKA (Fitzsimmons et al., 2010).

Although CPM has been used as a component of rehabilitation for arthrofibrosis following MUA and/or surgical release, the impact of CPM as an individual variable has not been demonstrated in the published medical literature. There is insufficient evidence to determine whether the addition of CPM to standard rehabilitation programs improves outcomes.

**Idiopathic Clubfoot**: Zeifang et al. (2005) conducted a blinded, randomized trial to determine whether CPM use after the surgical correction of clubfoot could improve the results in resistant clubfeet which required an extensive soft-tissue release. Of 37 post-surgery patients, 19 received CPM and 18 had standard immobilization in a cast. The Dimeglio clubfoot score was used as the primary outcome measure. CPM was applied for a minimum of four hours per day for each foot in the CPM group. The range of movement in the feet treated by CPM was significantly increased at six and 12 months after operation compared with those treated by casting (p=0.013 and p=0.009, respectively). However, at 48 months, the Dimeglio clubfoot score improved from 10.3 preoperatively to 3.89 for the surgery/casted feet and from 9.68 to 4.47 for the surgery/CPM feet.

Page 5 of 14

The authors stated that no significant difference was found after 48 months. They concluded that since no additional benefit could be shown in the long term with the use of CPM and the number of feet requiring additional surgery was similar in both groups, it is difficult to recommend the use of CPM treatment which is also much more expensive.

**Tibial Head Fracture**: Kabst et al. (2022) reported on a prospective randomized, nonblinded, controlled single-enter trial of 60 patients who underwent open reduction and internal fixation (ORIF) for the treatment of tibial head fracture (THF). The aim of the study was to evaluate whether the prolonged application of CPM led to improved outcomes in the postoperative, postdischarge rehabilitation period. Beginning on the first postoperative day, all patients received physical therapy (PT) and CPM therapy. After discharge, the CPM group (n=30) continued with conventional PT as well as CPM therapy for 21 days, at home. The non-CPM group (n=30) continued with PT alone. After six weeks post-surgery, all patients transitioned from partial weight-bearing to full weight-bearing exercise. Included in the study were individuals age ≥ 18 years with confirmed THF, free motion of the knee joint prior to the THF, and a freely movable contralateral knee joint. Individuals with a previous knee injury, pathological fracture, open tibial physis, pelvic fracture, or spinal or hip injury were excluded. Outcome measures included knee range of motion (ROM), knee functionality, and quality of life. Follow up evaluations occurred at six weeks and six months post-surgery. At six months, 15% of subjects were lost to follow up (non-CPM group: six [20%]; CPM group: three [10%]). The CPM group had a significant increase in ROM compared with the non-CPM group at six weeks and six months post-surgery (CPM group vs. non-CPM group:  $96.7 \pm 14.8^{\circ}$  vs.  $82.8 \pm 25.1^{\circ}$ ; p=0.012; and  $122.4 \pm 13.2^{\circ}$  vs.  $113.4 \pm 13.2^{\circ}$ 17.1°, respectively; p=0.040). Knee flexion of the non-CPM group was significantly smaller than in the CPM group at six weeks and six months post-op (non-CPM group vs. CPM group:  $91.4 \pm 24.1^{\circ}$ vs.  $102.0 \pm 14.5^{\circ}$ ; p=0.042; and  $116.7 \pm 14.6^{\circ}$  vs.  $124.8 \pm 11.6^{\circ}$ , respectively; p=0.032). There was no statistically significant difference between the groups in knee extension at either point in time. At six months post-surgery, the CPM group had significantly higher scores in some quality of life measures, versus the non-CPM group. When comparing the improvements from six weeks to six months post-surgery, the improvement in the CPM group was slightly lower than that in the non-CPM group, in measures of knee functionality and quality of life. Five patients required reoperation (four in the non-CPM group; one in the CPM group). Study limitations included short term follow up, single-center study, small sample size, with considerably more women in the CPM group.

