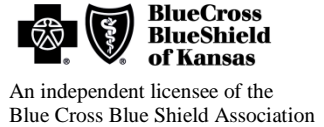


Medical Policy



Title: Continuous Passive Motion in the Home Setting

Professional

Original Effective Date: June 10, 1986
 Revision Date(s): June 21, 1990;
 May 16, 1991; July 16, 1996;
 December 4, 1996; January 1, 2000;
 August 1, 2002; May 3, 2004;
 May 14, 2004; July 6, 2005;
 December 28, 2006; April 19, 2007
 March 8, 2010; March 7, 2012;
 September 17, 2013; September 29, 2015;
 September 16, 2016; April 12, 2017;
 April 11, 2018

Institutional

Original Effective Date: March 8, 2010
 Revision Date(s): September 29, 2015;
 September 16, 2016; April 12, 2017;
 April 11, 2018

Current Effective Date: September 16, 2016 Current Effective Date: September 16, 2016

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Populations	Interventions	Comparators	Outcomes
Individuals: • With total knee arthroplasty	Interventions of interest are: • Continuous passive motion in the home	Comparators of interest are: • Physical therapy alone • Standard of care, if unable to tolerate physical therapy	Relevant outcomes include: • Symptoms • Functional outcomes
Individuals: • With intra-articular cartilage repair of the knee	Interventions of interest are: • Continuous passive motion in the home setting	Comparators of interest are: • Standard of care	Relevant outcomes include: • Symptoms • Functional outcomes

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> • With musculoskeletal conditions other than total knee arthroplasty or knee cartilage repair requiring physical therapy 	Interventions of interest are: <ul style="list-style-type: none"> • Continuous passive motion in the home 	Comparators of interest are: <ul style="list-style-type: none"> • Standard of care 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Functional outcomes
Individuals: <ul style="list-style-type: none"> • Who have had a stroke requiring physical therapy 	Interventions of interest are: <ul style="list-style-type: none"> • Continuous passive motion in the home setting 	Comparators of interest are: <ul style="list-style-type: none"> • Standard of care 	Relevant outcomes include: <ul style="list-style-type: none"> • Symptoms • Functional outcomes

DESCRIPTION

Continuous passive motion (CPM) devices are used to keep a joint in motion without patient assistance. CPM is being evaluated for treatment and postsurgical rehabilitation of the upper- and lower-limb joints and for a variety of musculoskeletal conditions.

OBJECTIVE

The objective of this policy is to determine whether continuous passive motion improves the net health outcome in patients undergoing postsurgical rehabilitation in the home setting.

BACKGROUND

Physical therapy (PT) of joints following surgery focuses both on passive motion to restore mobility and active exercises to restore strength. While passive motion can be administered by a therapist, CPM devices have also been used. Continuous passive motion (CPM) is thought to improve recovery by stimulating the healing of articular tissues and circulation of synovial fluid; reducing local edema; and preventing adhesions, joint stiffness or contractures, or cartilage degeneration. CPM has been most thoroughly investigated in the knee, particularly after total knee arthroplasty (TKA) or ligamentous or cartilage repair, but its acceptance in the knee joint has created interest in extrapolating this experience to other weight-bearing joints (ie, hip, ankle, metatarsals) and non-weight-bearing joints (ie, shoulder, elbow, metacarpals, interphalangeal joints). Use of CPM in stroke and burn patients is also being explored.

The device used for the knee moves the joint (eg, flexion/extension), without patient assistance, continuously for extended periods of time (ie, up to 24 h/d). An electrical power unit is used to set the variable range of motion (ROM) and speed. The initial settings for ROM are based on a patient’s level of comfort and other factors that are assessed intraoperatively. The ROM is increased by 3° to 5° per day, as tolerated. The speed and ROM can be varied, depending on joint stability. The use of the devices may be initiated in the immediate postoperative period and then continued at home for a variable period of time.

Over time, hospital lengths of stay have progressively shortened, and in some cases, surgical repair may be done either as an outpatient or with a length of stay of 1 to 2 days. As a result, there has been a considerable shift in the rehabilitation regimen, moving from an intensive in-hospital program to a less intensive outpatient program. Therefore, some providers may want patients to continue CPM in the home as a means of duplicating the services offered with a longer (7-day) hospital stay.

The focus of the current review is to examine the literature regarding home use of CPM as it is currently being prescribed postoperatively. The most important comparisons will be treatment outcomes of CPM when used alone or in addition to conventional PT, compared with conventional PT alone.

REGULATORY STATUS

Continuous passive motion devices are considered class I devices by the U.S. Food and Drug Administration (FDA) and are exempt from 510(k) requirements. This classification does not require submission of clinical data on efficacy but only notification of FDA prior to marketing. FDA product code: BXB.

