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Continuous Passive Motion in the Home Setting

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0458 [Insurance Code 215 ILCS 5/356z.61] (HB3809 Impaired Children) states all group or individual fully insured PPO, HMO, POS plans amended, delivered, issued, or renewed on or after January 1, 2025 shall provide coverage for therapy, diagnostic testing, and equipment necessary to increase quality of life for children who have been clinically or genetically diagnosed with any disease, syndrome, or disorder that includes low tone neuromuscular impairment, neurological impairment, or cognitive impairment.

Coverage

Use of continuous passive motion in the home setting **may be considered medically necessary** as an adjunct to physical therapy in the following situations:

- Under conditions of low postoperative mobility or inability to comply with rehabilitation exercises following a total knee arthroplasty (total knee arthroplasty) or total knee arthroplasty revision. This may include individuals 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.

- 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).

Use of continuous passive motion in the home setting for all other conditions i**s considered experimental, investigational and/or unproven**, including but not limited to the following:

- Postoperative rehabilitation for the following:
  - Shoulder surgery,
  - Total hip replacement (THR),
  - Temporomandibular joint (TMJ) surgery, or
  - Ankle or toe surgery, including bunionectomy;
- All surgical procedures on the knee not specified in this policy as being medically necessary;
- Prevention of thrombosis following ankle surgery;
- Rehabilitation of the shoulder, elbow or hand;
- Treatment of osteoarthritis in the shoulder, hip, or any other major joint;
- Aiding in the clearance of infection from a septic joint;
- Treatment of hemarthrosis in hemophiliac individuals;
- Treatment of contractures caused by burns, trauma, and Dupuytren's contractures;
- Treatment of any other conditions not listed above.

Policy Guidelines

Following total knee arthroplasty, continuous passive motion in the home setting will be allowable for up to 17 days after surgery while individuals are immobile or unable to bear weight.

Following articular cartilage repair procedures of the knee, continuous passive motion in the home setting will be allowable for up to 6 weeks during non-weight-bearing rehabilitation.

Description

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

Background

Physical therapy of joints following surgery focuses both on passive motion to restore mobility and on active exercises to restore strength. While passive motion can be administered by a therapist, continuous passive motion devices have also been used. Continuous passive motion is thought to improve recovery by stimulating the healing of articular tissues and the circulation

of synovial fluid; reducing local edema; and preventing adhesions, joint stiffness or contractures, or cartilage degeneration. (1) Continuous passive motion has been investigated primarily in the knee, particularly after total knee arthroplasty or ligamentous or cartilage repair. Acceptance of its use in the knee joint has created interest in continuous passive motion use for other weight-bearing joints (i.e., hip, ankle, metatarsals) as well as non-weight-bearing joints (i.e., shoulder, elbow, metacarpals, interphalangeal joints). Use of continuous passive motion in stroke and burn patients is also being explored.

The device used for the knee moves the joint (e.g., flexion and extension) without patient assistance, continuously for extended periods of time (i.e., up to 24 hours/day). (1) An electrical power unit is used to set the variable range of motion and speed. The initial settings for range of motion are based on a patient's level of comfort and other factors assessed intraoperatively. The range of motion is increased by 3 to 5 degrees per day, as tolerated. The speed and range of motion can be varied, depending on joint stability. The use of the device 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. (2) As a result, there has been a considerable shift in the rehabilitation regimen, moving range of motion from an intensive in-hospital program to a less intensive outpatient program. Some providers may want patients to continue continuous passive motion in the home setting as a means of duplicating services offered with a longer (7-day) hospital stay.

The focus of this policy is to examine the literature on the use of continuous passive motion in the home setting as it is currently being prescribed postoperatively. Relevant comparisons are treatment outcomes of continuous passive motion when used alone or with physical therapy, compared with physical therapy alone.

Regulatory Status

Continuous passive motion devices are considered class 1 devices by the U.S. Food and Drug Administration and are exempt from 510(k) requirements. This classification does not require submission of clinical data on efficacy but only notification of the Food and Drug Administration prior to marketing. Food and Drug Administration product code: BXB.

Rationale

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and 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 technology, two domains are examined: the relevance, and 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

Clinical Context and Therapy Purpose

The purpose of continuous passive motion in the home setting in individuals 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 policy.

Populations

The relevant population of interest is individuals 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 (PT) alone or standard of care, if unable to tolerate PT.

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

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. Continuous passive motion after total knee arthroplasty was the subject of a 2003 Cochrane review. (4) Reviewers reported that continuous passive motion combined with PT significantly increased active knee flexion and decreased length of stay. However, the analysis suggested the benefits of continuous passive motion in a hospital setting may be small and only short-term. (5) This Cochrane review was updated in 2010 and again in 2014. (6, 7) 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 continuous passive motion. Most selected studies examined short-term effects. Continuous passive motion 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 Continuous Passive Motion

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

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

Another 2014 Cochrane systematic review, which included 11 RCTs, found no evidence that continuous passive motion reduced venous thromboembolism after total knee arthroplasty. (8)

Randomized Controlled Trials

An RCT by McInnes et al. (1992) compared use of continuous passive motion initiated in the immediate postoperative period and continued through the 7-day hospital stay with standard rehabilitation alone. (3) At 6 weeks postoperatively, the most salient difference between groups was an increased incidence of arthrofibrosis requiring manipulation in the non-continuous passive motion group.

