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Title: Continuous Passive Motion Machine (CPM)

Description/Background

Continuous passive motion (CPM) devices are utilized 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.

Physical therapy 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 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 or ligamentous or cartilage repair, but its acceptance in the knee joint has created interest in extrapolating this experience to other weight-bearing joints (i.e., hip, ankle, metatarsals) and non-weight-bearing joints (i.e., shoulder, elbow, metacarpals and interphalangeal joints). Use of CPM in stroke and burn patients is also being explored.

The device moves the joint (e.g., flexion/extension), without patient assistance, continuously for extended periods, i.e., up to 24 hours/day. 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 three to five degrees 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 is done 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. Some providers may want patients to continue CPM in the home setting as a means of duplicating services offered with a longer (7-day) hospital stay.

The focus of the current review is to examine the literature on the use of CPM in the home setting as it is currently being prescribed postoperatively. Relevant comparisons are treatment outcomes of CPM when used alone or with PT, compared with PT alone.

Regulatory Status

CPM devices are considered class I devices by FDA and are exempt from 510(k) requirements. This classification does not require submission of clinical data regarding efficacy but only notification of the FDA before marketing. FDA product code: BXB.

Medical Policy Statement

The safety and effectiveness of the continuous passive motion machine have been established. It may be considered a useful therapeutic option when indicated.

Inclusionary and Exclusionary Guidelines

Inclusions:

The continuous passive motion (CPM) device when used as an adjunct to conventional physical therapy is an established therapy in the early postoperative phase of rehabilitation (must meet one):

- For patients following knee injury or surgery (e.g., total knee arthroplasty, ACL repair, etc.)
- For use during the non-weight-bearing rehabilitation period following articular cartilage repair procedures of the knee (e.g., microfracture, osteochondral grafting, autologous chondrocyte implantation, treatment of osteochondritis dissecans, repair of tibial plateau fractures).
- For patients who have sustained an injury to, or have undergone surgery of the articular tissues of the shoulder.

Exclusions:

Use of the CPM machine for other joints or joint conditions, including the hip, ankles, toes, fingers, etc.

Maximum benefit is generally obtained within 3 weeks of initiated use post-surgery and would not be appropriate for long-term intervention. While CPM is usually initiated in the hospital early post-operative phase, this policy addresses home use of this device.

CPT/HCPCS Level II Codes (Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)

Established codes:

E0935 E0936

Other codes (investigational, not medically necessary, etc.):

N/A

Note: Code(s) E0935 and E0936 may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.

Rationale

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 (TKA)

Clinical Context and Therapy Purpose

The purpose of continuous passive motion in the home setting in patients with total knee arthroplasty is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICO** was used to select literature to inform this review:

Populations

The relevant population(s) of interest are patients with total knee arthroplasty.

Interventions

The therapy being considered is continuous passive motion.

Comparators

The following therapies are currently being used for total knee arthroplasty: Physical therapy alone or standard of care, if unable to tolerate physical therapy

Outcomes

The general outcomes of interest are symptoms and functional outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Early Postoperative In-Hospital Setting

Systematic Reviews

The original evidence review was based on a 1997 TEC Assessment that concluded 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 a randomized controlled trial (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 to 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 to support the continued use of these devices in the home setting following early discharge. CPM after TKA was the subject of a 2003 Cochrane review.³ This review reported that CPM combined with physical therapy was found to increase active knee flexion and decrease length of stay statistically significantly. However, the analysis suggests 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 2014.^{5, 6} The updated review included 24 randomized trials with 1445 participants and examined short-term (<6 weeks), medium-term (6 weeks-6 months), and long-term (>6 months) effects of CPM. Most of the included studies examined short-term effects. CPM was applied for 1.5 to 24 hours a day, over 1 to 17 days. A summary of the review's findings are 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; risk ratio, 0.3)	Very Low
CPM reduced the risk of adverse events (13 fewer adverse events per 1000, relative risk, 0.9)	Low

Adapted from Harvey et al (2014).⁶ CPM: continuous passive motion; QOE: quality of evidence