POLICY

- A. Use of continuous passive motion (CPM) in the home setting may be considered **medically necessary** as an adjunct to physical therapy in the following situations:
1. Under conditions of low postoperative mobility or inability to comply with rehabilitation exercises following a total knee arthroplasty (TKA) or TKA revision. This may include patients with complex regional pain syndrome (reflex sympathetic dystrophy); extensive arthrofibrosis or tendon fibrosis; or physical, mental, or behavioral inability to participate in active physical therapy.
 2. During the non-weight-bearing rehabilitation period following intra-articular cartilage repair procedures of the knee (eg, microfracture, osteochondral grafting, autologous chondrocyte implantation, treatment of osteochondritis dissecans, repair of tibial plateau fractures).
- B. Use of CPM in the home setting for all other conditions is considered **not medically necessary**.

Policy Guidelines

1. If CPM is approved, allow for a rental period no longer than 21 days from date of first application.

RATIONALE

Literature review updates of the MEDLINE database, focusing on randomized trials of continuous passive motion (CPM) used in the home setting, were performed periodically through January 8, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Total Knee Arthroplasty

Early Postoperative In-Hospital Setting

Systematic Reviews

This evidence review was informed by a TEC Assessment (1997) that concluded continuous passive motion (CPM) met the TEC criteria as an adjunct to physical therapy (PT) in patients undergoing total knee arthroplasty (TKA).¹ Early studies of CPM machines focused on their use in the hospital setting, in which the impact on length of stay was frequently considered a key clinical outcome, and so the TEC Assessment did not specifically examine the point of service or the length of time CPM devices were used. A critical study identified in the TEC Assessment was an RCT by McInnes et al (1992) that compared use of CPM initiated in the immediate postoperative period and continued through the 7-day hospital stay with standard rehabilitation alone.² At 6 weeks postoperatively, the most salient difference between groups was an increased incidence of arthrofibrosis requiring manipulation in the non-CPM group.

Efficacy in the early postoperative period has been cited as a reason to support the continued use of these devices in the non-acute care hospital or home setting following early discharge. CPM after TKA was the subject of a 2003 Cochrane review.³ Reviewers reported that CPM combined with PT significantly increased active knee flexion and decreased length of stay. However, the analysis suggested that the benefits of CPM in a hospital setting may be small and only short-term.⁴ This Cochrane review was updated in 2010 and again in 2014.^{5,6} The updated review included 24 RCTs with 1445 participants and examined short-term (<6 weeks), medium-term (6 weeks to 6 months), and long-term (>6 months) effects of CPM. Most selected studies examined

short-term effects. CPM was applied for 1.5 to 24 hours a day, over 1 to 17 days. A summary of findings is provided in Table 1.

Table 1. 2014 Cochrane Review Findings on CPM

Findings	QOE
CPM increases passive and active knee flexion range of motion (mean difference, 2°), but the effects were too small to be clinically relevant	Moderate
CPM does not have clinically important short-term effects on pain (-0.4 points on a 10-point scale)	Low
CPM does not have clinically important medium-term effects on function or quality of life	Moderate
CPM may reduce the need for manipulation under anesthesia (25 fewer manipulations per 1000; RR=0.3)	Very low
CPM reduced the risk of adverse events (13 fewer adverse events per 1000, RR=0.9)	Low

Adapted from Harvey et al (2014).⁶

CPM: continuous passive motion; QOE: quality of evidence; RR: relative risk.

Another 2014 Cochrane systematic review, which included 11 RCTs, found no evidence that CPM reduced venous thromboembolism after TKA.⁷

Randomized Controlled Trials

Yashar et al (1997) randomized 178 patients undergoing TKA to CPM immediately postsurgery or to CPM 1 day postsurgery.⁸ A small but statistically significant improvement in flexion was found at the time of discharge among those started on immediate CPM, but this difference did not persist at 4 weeks. MacDonald et al (2000) reported on a randomized trial comparing immediate postoperative CPM with no CPM for 120 patients after TKA.⁹ Patients received a maximum of 24 hours with CPM. There were no differences between treatment groups in range of motion (ROM), length of stay, or analgesic requirements. In a trial reported by Pope et al (1997), 53 patients were randomized to 1 of 2 schedules of CPM (both for 48 hours) or to no CPM.¹⁰ The use of CPM was not associated with improved long-term function or ROM. Kumar et al (1996) randomized 73 patients who had undergone TKA to CPM immediately postsurgery or to a protocol of early passive flexion, referred to as the “drop and dangle” technique.¹¹ Patients assigned to passive flexion were discharged from the hospital 1 day earlier and also had a statistically better extension range of 2.8° at 6 months than the CPM group.