Acetabular Labral Repair: Munsch et al. (2021) conducted a randomized controlled trial (n=54) evaluating whether continuous passive motion (CPM) device usage improved outcomes following arthroscopic hip surgery. Patients were randomized into two groups; the CPM group used the device for two weeks postoperatively, while the no-CPM group did not. Subjects were age 14 to 50 years and underwent arthroscopic hip surgery for acetabular labral repair. Persons who were pregnant, undergoing a revision surgery, or having bilateral surgery were excluded. Subjects reported on their pain level and analgesic consumption at two days, seven days, and 14 days postoperatively. They reported on the Hip Outcome Score Activity of Daily Living (HOS ADL) preoperatively and at six weeks, 12 weeks, and six months postoperatively. Forty two subjects (78%) had complete data. In the first two weeks post-surgery, there was no statistically significant difference in the total morphine equivalent dose (MED) taken between the CPM group and the no-CPM group (239 MED vs. 331 MED, respectively; p=0.25). Subjects in the CPM group reported significantly lower pain scores at two weeks post-surgery than those in the no-CPM group (2.94 vs. 4.23; p=0.04). HOS ADL scores did not differ between the two groups at any time postsurgery. Limitations of the study included small sample size; high attrition rate; narrow scope of outcome measures; reliance on patient-reported outcomes; and effect of other rehabilitation interventions (if any).

#### Literature Review—Upper Extremity

Page 6 of 14

Continuous passive motion (CPM) has been used in the postoperative period following surgery to the upper extremity, particularly shoulder surgeries. There is insufficient evidence in the published medical literature to support the effectiveness of CPM following any upper extremity surgery or for any condition.

Elbow Contracture Release: O'Driscoll et al. (2022) conducted a prospective, single-center randomized controlled trial (n=51) to evaluate the safety and effectiveness of CPM compared to physical therapy (PT) for rehabilitation after arthroscopic elbow contracture release. All patients underwent arthroscopic contracture release with ulnar nerve decompression. Postoperatively, patients in the CPM group (n=24) received a continuous brachial plexus block for 48 hours. CPM was performed in the hospital for three days, after which the patients were discharged with a home CPM program for up to four weeks. Patients in the PT group (n=27) were discharged on the day of surgery, and attended supervised PT sessions for three days. Once home, the patients were to attend PT sessions three times per week for four weeks. Inclusion criteria were patients age ≥ 13 years with lack of elbow flexion and/or extension leading to functional impairment present ≥ six months which has failed conservative treatment; and planned arthroscopic capsulectomy or osteocapsular arthroplasty. Excluded from the study were patients with progressive or intractable neuropathy or neuritis; progressive or recurrent contracture secondary to inflammatory disease; elbow joint infection or history of previous joint infection; and persons with contraindications to CPM use, regional block, or rehab participation. Key outcome measures included rate of recovery and range of motion (ROM) at one year post-surgery. Follow ups occurred at six weeks, three months, and one year postoperatively. At one year, the CPM group had a significantly greater improvement in ROM, by  $9^{\circ}$  (p=0.007). The CPM group also had a faster rate of recovery versus the PT group at six weeks and three months post-surgery (p<0.001 and p=0.003, respectively). The percentage of lost motion recovered at one year was 15% higher in the CPM group than in the PT group (p=0.01). The between-group differences in flexion strength and endurance, grip strength, and forearm circumference indicated that CPM was beneficial during the early postoperative period, with no apparent effect at other time points. There were four cases of delayed-onset ulnar neuritis, two of which required reoperation; distributed equally between the groups. Author-noted limitations included baseline non-significant differences between groups in ROM scores; a single-center trial with single operative surgeon; small sample size; variability in CPM duration; and use of different centers for PT. Additional limitations were the different lengths of hospital stay (CPM group: three inpatient days; PT group: none/ambulatory); and an underrepresentation of women.

Humeral/Radial Fractures: Tille et al. (2024) conducted a randomized controlled trial (n=95) to evaluate the effect of postoperative CPM therapy in patients with proximal humeral fractures. All participants sustained an acute fracture of the proximal humerus and underwent plate osteosynthesis. Subjects were excluded if they underwent arthroplasty; or had additional ipsilateral fracture of the upper extremity, traumatic brain injury, brachial plexus lesion, substance abuse, or reduced compliance. Participants were randomized to a treatment group with (n=48, CPM) or without CPM therapy (n=47, CG). Seventy-two participants were female (79%); subjects in the CPM group were significantly younger (CPM: 67 yrs; CG: 74 yrs; p=0.032). All subjects were treated with open reduction and plate osteosynthesis. Both groups had a postoperative rehabilitation protocol of initial immobilization followed by 18 sessions of physiotherapy. Those in the CPM group also had CPM therapy for six weeks after surgery, 2-3 times daily. Outcome measures included functional (range of motion) and patient reported outcomes (Constant Shoulder Score [CSS]; Quick Disabilities of Shoulder, Arm and Hand Score [qDASH]; subjective shoulder value [SSV]; and pain). Follow-ups were completed at six weeks, three months, and 12 months post-surgery. Outcome data was reported for 60 subjects (32 CPM, 28 CG; 63% of initial cohort). At six weeks postop, subjects in the CPM group had a significantly better range of motion for forward flexion (CPM: 90° [min: 50°, max: 180°] vs CG: 80° [min: 20°, max: 170°], p=0.035); adduction (CPM: 30° [min: 20°, max: 50°] vs CG: 30° [min: 10°, max: 40°],