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

Randomized Controlled Trials

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

Other RCTs find that 2 to 4 hours of daily CPM in the hospital after total knee replacement does not improve postoperative outcomes at discharge or follow-up.¹²⁻¹⁵ For example, Bruun-Olsen et al randomly assigned 67 patients undergoing TKA to receive active physiotherapy exercises with or without CPM to assess whether there was short-term benefit on pain or function.¹² In both groups, exercises were performed daily for 30 minutes, starting 1 day after surgery until discharge at 1 week. For the experimental group, CPM was provided for 4 hours on the day of surgery, followed by 6 hours daily in addition to therapist-guided exercises. Blinded assessment 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 that were within 2 degrees of each other. Functional testing at 3 months showed no benefit of adjunctive CPM. The lack of improvement with CPM in recent studies may be due to the current practice of permitting patients to mobilize or commence 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 a 2014 randomized trial by Herbold et al, 141 TKA patients were assigned to either 3 hours of CPM daily or to 2 hours total CPM during their inpatient rehabilitation stay.¹⁶ After an average length of stay of 8 days for both groups, there were no significant differences between the CPM and no CPM groups for active ROM, Timed Up and Go test, knee girth, Functional Independence Measure scores, ambulation device at discharge, or on the self-reported Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

Chen et al (2000) randomly assigned 51 patients in an inpatient rehabilitation service who had undergone TKA to receive conventional active physical therapy or physical therapy 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 difference was noted in range of passive motion between the 2 groups, as measured on admission, on the third and seventh days, and at the time of discharge (8 days after admission). Thus, the use of CPM in the rehabilitation hospital offered no added benefit.

In 2012, a retrospective comparative study by the same group as the RCT by Herbold et al 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 (HIPPS) code. Use of CPM (2 hours/day) was determined primarily by the referring physician and was used in 29% of the pool of 633 patients who had poor initial ROM. The 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 HIPPS.

Home Setting

A study by Worland et al (1998) was the only identified controlled study that compared the use of CPM and active physical therapy in the home setting. In this study, 80 patients undergoing TKA were randomly assigned to receive, at discharge, home CPM (3 hours/day for 10 days) versus active physical therapy, as offered by professional physical therapists.¹⁹ Most studies have examined CPM as an adjunct to active physical therapy; therefore, this study is unique in that CPM is proposed as an alternative. At 2 weeks, knee flexion was similar in the 2 groups, but a flexion contracture was noted in 1 patient in the CPM-only group. At 6 months, no differences were found in knee scores or knee flexion.

In another RCT published in 2008, 60 patients with limited flexion range of motion (< 80 degrees) at the time of hospital discharge were assigned to standard physical therapy alone or in combination with CPM in the home (4 hours per day) until assessment on postoperative day 17.²⁰ Blinded assessment showed a trend for an increase in range of motion for the CPM group (e.g., 89 degrees versus 84 degrees, respectively, $p=0.07$), with no differences in function between the groups as measured by the Knee Society Score (function subscore 43 versus 40, respectively) or the WOMAC difficulty score (49 versus 45, respectively). No differences were observed between groups in range of motion 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 been performed comparing CPM as an adjunct to physiotherapy for patients undergoing TKA. Most 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. Some of these trials report an improvement in range of motion for patients receiving CPM, but these improvements are short term, of small magnitude, and of uncertain clinical significance. Those RCTs that specifically evaluated CPM in the home setting did not show improved outcomes with CPM.

Articular Cartilage Repair of the Knee

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

In 2010, Fazalare et al published a systematic review of CPM following knee cartilage defect surgery.²⁶ The review found use of CPM following ACI, microfracture and osteochondral autografts and allografts in numerous studies in the previous 5 years. Four level III (cohort) studies with 262 patients were identified that specifically compared CPM to no CPM; no randomized trials were identified. Procedures in these 4 studies included microfracture, periosteal transplant of the patella, and high tibial osteotomy with either diagnostic arthroscopy or abrasion arthroplasty. CPM regimens ranged from six days to eight weeks. Heterogeneity in the studies and outdated surgical techniques limit conclusions from these trials. Clinical outcomes did not permit a definitive conclusion of efficacy of CPM. However, reviewers cited several studies in which other outcomes (e.g., 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 to 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 PHYSICAL THERAPY