Other RCTs have found that 2 to 4 hours of daily CPM in the hospital after TKA did not improve postoperative outcomes at discharge or follow-up.¹²⁻¹⁵ In 1 trial, Bruun-Olsen et al (2009) randomized 63 patients undergoing TKA to active PT exercises with or without CPM to assess any short-term benefit on pain or function.¹² In both groups, exercises were performed daily for 30 minutes, starting 1 day after surgery and continuing until discharge at 1 week. For the experimental group, CPM was administered for 4 hours on the day of surgery, followed by 6 hours daily in addition to therapist-guided exercises. Blinded assessments at 1 week and 3 months after surgery showed similar results for pain and function in the 2 groups. At 1 week, both groups had visual analog scale (VAS) pain ratings of 40 and flexion scores within 2° of each other. Functional testing at 3 months showed no benefit of adjunctive CPM. The lack of improvement with CPM in these studies might have been attributable to patients mobilizing or commencing flexion immediately following surgery.¹⁴ A 2014 study of 150 patients undergoing TKA found no benefit of CPM when used over a 2-day postoperative hospital stay.¹⁵

Non-Acute Care Hospital Setting

In an RCT, Herbold et al (2014) assessed 141 TKA patients assigned to daily conventional therapy lasting 3 hours or daily CPM for 2 hours throughout their inpatient rehabilitation stay.¹⁶

After an average length of stay of 8 days, there were no significant differences between the CPM and no CPM groups for active ROM, Timed Up and Go test, knee girth, FIM scores, ambulation device at discharge, or on the self-reported Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores.

Chen et al (2000) randomized 51 patients in an inpatient rehabilitation service who had undergone TKA to conventional active PT or to PT plus CPM.¹⁷ Referral to the rehabilitation center was made 5 to 6 days after surgery, and most had received CPM as part of the initial hospitalization. Knee flexion was the principal outcome. No significant differences were noted in passive ROM between the 2 groups, as measured on admission, on the third and seventh days, and at the time of discharge (8 days postadmission). Thus, the use of CPM in the rehabilitation hospital offered no added benefit.

In a 2012 retrospective comparative study, the same group as the Herbold RCT evaluated the use of CPM in 61 matched pairs of patients admitted to a rehabilitation hospital.¹⁸ Outcomes following use of CPM were compared with those from a cohort of 61 inpatients who also had poor initial ROM, defined as less than 75° of active knee flexion at the time of admission, and matched for postoperative day at admission, age, length of stay, and Health Insurance Prospective Payment System code. Use of CPM (2 h/d) was determined primarily by the referring physician and used in 29% of the pool of 633 patients who had poor initial ROM. Average length of stay was 7.85 days. There were no significant differences in outcomes at discharge, including knee flexion or extension, discharge to the community, need for home care services, need for an assistive device, or functional scores on the Health Insurance Prospective Payment System.

Home Setting

A study by Worland et al (1998) compared the use of CPM with active PT in the home setting. At discharge, they randomized 80 patients undergoing TKA to home CPM (3 h/d for 10 days) or to active PT.¹⁹ Most studies have examined CPM as an adjunct to active PT, while this study proposed CPM as an alternative to PT. At 2 weeks, knee flexion was similar in both groups, but a flexion contracture was noted in 1 patient in the CPM group. At 6 months, no differences were found in knee scores or knee flexion.

In another RCT, Lenssen et al (2008) evaluated 60 patients with limited flexion ROM (<80°) at the time of hospital discharge who were assigned to standard PT alone or PT plus CPM in the home (4 h/d) until assessment on postoperative day 17.²⁰ Blinded assessment showed a trend for increased ROM for the CPM group (eg, 89° vs 84°, respectively, $p=0.07$), with no differences in function between groups, as measured by the Knee Society Score (function subscore 43 vs 40, respectively) and the Western Ontario and McMaster Universities Osteoarthritis Index difficulty score (49 vs 45, respectively). No differences were observed between groups in ROM or function at the 6-week or 3-month assessment. In addition, no differences were observed for the secondary outcome measures (perceived effect, medication use, satisfaction with treatment, adherence) at either of the assessment times.

Section Summary: Total Knee Arthroplasty

Numerous RCTs have compared CPM as adjunctive therapy with PT for patients undergoing TKA. Most trials used CPM in the inpatient setting and are less relevant to today's practice patterns of shorter hospital stays followed by outpatient rehabilitation. Some of these trials reported improvements in ROM for patients receiving CPM, but these improvements were short-term, of

small magnitude, and of uncertain clinical significance. The RCTs that specifically evaluated CPM in the non–acute care hospital setting or home setting did not show improved outcomes with CPM.

