

# Medical Coverage Policy



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## Continuous Passive Motion (CPM) Devices

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[Stretch Devices for Joint Stiffness and Contractures](#)  
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#### INSTRUCTIONS FOR USE

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### Overview

This Coverage Policy addresses the use of continuous passive motion (CPM) devices.

### Coverage Policy

**The use of a continuous passive motion (CPM) device for rehabilitation or treatment for any indication is considered experimental/investigational/unproven.**

### 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, and it 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, and 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

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. 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 anterior cruciate ligament (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 and hip, and temporomandibular joint.

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

CPM machines are considered Class II devices and are generally approved through the 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 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.).

### **Professional Societies/Organizations**

The American Academy of Orthopaedic Surgeons (AAOS) Clinical Practice Guideline on Surgical Management of Osteoarthritis of the Knee (Weber, et al., 2016) states “Strong evidence supports that CPM after knee arthroplasty (KA) does not improve outcomes (Strength of Recommendation: Strong Evidence)”.

The AAOS Clinical Practice Guideline on Management of Rotator Cuff Injuries does not address CPM (Weber and Chahal, 2020).

The AAOS Clinical Practice Guideline Management of Anterior Cruciate Ligament Injuries does not address CPM (Shea and Carey, 2015).

### **Literature Review: Technology Assessment**

A Hayes Medical Technology Directory on Continuous Passive Motion for Knee Indications (March 15, 2018) suggests that for continuous passive motion (CPM) for prevention of contracture after total knee arthroplasty (TKA) surgery moderate-quality evidence suggests no benefit in range of motion (ROM), function, or quality of life.

A Hayes Medical Technology Directory on Continuous Passive Motion Devices for Shoulder Indications (May 9, 2018) noted that substantial variation of approaches for CPM and PT protocols create difficulty in drawing definitive conclusions about the overall effectiveness of CPM as an adjunct to PT following rotator cuff repair.

### **Literature Review: Lower Extremity**

**Total Knee Arthroplasty (TKA):** 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.”

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 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 the functional outcomes. No significant reduction in length of stay (LOS) and 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, received an additional physiotherapeutic therapy program. The follow-up period was 30 days. Pain, knee associated problems (KOOS), active range of motion (ROM), 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.

Herbold et al. (2014) conducted a randomized controlled trial to evaluate the effects of using a CPM device for individuals with poor ROM after a TKR admitted for post-acute rehabilitation to an inpatient rehabilitation facility (IRF). A total of 141 patients with initial active knee flexion  $<75^{\circ}$  on admission to the IRF were randomized into two groups: group 1 (n=71) received the conventional three hours of therapy per day, and group 2 (n=70) received the addition of daily CPM use for two hours throughout their length of stay. The outcome measures studied were active range of motion (AROM), TUG score, knee girth, total FIM scores, ambulation device at discharge, LOS, and self-reported WOMAC score. Results demonstrated all subjects significantly improved from admission to discharge in all outcome measures. However, there were no statistically significant differences in any of the discharge outcome measures of the CPM group compared with the non-CPM group in this study of patients with initially poor knee flexion ROM.

Joshi et al. (2015) conducted a randomized controlled trial including 109 patients who were randomly assigned to two groups, CPM or no CPM (n=52), applied after TKA in the acute care setting. All patients received the same physical therapy protocol (3 sessions per day). The CPM group (n = 57) underwent three CPM sessions per day, each lasting two hours (total of six hours per day), with ROM increased as tolerated. This regimen began on postoperative day one and persisted until patient was discharged from the hospital. Both groups had a knee flexion of  $115^{\circ}$  at 6 weeks and  $120^{\circ}$  at 3 months, with no significant differences (p=0.69 and p=0.41, respectively).