p=0.049); and abduction (CPM: 80° [min: 40°, max: 180°] vs CG: 70° [min: 20°, max: 180°], p=0.048). There were no significant differences in the other planes of motion or other outcome measures. At three and 12 months' follow-up, there were no significant differences between the groups in any outcome measure. Seven patients experienced complications (CPM 3, CG 4). Overall, CPM therapy resulted in a slightly better functional range of motion six weeks after surgery, but the beneficial results were not sustained over time, and patient-reported outcomes were not significantly different between the groups at any time point. Limitations of the study included the small sample size; single-center design; age difference between the groups; lack of blinding of the assessors; heterogeneous physical therapy regimens; unknown compliance rate with prescribed CPM therapy; and loss to follow-up.

Shirzadi et al. (2020) conducted a randomized controlled trial (n=21) to evaluate the effectiveness of CPM in addition to routine therapy for rehabilitation after distal radius fracture (DRF) repair, versus routine therapy alone. Patients began rehabilitation once the external fixator or cast had been removed, approximately four to size weeks post-surgery. Both groups performed routine exercises for DRF rehabilitation three times per week for four weeks. In addition to this therapy, the experimental group used a CPM device to apply passive stretch in wrist flexion/extension and forearm supination/pronation for 30 minutes per session. The study involved adult patients who underwent pin fixation for an unstable DRF. Patients with a prior wrist fracture on the affected side, residual loss of ROM, inflammatory joint disease, or concurrent ipsilateral upper arm fracture were excluded. Outcomes measured included pain, the Patient-Rated Wrist and Hand Evaluation (PRWHE), and wrist range of motion (ROM). Follow ups were completed at four, six, and twelve weeks, and data were collected on all but one patient. Both groups had reduced pain scores and improvements in ROM, with no significant differences between the groups. The study was limited by the small sample size and reliance on self-reported outcomes. The authors concluded the use of CPM increased costs without providing additional benefit over routine therapy.

Handoll et al. (2015) conducted a Cochrane systematic review to assess the effectiveness of rehabilitation interventions with conservatively or surgically treated distal radial fractures. There was very low quality evidence from single studies of a short-term benefit of continuous passive motion immediately after removal of external fixation, intermittent pneumatic compression and ultrasound therapy. The authors concluded that there was not enough evidence available to determine the best form of rehabilitation for people with wrist fractures.

**Metacarpophalangeal (MCP) Joint Arthroscopy/Arthroplasty:** Massy-Westropp et al. (2008) conducted a Cochrane systematic review to compare the effectiveness of postoperative therapy regimes for increasing hand function after MCP arthroplasty in adults with rheumatoid arthritis. The majority of evidence for various splinting and exercise regimes consisted of case series and case reports. Only one randomized controlled trial, considered to be poor quality, met the inclusion criteria. Results from this trial suggested that the use of continuous passive motion is not effective in increasing motion or strength after MCP arthroplasty.

**Rotator Cuff Repair:** Du Plessis et al. (2011) conducted a systematic review to evaluate the effectiveness of CPM combined with usual physiotherapy management on increasing shoulder joint range of motion and muscle strength, and reducing pain in adults following rotator cuff repair. Three randomized controlled trials met the inclusion criteria. CPM was found to improve shoulder range of motion in two studies; one study found a decrease in pain in the intervention group, and one study found that CPM improved muscle strength. Inability to obtain raw data precluded critical analysis of the included studies, however. Additional limitations of the studies included varied outcome measurements, control group interventions, and duration of application of CPM.