Articular Cartilage Repair of the Knee

Although no RCTs were identified comparing health outcomes with or without the use of CPM, CPM is routinely used as part of the rehabilitation protocol for as long as 6 weeks when weight-bearing is restricted following autologous chondrocyte implantation.²¹⁻²³ Basic research supports the use of CPM to facilitate greater healing of articular cartilage of full-thickness defects that penetrate the subchondral bone compared with either immobilization or intermittent mobilization.^{24,25}

Fazalare et al (2010) published a systematic review of CPM after knee cartilage defect surgery.²⁶ Reviewers found that CPM had been used following autologous chondrocyte implantation, microfracture, and osteochondral autografts in numerous studies in the previous 5 years. Four level III (cohort) studies with 262 patients were identified that compared CPM with no CPM; no RCTs were identified. Procedures in these 4 studies included microfracture, periosteal transplant of the patella, and high tibial osteotomy with diagnostic arthroscopy or abrasion arthroplasty. CPM regimens ranged from 6 days to 8 weeks. Heterogeneity in the studies and outdated surgical techniques limited conclusions drawn from these trials. Clinical outcomes did not permit a definitive conclusion of efficacy of CPM. However, reviewers cited several studies in which other outcomes (eg, histologic outcomes on follow-up biopsies) did favor CPM.

Another systematic review, by Howard et al (2010), evaluated CPM and other postoperative practices after knee cartilage repair.²⁷ Reviewers cited several basic science studies using animal models that appear to support CPM. They identified 2 clinical studies, both of which were retrospective nonrandomized comparative studies. In 1 study (N=43), there were no differences between groups in clinical or functional outcomes at an average follow-up of 4.2 years. In the other study (N=77), patients in the CPM group (n=46) had greater improvement in grading of the cartilage lesion compared with patients who did not have access to CPM (n=31).

Section Summary: Articular Cartilage Repair of the Knee

Current evidence on use of CPM to facilitate knee rehabilitation after articular cartilage repair includes systematic reviews. These reviews reported methodologic issues with available cohort studies and a paucity of studies assessing clinical application of CPM to knee rehabilitation.

Other Musculoskeletal Conditions Requiring PT

Articular Knee Fractures

Hill et al (2014) randomized 40 patients with articular fractures of either the proximal part of the tibia or the distal end of the femur to standardized PT with or without CPM for 48 hours postoperatively.²⁸ At the 48-hour assessment, the CPM group had significantly greater knee flexion (43° difference, $p < 0.005$). However, 6 of 20 patients were unable to tolerate CPM, and there was no benefit to adding 48 hours of CPM when assessed at any of the follow-up visits (2, 6, 12, 24 weeks).

Anterior Cruciate Ligament Repair

This literature review did not identify any RCTs of CPM in the home setting after repair of the anterior cruciate ligament (ACL). However, the studies of CPM after ACL repair in the immediate

postoperative period may be relevant to the non–acute care hospital or home setting for patients discharged following a shorter hospital stay. The TEC Assessment (1997) concluded that CPM as an adjunct to conventional PT in the immediate postoperative period after ACL repair offered no demonstrable advantage over conventional PT alone.¹ In a systematic review of ACL reconstruction rehabilitation, Wright et al (2008) discussed 6 RCTs on CPM published before 1996; no RCTs published after the 1997 TEC Assessment were identified.²⁹ Reviewers found no substantial advantage for CPM use and concluded that CPM for ACL rehabilitation could not be justified. Wright et al also noted that most current ACL rehabilitation protocols initiate early motion within the first postoperative week.

Rotator Cuff Repair

Du Plessis et al (2011) published a systematic review of CPM following rotator cuff repair.³⁰ Three RCTs were included, though meta-analysis could not be conducted due to heterogeneity across trials. Two of the RCTs, by Lastayo et al (1998) and Raab et al (1996) are discussed below.^{31,32} The third trial was a German-language report by Michael et al (2005) that found a significant reduction of 12 days in the time to reach 90° abduction compared with the PT control group, with no significant difference in pain between the 2 groups.³³

The trial by Lastayo et al (1998) randomized 31 patients undergoing rotator cuff repair to a 4-week home program of CPM (average, 3 h/d) or to manual passive elevation and rotation exercises.³¹ No significant difference in outcomes was observed between the 2 approaches. Previously, Raab et al (1996) had randomized 26 patients to postoperative PT alone or to PT plus CPM.³² Patients were evaluated with preoperative and 3-month postoperative shoulder scores that included pain, function, muscle strength, and ROM. A statistically significant improvement was found in ROM for those receiving CPM, although there was no significant improvement in overall shoulder score between groups. Both of these RCTs were likely underpowered to show differences on important clinical outcomes.