Articular Knee Fractures

Hill et al (2014) randomized 40 patients with intra-articular fractures of either the proximal part of the tibia or the distal end of the femur to standardized PT with or without the use of CPM for 48 hours postoperatively.²⁸ At the 48-hour assessment, the CPM group had significantly

greater knee flexion (43° difference, $p < .005$). 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

The literature search did not identify any additional randomized controlled trials of CPM in the home setting after repair of the anterior cruciate ligament. Therefore, the studies of CPM after anterior cruciate ligament (ACL) repair in the immediate postoperative period may possibly be relevant to the home setting for patients who are discharged with an abbreviated hospital stay. The 1997 TEC Assessment concluded that CPM in the immediate postoperative period as an adjunct to conventional physical therapy offered no demonstrable advantage over conventional physical therapy alone.¹ In a 2008 systematic review of ACL reconstruction rehabilitation, Wright et al. discussed six randomized trials on CPM that had been published before 1996. No randomized-controlled studies published after the 1997 TEC Assessment were identified.²⁹ The review 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 institute early motion within the first postoperative week.

A 2022 review was conducted to synthesize evidence from systematic reviews for rehabilitation interventions following anterior cruciate ligament injury.³⁰ This review identified 1 systematic review that included evidence for continuous passive motion by Gatewood et al (2017).³¹ The authors identified 2 RCTs of continuous passive motion in the immediate postoperative setting, 1 of which was not included in the review by Wright et al (2008). In this study, 60 patients (95% of whom were men) were randomized to use of a continuous active motion device or continuous passive motion device for 7 days, beginning on postoperative day 1.³² No difference was identified between groups in knee range of motion or pain at postoperative day 7. Patients in the continuous active motion group demonstrated a significant improvement in joint position sense (measured by passive angle reproduction) relative to the continuous passive motion group at postoperative day 7, with a between-group difference of 2.2 degrees.

Rotator Cuff

In 2011, Du Plessis et al published a systematic review of CPM following rotator cuff repair.³³ Two of the RCTs, by Lastayo et al and Raab et al are discussed below.^{34,35} The third study included in the systematic review was a German language report that found a significant reduction of 12 days in the time to reach 90 degree abduction compared to a physiotherapy control group, with no significant difference in pain between the 2 groups.

The trial conducted by Lastayo et al (1998) randomized 31 patients undergoing rotator cuff repair to 1 of 2 types of postoperative management: a 4-week home program of CPM (average of 3 hours per day) or manual passive elevation and rotation exercises.³⁴ No significant difference in outcomes was observed between the 2 approaches. Raab et al conducted a trial that randomly assigned 26 patients to undergo postoperative physical therapy alone or CPM in addition to physical therapy.³⁵ Patients were evaluated with pre- and 3-month postoperative shoulder scores that incorporated pain, function, muscle strength, and ROM. A significant improvement was found in the subscore of ROM, although there was no significant improvement in overall shoulder score in the CPM group compared to the control group. Both of these RCTs were likely underpowered to show differences on important clinical outcomes.

In 2010, Garofalo reported a randomized study on the effects of CPM after rotator cuff repair.³⁶ During weeks 1 to 4 post surgery, 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 the 5th to the 28th week, all patients underwent the same physical therapy protocol. Range of motion (ROM) and VAS for pain were measured at 2, 5, 6 and 12 months by an independent examiner. In the CPM group, VAS was slightly better at 2.5-month follow-up (7.5 versus 9.1), but not at the 6-month (0.5 versus 0.6) or 12-month (0.2 versus 0.2) evaluation. Use of pain medication was not examined. Range of motion was significantly better in the group of patients who used CPM at 2.5-month follow-up (e.g., forward flexion of 133.0 versus 120.7) and 6 months (158.1 versus 151.7), but not at 12 months (165.2 versus 158.0 – all respectively).