Garofalo et al. (2010) conducted a randomized controlled trial to evaluate the use of CPM following arthroscopic rotator cuff repair (n=100). Patients were randomized to a postoperative

Page 8 of 14

physical therapy regimen consisting of passive self-assisted range of motion exercise supervised by a physiotherapist (n=46, group A) or passive self-assisted ROM exercise associated with use of CPM for a total of two hours per day (n=54, group B) for four weeks. CPM was used in four 30-minute sessions. During weeks five through twelve, the same therapy (i.e., passive mobilization with the physiotherapist) was administered to both groups, and for weeks 13 through 28, active-assisted ROM exercises were added, along with progressive isometric reinforcement exercise. An independent examiner assessed patients at two, five, six, and twelve months based on VAS, range of motion for abduction (ABD), forward flexion (FF) and external rotation in abduction (ER2). At 2.5 months, patients in group B had significantly better values for VAS (7.5  $\pm$  0.1) (p<0.01), FF (133  $\pm$  21.1) (p<0.01), ABD (66.7  $\pm$  14.5) (p<0.05) and ER2 (63.5  $\pm$  15.4) (p<0.05) than group A: VAS (9.1  $\pm$  0.2), FF (120.7  $\pm$  20.6), ABD (60.1  $\pm$  14) and ER2 (56  $\pm$  14). At six months however, there was no longer any significant difference in the VAS values, and at one year there were no statistically significant differences between the values for any of the parameters.

Lastayo et al. (1998) conducted a randomized outcome study of 31 patients (32 rotator cuffs) who had rotator cuff repair. The patients were randomly assigned to CPM (n=17) or manual passive range-of-motion exercises (n=15). The Shoulder Pain and Disability Index was used to subjectively evaluate the treatment results, and there was no significant difference between the two groups (p=0.853). Using the Visual Analog Scale, the level of pain decreased in both groups, but there was no significant difference in the mean scores in each group (p=0.92). No significant difference in ROM (p>0.20) or strength (p $\geq$ 0.20) was reported. The data suggests that although both CPM and manual passive range-of-motion provided improvement in ROM, strength, function and pain relief, there was no significant difference between the two groups.

Raab et al. (1996) conducted a prospective, randomized controlled study on 26 patients who underwent rotator cuff repair and completed three-month follow-up. Patients were randomized to the control group (n=12) who received PT only or the study group (n=14) who received PT plus CPM. Outcomes were evaluated using a shoulder score questionnaire which consisted of four areas: function, pain, muscle strength and ROM. No significant difference in shoulder scores were reported at three month follow-up, although significant improvements in the study group were noted in specific subgroups, including: pain relief in female patients (p=0.00185), pain relief in patients age 60 or older (p=0.0364), and increased ROM (p=0.0138) in the study group.

#### **Literature Review—Technology Assessment**

In the 2021 Comparative Effectiveness Review of Prehabilitation and Rehabilitation for Major Joint Replacement, the Agency for Healthcare Research and Quality (AHRQ) specifically excluded studies with a primary intervention of CPM, due to strong evidence that it is ineffective.

#### **Professional Societies/Organizations**

American Academy of Orthopaedic Surgeons (AAOS): The 2015 AAOS Clinical Practice Guideline on Surgical Management of Osteoarthritis of the Knee stated "Strong evidence supports that CPM after knee arthroplasty (KA) does not improve outcomes (Strength of Recommendation: Strong Evidence)". The 2022 update of the guideline does not indicate or mention the use of CPM.

American Physical Therapy Association (APTA): The American Physical Therapy Association (APTA) published its clinical practice guideline Physical Therapist Management of Total Knee Arthroplasty (Jette, et al., 2020), which addresses CPM used for mobilization. The updated guideline states "Physical therapists should NOT use CPMs for patients who have undergone primary, uncomplicated TKA. (Evidence Quality: High; Recommendation Strength: Moderate)."

**National Institute for Health and Care Excellence (NICE):** The NICE guideline on rehabilitation after traumatic injury recommended providers consider the use of controlled motion

Page 9 of 14

devices to help with range of movement in the knee and ankle joints, in individuals unable to engage in range of movement exercises independently (NICE, 2022).

# **Medicare Coverage Determinations**

	Contractor	Determination Name/Number	Revision Effective
			Date
NCD	National	Durable Medical Equipment Reference List	5/16/2023
		(280.1)	
LCD		No Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information. (NCD = National Coverage Determination; LCD = Local Coverage Determination)

### **Coding Information**

#### Notes:

- 1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
- 2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

#### **Considered Not Medically Necessary:**

HCPCS Codes	Description
E0935	Continuous passive motion exercise device for use on knee only
E0936	Continuous passive motion exercise device for use other than knee

\*Current Procedural Terminology (CPT $^{\otimes}$ ) ©2023 American Medical Association: Chicago, IL.

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Page 10 of 14

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### **Revision Details**

Type of Revision	Summary of Changes	Date
Annual review	<ul> <li>No clinical policy statement changes.</li> </ul>	8/15/2024

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