Garofalo et al (2010) reported on a randomized trial assessing the effects of CPM after rotator cuff repair.³⁴ During weeks 1 to 4 postsurgery, all 100 patients underwent passive self-assisted ROM exercise, with half of the patients also receiving CPM for four 30-minute sessions per day. The physical therapist–supervised exercises included pendulum movements and progressive passive abduction, forward flexion, and external rotation. When patients were not exercising, the shoulder was immobilized in a sling brace. From weeks 5 to 28 postsurgery, all patients underwent the same PT protocol. ROM and VAS ratings for pain were measured at 2.5, 6, and 12 months by an independent examiner. Between groups, VAS ratings were slightly better for patients who received CPM at 2.5-month follow-up (7.5 vs 9.1), but not at the 6-month (0.5 vs 0.6) or 12-month (0.2 vs 0.2) assessments, all respectively. ROM was significantly better in the group receiving CPM vs those who did not at 2.5-month follow-up (eg, forward flexion, 133.0° vs 120.7°) and 6 months (158.1° vs 151.7°), but not at 12 months (165.2° vs 158.0°), all respectively.

Subsection Summary: Rotator Cuff Repair

Three RCTs of CPM following rotator cuff surgery were identified in the English-language literature. Two of these trials reported short-term improvements in ROM for patients undergoing CPM, and one reported a short-term reduction in pain. None reported long-term improvements or benefits in functional status. Therefore, the clinical significance of the short-term improvements

reported is uncertain. In addition, there is uncertainty about the optimal PT regimen after shoulder surgery, and so the optimal comparator for CPM is not clear.

Hip Osteoarthritis

One older pilot study (1999) examined the use of CPM in patients with hip osteoarthritis in the absence of surgical intervention.³⁵ In this uncontrolled study, CPM was used for 1.2 to 7.6 hours daily during the 12-week trial. While improvements were noted in patients' pain assessments, a controlled trial is needed to validate this treatment effect, particularly compared with a program of regular walking.

Adhesive Capsulitis of the Shoulder

Dundar et al (2009) compared CPM with PT in a randomized trial of 57 patients with adhesive capsulitis (frozen shoulder).³⁶ CPM or PT was provided for 1 hour a day (5 d/wk) for 4 weeks. Pain and function levels were similar in the 2 groups at baseline, with VAS scores for pain ranging from 5.44 (at rest) to 6.34 (with movement). Assessments at baseline, 4, and 12 weeks showed reductions in pain and improvements in function levels for both groups. However, CPM resulted in greater pain reduction than PT (at rest, 47% vs 25%; with movement, 35% vs 21%; at night, 36% vs 19%, all respectively). There were no differences between groups in ROM or function. This trial provided modest support for the inclusion of CPM in a PT regimen for this patient population.

An RCT by Ekim et al (2016) compared CPM (n=20) with PT (n=21) for the treatment of adhesive capsulitis in patients who had diabetes.³⁷ CPM or PT was provided for 1 hour a day (5 d/wk) for 4 weeks. All patients received electrotherapy and, after the 4-week initial treatment phase, were instructed to continue with an 8-week at home exercise program. Outcome measures were pain (at rest, in motion, at night) and ROM (active and passive). Pain decreased significantly in both treatment groups, though patients in the CPM group reported a larger improvement in pain scores than those in the PT group. ROM improved significantly in both treatment groups as well. Patients in the CPM group reported larger improvements in abduction and flexion measures than patients in the CPM group, while external and internal rotation improvements were similar across groups.

Elbow Contracture

Postoperative management of open elbow contracture release with CPM was assessed in a matched cohort study by Lindenhovius et al (2009).³⁸ Sixteen patients who had used CPM after open contracture release and 16 patients who had not were matched by age, sex, diagnosis, ROM, and radiographic appearance. Improvements in ROM did not differ between groups at the early (range, 4-10 months) and the final (range, 11-56 months) evaluations.

Hand Repair

The TEC Assessment (1997) reviewed a multicenter study of CPM in patients who had undergone flexor tendon repair, and found the data inadequate to permit scientific conclusions about CPM application.¹

Ring et al (1998) conducted a randomized trial that examined the role of CPM in patients undergoing silicone interposition arthroplasty of the metacarpophalangeal joints secondary to rheumatoid arthritis.³⁹ Patients were randomized to a 6-week protocol of CPM (10 hands [40

joints]) or to a standard dynamic splint protocol (15 hands [60 joints]). The trial did not show better outcomes in the CPM group.

A retrospective chart review (2008) compared 15 patients who had received CPM after tenolysis with 21 who did not.⁴⁰ Patients who received CPM improved total active motion by 40° (range, 137°-177°), while patients who did not improved total active motion by 32° (range, 152°-184°); this difference was not statistically significant.