Subsection Summary: Rotator Cuff

Three RCTs of CPM following rotator cuff surgery have been identified in the English-language literature. Two of these trials report short-term improvements in ROM for patients undergoing CPM, and 1 reports 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 pilot study looked at the use of CPM of the hip in patients with osteoarthritis in the absence of surgical intervention.³⁷ This uncontrolled study examined the use of CPM for one to seven hours daily for a 12-week trial. While improvements were noted in the patient's assessment of pain, a controlled trial is needed to validate this treatment effect, particularly in comparison to a program of regular walking.

Adhesive Capsulitis of the Shoulder

Dundar et al (2009) compared CPM with physiotherapy in a randomized trial of 57 patients with adhesive capsulitis (frozen shoulder).³⁸ CPM or physical therapy was provided for 1 hour per day (5 days a week) for 4 weeks. Pain and function were similar in the 2 groups at baseline, with visual analog scale (VAS) scores for pain ranging from 5.44 (at rest) to 6.34 (with movement). Assessments at baseline, 4 and 12 weeks showed improvements in pain and function in both groups. CPM resulted in better pain reduction than physiotherapy (at rest, 47% versus 25%; with movement, 35% versus 21%; and at night, 36% versus 19%, all respectively). There were no differences between groups in range of motion or functional ability. This study provides modest support for the inclusion of CPM in a PT program for this patient population.

An RCT by Ekin et al (2016) compared CPM (n=20) with PT (n=21) for the treatment of adhesive capsulitis in patients with diabetes.³⁹ 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).⁴⁰ Sixteen patients who had used CPM after open contracture release and 16 patients who had not used CPM after surgery were matched for age, gender, diagnosis, range of motion and radiographic appearance. Chart review was utilized when possible; patients who had insufficient follow-up in the medical record were invited back for follow-up and radiograph. Twenty-three patients (72%) were evaluated by an investigator who was not involved in their care. Improvements in range of motion were not different between the two groups for either early (four to 10 months) or final (10–56 months) evaluations.

Hand Repair

In 1997, TEC Assessment reviewed a multicenter study of CPM in patients who had undergone flexor tendon repair. The TEC Assessment concluded that data were inadequate to permit scientific conclusions regarding these applications.¹

Ring et al (1998) examined the role of CPM in 15 hands (60 joints) undergoing silicone interposition arthroplasty of the metacarpophalangeal joint secondary to rheumatoid arthritis.⁴¹ Patients were randomly assigned to receive a 6-week protocol CPM plus the standard dynamic splint protocol versus the dynamic splint protocol alone. The authors did not identify any clear advantages of adding CPM to the standard protocol.

In 2008, a retrospective chart review compared 15 patients who had received CPM after tenolysis with 21 who did not.⁴² Patients who receive CPM improved total active motion by 40° (range, 137°–177°), while patients who did not improve total active motion by 32° (range, 152°–184°); however, this difference was not statistically significant.

Foot Repair

One study (2005) compared passive motion versus immobilization following surgical treatment of idiopathic clubfoot in 38 infants (50 feet).⁴³ The infants were randomly assigned to CPM (4 hours each day) or casting during days 10 to 42 following surgery. Blinded analysis showed improvements in the Dimeglio clubfoot score (9.7 to 3.1) that were significantly greater than in the control group (10.3 to 4.2) through 12 months (97% follow-up). Between 12 and 18 months, this trend reversed, and by 48 months after surgery, there was no significant difference between the two groups. Compliance with this treatment may be low.⁴¹

Back Pain

An RCT by Gavish et al (2015) evaluated a specific CPM device for treatment of chronic low back pain in 36 patients.⁴⁵ Although patients treated with the device appeared to have improved outcomes on a numeric rating scale of back pain compared to waiting-list controls, the study has 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. No RCTs of continuous passive motion conducted in the home setting after anterior cruciate ligament repair were identified; RCTs conducted in the immediate postoperative setting do not indicate clinical benefit with use of continuous passive motion compared to conventional PT. 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 is also being studied as a means to aid recovery of motor skills following stroke. One study (2005) randomized 35 patients to daily sessions of use of a shoulder joint CPM device (25 minutes) or daily group therapy sessions consisting of self-range motion for post-stroke rehabilitation.⁴⁶ All patients also received standard post-stroke therapy for 3.5 hours per day. Following 20 days of therapy, there was a trend for greater shoulder joint stability in the passive motion group (n=17, p less than 0.06) compared with the control group (n=15). No statistically significant differences were found for measures of motor impairment. This study is limited by the small sample size and the short follow-up period, suggesting it may have had inadequate power to detect important differences in key outcomes.