In a randomized controlled trial, Maniar et al. (2012) compared no-CPM, 1-day-CPM, and 3-day-CPM. In an acute care hospital, a total 84 post-TKA underwent standard PT and were also randomized into three groups, no CPM; 2 CPM applications of 15 minutes each on day 2 after TKA; or 3-day-CPM group, which received 2 CPM applications of 15 minutes each daily for 3 days (days 2, 3 and 4 after TKA). Outcomes included "timed up and go" test, pain, Western Ontario and McMaster Universities (WOMAC), short form-12 (SF-12), range of motion, knee and calf swelling, and wound healing parameters. Results at 90 day follow-up showed no statistically significant difference among the 3 groups in each parameter. In the 2 CPM groups, a statistically significant swelling still persisted at day 42 (p= .009 in 1-day-CPM group and p< .001 in 3-day-CPM group). However, at day 90, the swelling in both CPM application groups returned to within no significant difference of the preoperative values. The authors noted that the suprapatellar swelling regressed slowly in the CPM application groups as compared with the control group and they have since then discontinued its use without any untoward effect.

He et al. (2011) conducted a systematic review to evaluate continuous passive motion for preventing thrombosis after total knee arthroplasty. Ten randomized controlled trials involving 764 patients met the inclusion criteria. Four studies (361 patients) reported the incidence of deep vein thrombosis (DVT). In the CPM group (182 patients) 36 developed DVT (20%) compared to 28 (16%) in the control group of 179 patients. The meta-analysis showed no evidence that CPM had any effect on preventing venous thromboembolism after TKA (RR 1.27, 95% CI 0.87 to 1.86). None of the trials reported any deaths of the included participants. The authors concluded that there is not enough evidence from the available randomized controlled trials to conclude that CPM reduces venous thromboembolism after TKA.

Bruun-Olsen et al. (2009) conducted a randomized controlled trial to determine the short time effects (after one week and three months) of CPM on pain, range of motion, timed walking and stair climbing following TKA. A total of 63 patients were studied, 30 patients received CPM and active exercises and 33 received active exercises only. Outcomes were assessed by goniometer, visual analogue scale (VAS), timed 'Up and Go' test (TUG), timed 40 minute walking distance and timed stair climbing. There were no statistically significant differences between the two groups with regard to pain, range of motion or swelling at either one week or three months compared with baseline ( $p>0.05$ ). Nor were there any statistically significant differences between the groups in walking ability as measured by the TUG, walking on a flat surface or climbing stairs compared with baseline ( $p>0.05$ ). The authors concluded that CPM as an adjunct to active exercises did not have any additional beneficial effects on pain, knee ROM, or walking ability compared with active exercises alone neither at one week nor at three months after TKA.

Lenzen et al. (2008) conducted a randomized controlled trial to evaluate the effectiveness of prolonged CPM use in the home following TKA ( $n=60$ ). Patients were randomly assigned to the experimental group ( $n=30$ ) treated with CPM and physical therapy (PT) for 17 consecutive days or to the usual care group ( $n=30$ ) treated with approximately four days of CPM and PT followed by PT alone for two weeks after discharge. From 18 days to three months after surgery, both groups received PT alone. Outcome measures included ROM and functional recovery (e.g., ambulation) and were assessed at time of discharge, six weeks, and three months after surgery. The only statistically significant difference between the two groups which favored the experimental group was in ROM at time of discharge ( $p = 0.04$ ). No significant difference in ROM was noted at any other assessment period. This study suggests that prolonged use of CPM may have short-term effects on ROM but this did not translate into improved function nor did the improvement continue into the long-term. .

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. .

Brosseau et al. (2004) conducted a meta-analysis of randomized clinical trials, controlled clinical trials, case control and cohort studies published through 2003 to determine the effectiveness of CPM following knee arthroplasty. CPM in combination with standard PT was compared to standard PT alone. The outcome measures were active and passive knee ROM, length of hospital stay, pain, swelling, fixed flexion deformity and quadriceps strength at end of treatment and during follow-up. Fourteen studies 952 patients met the inclusion criteria. The results suggested that CPM combined with PT is effective at increasing active knee flexion compared to PT interventions alone. Patients who received CPM in addition to PT were discharged from the hospital earlier and required fewer postoperative knee manipulations than those who received PT alone.