Foot Repair

One study (2005) has compared CPM with immobilization following surgical treatment of idiopathic club foot in 37 infants (50 feet).⁴¹ The infants were randomized to CPM (4 h/d) or to casting during days 10 to 42 following surgery. Blinded analysis showed improvements in the Dimeglio Clubfoot Score with CPM (from 9.7 to 3.1) that were significantly greater than those in the control group (from 10.3 to 4.2) through 12 months (97% follow-up). Between 12 and 18 months, this trend reversed and by 48 months postsurgery, there was no significant difference between groups. Another study (2007) by the same group reported low compliance with this treatment.⁴²

Back Pain

An RCT by Gavish et al (2015) evaluated a CPM device for treatment of chronic low back pain in 36 patients.⁴³ Although patients treated with the device appeared to have improved outcomes on a numeric rating scale of back pain compared with waiting-list controls, the trial had significant methodologic problems. Patients who received other treatments were excluded, a large number of subjects dropped out, and control patients did not receive any conservative management.

Section Summary: Other Musculoskeletal Conditions Requiring PT

There is a wide range of studies assessing the use of CPM for musculoskeletal conditions other than TKA and knee cartilage repair. Three small RCTs of CPM after rotator cuff surgery showed some evidence that CPM after this shoulder surgery improved short-term pain and ROM; however, the trials were not high quality, and the small differences in outcomes may not be clinically important. Two trials reported short-term improvements in ROM for patients undergoing CPM, and one reported a short-term reduction in pain. None reported long-term improvements, and there are no reported benefits in functional status. Therefore, the clinical significance of the short-term improvements reported is uncertain. In addition, there is uncertainty about the optimal PT regimen following shoulder surgery such that the optimal treatment comparator for CPM is unclear. Two small RCTs compared CPM with conventional PT for treatment of adhesive capsulitis. One of the trials focused on diabetic patients with adhesive capsulitis. Both reported comparable improvements in ROM and functional ability between treatment groups. For other musculoskeletal conditions, RCTs do not exist; case series either did not show efficacy of CPM or had important methodologic flaws.

Stroke

CPM has been studied as a means to aid recovery of motor skills following stroke. One study (2005) randomized 35 patients to daily sessions of CPM (25 minutes) or to daily group therapy sessions consisting of self-directed ROM for poststroke rehabilitation.⁴⁴ All patients also received standard poststroke therapy for 3.5 hours a day. After 20 days of therapy, there was a trend for greater shoulder joint stability in the CPM group (n=17, p=0.06) compared with the control

group (n=15). No statistically significant differences were found for measures of motor impairment. This trial had a small sample size and short follow-up period.

Section Summary: Stroke

A small randomized trial has reported a trend toward improvement for the outcome of shoulder joint stability with CPM, but shows no statistical difference between CPM plus PT and PT alone. This trial was small and treatment lasted only 20 days.

SUMMARY OF EVIDENCE

For individuals who have TKA who receive CPM in the home setting, the evidence includes RCTs, case series, and systematic reviews. Relevant outcomes are symptoms and functional outcomes. Early trials generally used CPM in the inpatient setting and are less relevant to today's practice patterns of short hospital stays followed by outpatient rehabilitation. Current postoperative rehabilitation protocols differ considerably from when the largest body of evidence was collected, making it difficult to apply available evidence to the present situation. For use of CPM after TKA, recent studies have suggested that institutional and home use of CPM has no benefit compared with standard PT. There were no studies evaluating CPM in patients who could not perform standard PT. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have articular cartilage repair of the knee who receive CPM in the home setting, the evidence includes nonrandomized studies, case series, and studies with nonclinical outcomes (eg, histology), and systematic reviews of these studies. Relevant outcomes are symptoms and functional outcomes. Systematic reviews of CPM for this indication have cited studies reporting better histologic outcomes in patients following CPM. A few studies have reported clinical outcomes, but inadequacies of these studies do not permit conclusions on efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have musculoskeletal conditions other than TKA or knee cartilage repair requiring PT who receive CPM in the home setting, the evidence includes RCTs for some conditions and case series for others. Relevant outcomes are symptoms and functional outcomes. Three small RCTs of CPM after rotator cuff surgery showed some evidence that CPM after this shoulder surgery improved short-term pain and range of motion; however, the trials were not high quality, and the small differences in outcomes may not be clinically important. Two trials reported short-term improvements in range of motion for patients undergoing CPM, and one reported a short-term reduction in pain. None reported long-term improvements, and there are no reported benefits in functional status. Therefore, the clinical significance of the short-term improvements reported is uncertain. In addition, there is uncertainty about the optimal PT regimen following shoulder surgery such that the optimal treatment comparator for CPM is unclear. Two small RCTs compared CPM with conventional PT for treatment of adhesive capsulitis. One of the trials focused on diabetic patients with adhesive capsulitis. Both reported comparable improvements in range of motion and functional ability between treatment groups. For other musculoskeletal conditions, RCTs do not exist; case series either did not show efficacy of CPM or had important methodologic flaws. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have had a stroke requiring PT who receive CPM in the home setting, the evidence includes a small RCT. Relevant outcomes are symptoms and functional outcomes. This trial reported a trend toward improved shoulder joint stability, but no statistical difference between CPM plus PT and PT alone. The trial was small and treatment lasted only 20 days. The evidence is insufficient to determine the effects of the technology on health outcomes.