In a 2022 randomized, single-blind crossover study, 18 patients aged 20 to 79 years with mild to severe arm-hand impairment following unilateral stroke were assigned (at least 6 months post-stroke) to undergo home-based therapy sessions twice daily, 5 days per week for 4 weeks, consisting of either task-specific motor training with an occupational therapist or home-based therapy with a robotic exoskeleton system combining continuous passive motion and robot-assisted gripping exercises.⁴⁷ All patients received standard-of-care occupational therapy and physical therapy (PT) for 2 hours per week. Crossover occurred following a 12-week washout. Patients initially assigned to the robotic exoskeleton intervention followed by task-specific motor training experienced significantly greater improvement in wrist extension range of motion at the end of treatment compared to those who received interventions in the opposite order. Assessments of manual dexterity and motor performance of the upper extremity were significantly improved following exoskeleton therapy, whereas no significant differences in these measures were noted following task-specific motor training. A significantly greater proportion of patients reported improvements in global symptoms after exoskeleton therapy (77%) than after task-specific motor training (11%).

Section Summary: Stroke

Two small randomized trials have reported mixed results with different continuous passive motion devices in combination with PT or occupational therapy compared to PT or occupational therapy alone in patients who have experienced stroke, including a statistically non-significant trend toward improvement for the outcome of shoulder joint stability and significant improvements in wrist extension range of motion, manual dexterity, and global symptoms related to upper extremity movement. Both trials were small and treatment lasted only 20 days in the shoulder joint study by Lynch et al.

SUMMARY OF EVIDENCE

For individuals who have total knee arthroplasty (TKA) who receive continuous passive motion (CPM) in the home, the evidence includes randomized clinical trials (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 the 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 to standard PT. There were no studies evaluating CPM in patients who cannot perform standard PT. The evidence is sufficient 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, the evidence includes nonrandomized studies, case series, and studies with nonclinical outcomes (e.g., histology). Relevant outcomes are symptoms and functional outcomes. Systematic reviews of CPM for this indication cite 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 of efficacy. The evidence is sufficient to determine the effects of the technology on health outcomes.

For individuals who have other musculoskeletal conditions other than TKA or knee cartilage repair requiring PT who receive CPM in the home, the evidence includes RCTs for some conditions and only 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 rotator cuff repair of the shoulder improves short-term pain and range of motion; however, the studies were not of high quality, and the small differences in outcomes may not be clinically important. Two of these trials reported short-term improvements in range of motion for patients undergoing CPM, and 1 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 comparison 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. Although no RCTs of continuous passive motion in the home setting after repair of the anterior cruciate ligament were identified, indirect evidence from RCTs conducted in the inpatient immediate postoperative setting following anterior cruciate ligament repair indicated no additional benefit with continuous passive motion compared to conventional PT. 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 continuous passive motion in the home setting, the evidence includes 2 small RCTs. Relevant outcomes are symptoms and functional outcomes. These trials reported mixed results; 1 RCT indicated a non-significant trend toward improvement in shoulder joint stability with continuous passive motion and PT relative to PT alone, while the other indicated significant improvement in functional outcomes related to wrist movement and global upper extremity movement symptoms with continuous passive motion plus conventional therapy relative to conventional therapy alone. Both trials were small and treatment lasted only 20 days in the shoulder joint study. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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			
NCT05226988	Effect of Hybrid Robot-assisted Training Using End-effector and Exoskeleton Devices in Distal Upper Extremity After Stroke: Motor Control, Motor and Daily Function, Quality of Life	70	Oct 2025
Unpublished			
NCT01420887	Preservation of joint function using postoperative continuous passive motion (CPM): a pilot study	50	May 2020

NCT: national clinical trial

SUPPLEMENTAL INFORMATION

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

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 Orthopedic 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 Input

In response to requests, Blue Cross Blue Shield Association received input from two physician specialty societies and five 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 total knee arthroplasty (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 Input