**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, however, obtained in the CAM group (CPM,  $4.2\pm1.6$  degrees; CAM,  $1.9\pm1.2$  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 advantaged 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 ( $p<.05$ ) narcotics within the first postoperative 24 hours and used patient-controlled analgesia (PCA) less frequently ( $p<.05$ ) compared to the no-CPM group. The CPM group also received significantly less ( $p<.05$ ) 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. .

**Periosteal Transplantation:** Alfredson et al. (1999) conducted a retrospective study of 57 consecutive patients with an isolated full-thickness cartilage defect of the patella and disabling knee pain of long duration. Patients were treated by autologous periosteal transplantation to the cartilage defect. The first 38 consecutive patients (group A) were postoperatively treated with CPM, and the next 19 consecutive patients (group B) were treated with active motion for the first five days postoperatively. In both groups, the initial regimens were followed by active motion, slowly progressive strength training, and slowly progressive weight bearing. In group A, after a mean follow-up of 51 months, 29 patients (76%) were graded as excellent or good, seven patients (19%) were graded as fair, and two patients (5%) were graded as poor. In group B, after a mean follow-up of 21 months, 10 patients (53%) were graded as excellent or good, six patients (32%) were graded as fair, and three patients (15%) were graded as poor. Nine of the fair or poor cases (50%) were diagnosed with chondromalacia of the patella. The authors concluded that the results are good when CPM is used following autologous periosteal transplantation in patients with full-thickness cartilage defects of the patella and disabling knee pain. The clinical results using active motion postoperatively were not acceptable, especially in patients with chondromalacia of the patella.

**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 Club Foot:** Zeifang et al. (2005) conducted a blinded, randomized trial to determine whether CPM use after the surgical correction of club foot could improve the results in resistant club feet which required an extensive soft-tissue release. Of 37 idiopathic club feet, following surgery, 19 receive CPM and 18 had standard immobilization in a cast. The Dimeglio club foot 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 club foot score improved

from 10.3 pre-operatively to 3.89 for the surgery/casted feet and from 9.68 to 4.47 for the surgery/CPM feet. 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.

**Literature Summary-Lower Extremity:** Continuous passive motion (CPM) has been used following total knee arthroplasty (TKA) since the 1980's, 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 with that achieved with physical therapy alone. There is insufficient evidence in the published 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.

### **Literature Review: Upper Extremity**

**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.

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>or = to 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.

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 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 2, 5, 6, and 12 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.

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 (0.0364), and increased ROM (0.0138) in the study group.

**Distal Radial Fracture:** 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.

Ring et al. (1998) conducted a randomized, controlled trial (n=22) of CPM after metacarpophalangeal joint arthroscopy for rheumatoid arthritis. Patients were assigned to two groups for treatments following surgery. The treatments, including static and dynamic splints, were compared to CPM intermittent active flexion and extension. No benefit was seen with CPM, and some patients reported fatigue due to the weight of the CPM device compared to controls.

**Literature Summary-Upper Extremity:** There is insufficient evidence in the published medical literature evaluating the benefits of CPM following any upper extremity surgery or for any condition.

**The American Board of Internal Medicine's (ABIM) Foundation Choosing Wisely® Initiative:** The American Physical Therapy Association states 'Don't use continuous passive motion machines for the postoperative management of patients following uncomplicated total knee replacement' (Released September 15, 2014).

#### Use Outside the U.S.

No relevant information found.

## Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Durable Medical Equipment Reference List (280.1)	2005
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.

## Coding/Billing Information

**Note:** 1) This list of codes may not be all-inclusive.  
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

#### Considered Experimental/Investigational/Unproven:

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

ICD-10-CM Diagnosis Codes	Description
	All codes

**\*Current Procedural Terminology (CPT®) ©2019 American Medical Association: Chicago, IL.**

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