CLINICAL INPUT RECEIVED THROUGH PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2016 Input

In response to requests for input on the use of CPM following knee intra-articular repair procedures, input was received from 2 physician specialty societies and 1 academic medical center while this policy was under review in 2016. Input agreed that CPM is considered medically necessary as an adjunct to PT during the non-weight-bearing rehabilitation period following intra-articular cartilage repair procedures of the knee. One reviewer referred to the 2015 American Academy of Orthopaedic Surgery guidelines on the surgical management of osteoarthritis of the knee, which concluded that there was strong evidence that CPM after knee arthroplasty does not improve outcomes.

2010

In response to requests, input was received from 2 physician specialty societies and 5 academic medical centers while this policy was under review in 2010. Overall, clinical input supported the use of CPM under conditions of low postoperative mobility or inability to comply with rehabilitation exercises following a TKA or TKA revision or during the non-weight-bearing rehabilitation period following intra-articular cartilage repair procedures of the knee. Support was limited for use of CPM in joints other than the knee, or in situations/conditions other than those described in this policy.

2008

In response to requests, input was received from 1 physician specialty society and 2 academic medical centers while this policy was under review in 2008. The 3 reviewers interpreted the existing literature as providing support for the use of CPM for the knee for at least 7 days postoperatively, whether in the hospital or home, and suggested that longer use of CPM would be warranted for special conditions.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons (AAOS) published evidence-based guidelines on the surgical management of osteoarthritis of the knee in 2015.⁴⁵ AAOS identified 2 high-quality studies and 5 moderate-quality studies that evaluated the use of CPM. In 1 high-quality study, CPM was used for about 2 weeks after discharge. AAOS concluded that, "the combined results provide strong evidence that the surgical outcomes for those who used continuous passive motion are not better than for those who did not use continuous passive motion."

French Physical Medicine and Rehabilitation Society

Clinical practice guidelines from the French Physical Medicine and Rehabilitation Society conclude that evidence is not sufficient to recommend substituting CPM for other rehabilitation techniques aimed at early mobilization after TKA.⁴⁶ The evidence review found no positive effect of CPM over intermittent early mobilization, at short- or long-term follow-up.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01420887	Preservation of Joint Function Using Postoperative Continuous Passive Motion (CPM): A Pilot Study	50	Dec 2018

NCT: national clinical trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

E0935	Continuous passive motion exercise device for use on knee only
E0936	Continuous passive motion exercise device for use other than knee
E1399	Durable medical equipment, miscellaneous

ICD-10 Diagnoses

These diagnoses are otherwise subject to medical policy as stated above

M07.641	Enteropathic arthropathies; right hand
M07.642	enteropathic arthropathies; left hand
M07.661	Enteropathic arthropathies, right knee
M07.662	Enteropathic arthropathies, left knee
M07.671	Enteropathic arthropathies, right ankle and foot
M07.672	Enteropathic arthropathies, left ankle and foot
M12.541	Traumatic arthropathy; right hand
M12.542	Traumatic arthropathy; left hand
M12.561	Traumatic arthropathy, right knee
M12.562	Traumatic arthropathy, left knee
M12.571	Traumatic arthropathy, right ankle and foot
M12.572	Traumatic arthropathy, left ankle and foot
M12.841	Other specific arthropathies, not elsewhere classified; right hand
M12.842	Other specific arthropathies, not elsewhere classified; left hand

- M12.861 Other specific arthropathies, not elsewhere classified, right knee
- M12.871 Other specific arthropathies, not elsewhere classified, right ankle and foot
- M12.872 Other specific arthropathies, not elsewhere classified, left ankle and foot
- M17.0 Bilateral primary osteoarthritis of knee
- M17.11 Unilateral primary osteoarthritis, right knee
- M17.12 Unilateral primary osteoarthritis, left knee
- M18.0 Bilateral primary osteoarthritis of first carpometacarpal joints
- M18.11 Unilateral primary osteoarthritis of first carpometacarpal joint; right hand
- M18.12 Unilateral primary osteoarthritis of first carpometacarpal joint; left hand
- M19.041 Primary osteoarthritis; right hand
- M19.042 Primary osteoarthritis; left hand
- M23.51 Chronic instability of knee, right knee
- M23.52 Chronic instability of knee, left knee
- Z96.621 Presence of right artificial elbow joint
- Z96.622 Presence of left artificial elbow joint
- Z96.631 Presence of right artificial wrist joint
- Z96.632 Presence of left artificial wrist joint
- Z96.651 Presence of right artificial knee joint
- Z96.652 Presence of left artificial knee joint
- Z96.653 Presence of artificial knee joint, bilateral
- Z96.659 Presence of unspecified artificial knee joint
- Z96.661 Presence of right artificial ankle joint
- Z96.662 Presence of left artificial ankle joint