In response to requests, Blue Cross Blue Shield Association received input from one physician specialty society and two academic medical centers while this policy was under review in 2008. The three reviewers interpreted the existing literature as providing support for the use of CPM for the knee for at least seven 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 Physical Therapy Association

In 2020, the American Physical Therapy Association (APTA) published a clinical practice guideline on physical therapists' management of patients undergoing total knee arthroplasty.⁴⁸ The APTA identified 4 high-quality studies, 6 moderate-quality studies, and 2 low-quality studies evaluating the effect of continuous passive motion devices on knee flexion and extension range of motion and need for manipulation under anesthesia, with moderate-quality studies indicating benefit with continuous passive motion contradicted by high-quality studies indicating no significant difference. Meta-analyses did not indicate a significant impact of continuous passive motion on function or hospital length of stay. The APTA concluded that "physical therapists should NOT use CPMs [continuous passive motion devices] for patients who have undergone primary, uncomplicated TKA [total knee arthroplasty]."

American Academy of Orthopedic Surgeons

The American Academy of Orthopedic Surgeons (AAOS) published evidence-based guidelines on the surgical management of osteoarthritis of the knee in 2015.⁴⁹ 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." The 2022 update to the AAOS guidelines, which replaces the 2015 version, does not address use of continuous passive motion.⁵⁰

U.S. Preventative Services Task Force Recommendations

The use of continuous passive motion devices is not a preventive service.

Government Regulations

National/Local:

Medicare National Coverage Determinations-Durable Medical Equipment Reference List (280.1) Manual 100-3, Effective on or after 9/4/20023:

“Continuous passive motion devices are covered for patients who have received a total knee replacement. To qualify for coverage, use of the device must commence within 2 days following surgery. In addition, coverage is limited to that portion of the 3-week period following surgery during which the device is used in the patient's home. There is insufficient evidence to justify coverage of these devices for longer periods of time or for other applications.”⁵²

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through February 6, 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/10/02	7/10/02	7/10/02	Joint policy established
9/10/03	9/10/03	10/14/03	Routine maintenance
2/28/05	2/28/05	3/11/05	Routine maintenance
11/1/07	8/21/07	10/22/07	Code update
11/1/08	8/19/08	10/28/08	Routine maintenance, medical policy statement verbiage changed
5/1/10	2/16/10	2/16/10	Routine maintenance
11/1/11	8/16/11	8/16/11	Routine maintenance. Added additional inclusionary guideline for CPM devices: "during the non-weight-bearing rehabilitation period following intra-articular cartilage repair procedures of the knee (e.g., microfracture, osteochondral grafting, autologous chondrocyte implantation, treatment of osteochondritis dissecans, repair of tibial plateau fractures)."
9/1/13	6/18/13	6/26/13	Routine maintenance. Rationale updated; references added.
5/1/15	2/17/15	2/27/15	Routine maintenance; updated references and rationale. No change in policy status.
5/1/16	2/16/16	2/16/16	Routine maintenance
5/1/17	2/21/17	2/21/17	Routine policy maintenance, updated rationale and reference section (#42 & 43). No change in policy status.

5/1/18	2/20/18	2/20/18	Removed "Intra"-articular from policy statement bullet #2. Updated rationale, added reference #36. No change in policy status.
5/1/19	2/19/19		Routine policy maintenance, no change in policy status. Added the following language "Maximum benefit is generally obtained within 3 weeks of initiated use post-surgery and would not be appropriate for long-term intervention. While CPM is usually initiated in the hospital early post-operative phase, this policy addresses home use of this device."
5/1/20	2/18/20		Routine policy maintenance. No change in policy status.
5/1/21	2/16/21		Routine policy maintenance. No change in policy status.
5/1/22	2/15/22		Routine policy maintenance. No change in policy status.
5/1/23	2/21/23		Routine policy maintenance. No change in policy status. (ds)
5/1/24	2/20/24		Routine policy maintenance. No change in policy status. References updated. Vendor: Northwood (ky)

Next Review Date: 1st Qtr. 2024

**BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: CONTINUOUS PASSIVE MOTION MACHINE (CPM)**

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, criteria applies
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.