REVISIONS

03-08-2010	<p>In Policy Section:</p> <ul style="list-style-type: none"> ▪ Revised wording in C. From: "The use of a CPM device for any primary or adjunct therapeutic application other than those listed above is considered investigational/ not medically necessary." <p>To: "The use of a CPM device for any primary or adjunct therapeutic application other than those listed above is considered experimental / investigational."</p> <ul style="list-style-type: none"> ▪ Revised wording in A., third paragraph from: "CPM is approved without review-for a rental period no longer than 21 days from date of first application." <p>To: "If CPM is approved, allow for a rental period no longer than 21 days from date of first application."</p> <p>In Coding Section: Added HCPCS Code: E0936 (effective 01-01-07) Added Rationale Section Updated References</p>
03-07-2012	<p>In the Policy section:</p> <ul style="list-style-type: none"> ▪ In Item A, #1, removed "TKA" at the end to read "or revision." ▪ In Item A, added "#2. Partial knee arthroplasty (27446) ▪ In Item A, added the following: <ul style="list-style-type: none"> ○ " 6. Osteochondral grafting ○ 7. Treatment of osteochondritis dissecans ○ 8. Repair of tibial plateau fractures" <p>Updated the Rationale section. Updated the Reference section.</p>
09-17-2013	<p>In Coding section:</p>

	<ul style="list-style-type: none"> ▪ Added ICD-10 Diagnosis codes (<i>Effective October 1, 2014</i>)
	Updated Rationale section.
	Updated Reference section.
09-29-2015	Policy title revised from "Continuous Passive Motion for Home Use"
	Updated Description section.
	Updated Rationale section.
	Updated References section.
09-16-2016	Updated Description section.
	<p>In Policy section section:</p> <ul style="list-style-type: none"> ▪ Policy language previously stated, " A.Continuous passive motion (CPM) is considered medically necessary for the following surgeries: <ol style="list-style-type: none"> 1. Total knee arthroplasty (TKA) or revision 2. Partial knee arthroplasty 3. Anterior cruciate ligament (ACL) repair 4. Autologous chondrocyte implantation (ACI) 5. Microfracture of the knee 6. Osteochondral grafting 7. Treatment of osteochondritis dissecans 8. Repair of tibial plateau fractures <p>Continuous passive motion (CPM) will be reviewed for medical necessity for the following surgeries:</p> <ol style="list-style-type: none"> 1. Ankle 2. Elbow 3. Wrist 4. Hand <p>If CPM is approved, allow for a rental period no longer than 21 days from date of first application.</p> <p>B. Continuous passive motion (CPM) is denied not medically necessary for the following surgeries:</p> <ol style="list-style-type: none"> 1. Shoulder 2. Interphalangeal joints of lower extremities to include the great toe <p>C. The use of a CPM device for any primary or adjunct therapeutic application other than those listed above is considered experimental / investigational."</p> ▪ Current policy language states, " A.Use of continuous passive motion (CPM) in the home setting may be considered medically necessary as an adjunct to physical therapy in the following situations: <ol style="list-style-type: none"> 1. Under conditions of low postoperative mobility or inability to comply with rehabilitation exercises following a total knee arthroplasty (TKA) or TKA revision. This may include patients with complex regional pain syndrome (reflex sympathetic dystrophy); extensive arthrofibrosis or tendon fibrosis; or physical, mental, or behavioral inability to participate in active physical therapy. 2. During the non-weight-bearing rehabilitation period following intra-articular cartilage repair procedures of the knee (eg, microfracture, osteochondral grafting, autologous chondrocyte implantation, treatment of osteochondritis dissecans, repair of tibial plateau fractures. <p>B. Use of CPM in the home setting for all other conditions is considered not medically necessary.</p> <p>Policy Guidelines</p> <ol style="list-style-type: none"> 1. If CPM is approved, allow for a rental period no longer than 21 days from date of first application."
	Updated Rationale section.
	Updated References section.

04-12-2017	Updated Description section.
	Updated Rationale section.
	Updated References section.
04-11-2018	Updated Description section.
	Updated Rationale section.
	In Coding section: ▪ Removed ICD-9 codes.
	Updated References section.

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