Yashar et al. (1997) randomized 178 patients undergoing total knee arthroplasty to continuous passive motion immediately postsurgery or to continuous passive motion 1 day postsurgery. (9) A small but statistically significant improvement in flexion was found at the time of

discharge among those started on immediate continuous passive motion, but this difference did not persist at 4 weeks. MacDonald et al. (2000) reported on a randomized trial comparing immediate postoperative continuous passive motion with no continuous passive motion for 120 patients after total knee arthroplasty. (10) Patients received a maximum of 24 hours with continuous passive motion. There were no differences between treatment groups in range of motion, 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 continuous passive motion (both for 48 hours) or to no continuous passive motion. (11) The use of continuous passive motion was not associated with improved long-term function or range of motion. Kumar et al. (1996) randomized 73 patients who had undergone total knee arthroplasty to continuous passive motion immediately postsurgery or to a protocol of early passive flexion, referred to as the "drop and dangle" technique. (12) Patients assigned to passive flexion were discharged from the hospital one day earlier and also had a statistically better extension range of 2.8 at 6 months than the continuous passive motion group.

Other RCTs have found that 2 to 4 hours of daily continuous passive motion in the hospital after total knee arthroplasty did not improve postoperative outcomes at discharge or follow-up. (13-16) In one trial, Bruun-Olsen et al. (2009) randomized 63 patients undergoing total knee arthroplasty to active PT exercises with or without continuous passive motion to assess any short-term benefit on pain or function. (13) 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, continuous passive motion 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 pain ratings of 40 and flexion scores within 2 of each other. Functional testing at 3 months showed no benefit of adjunctive continuous passive motion. The lack of improvement with continuous passive motion in these studies might have been attributable to patients mobilizing or commencing flexion immediately following surgery. (15) A 2014 study of 150 patients undergoing total knee arthroplasty found no benefit of continuous passive motion when used over a 2-day postoperative hospital stay. (16)

Non-Acute Care Hospital Setting

In a RCT, Herbold et al. (2014) assessed 141 total knee arthroplasty patients assigned to daily conventional therapy lasting 3 hours or daily continuous passive motion for 2 hours throughout their inpatient rehabilitation stay. (17) After an average length of stay of 8 days, there were no significant differences between the continuous passive motion and no continuous passive motion groups for active range of motion, 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 scores.

In 2000, Chen et al. randomized 51 patients in an inpatient rehabilitation service who had undergone total knee arthroplasty to conventional active PT or to PT plus continuous passive motion. (18) Referral to the rehabilitation center was made 5 to 6 days after surgery, and most

had received continuous passive motion as part of the initial hospitalization. Knee flexion was the principal outcome. No significant differences were noted in passive range of motion 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 continuous passive motion in the rehabilitation hospital offered no added benefit.

In a 2012 retrospective comparative study, the same group as the Herbold et al. RCT evaluated the use of continuous passive motion in 61 matched pairs of patients admitted to a rehabilitation hospital. (19) Outcomes following use of continuous passive motion were compared with those from a cohort of 61 inpatients who also had poor initial range of motion, 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 continuous passive motion (2 hours/day) was determined primarily by the referring physician and used in 29% of the pool of 633 patients who had poor initial range of motion. 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 continuous passive motion with active PT in the home setting. At discharge, they randomized 80 patients undergoing total knee arthroplasty to home continuous passive motion (3 hours/day for 10 days) or to active PT. (20) Most studies have examined continuous passive motion as an adjunct to active PT, while this study proposed continuous passive motion 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 continuous passive motion 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 range of motion (<80) at the time of hospital discharge who were assigned to standard PT alone or PT plus continuous passive motion in the home (4 hours/day) until assessment on postoperative day 17. (21) Blinded assessment showed a trend for increased range of motion for the continuous passive motion group (e.g., 89 vs. 84, respectively; p=.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 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 compared continuous passive motion as adjunctive therapy with PT for patients undergoing total knee arthroplasty. Most trials used continuous passive motion 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 range of motion for patients receiving continuous passive motion but these improvements were short-term, of small magnitude, and of uncertain clinical significance. The RCTs that specifically evaluated continuous passive motion in the non-acute care hospital setting or home setting did not show improved outcomes with continuous passive motion.

Articular Cartilage Repair of the Knee

Clinical Context and Therapy Purpose

The purpose of continuous passive motion in the home setting in individuals with articular cartilage repair of the knee 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 policy.

Populations

The relevant population of interest is individuals with articular cartilage repair of the knee.

Interventions

The therapy being considered is continuous passive motion.

Comparators

The following therapies are currently being used for articular cartilage repair of the knee: standard of care.

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.

Although no RCTs were identified comparing health outcomes with or without the use of continuous passive motion, continuous passive motion is routinely used as part of the rehabilitation protocol for as long as 6 weeks when weight-bearing is restricted following autologous chondrocyte implantation. (22-24) Basic research supports the use of continuous passive motion to facilitate greater healing of articular cartilage of full-thickness defects that

penetrate the subchondral bone compared with either immobilization or intermittent mobilization. (25, 26)

Fazalare et al. (2010) published a systematic review of continuous passive motion after knee cartilage defect surgery. (27) Reviewers found that continuous passive motion 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 continuous passive motion with no continuous passive motion; 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. Continuous passive motion 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 continuous passive motion. However, reviewers cited several studies in which other outcomes (e.g., histologic outcomes on follow-up biopsies) did favor continuous passive motion.

Another systematic review by Howard et al. (2010) evaluated continuous passive motion and other postoperative practices after knee cartilage repair. (28) Reviewers cited several basic science studies using animal models that appear to support continuous passive motion. 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 continuous passive motion group (n=46) had greater improvement in grading of the cartilage lesion compared with patients who did not have access to continuous passive motion (n=31).

Section Summary: Articular Cartilage Repair of the Knee

Current evidence on use of continuous passive motion 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 continuous passive motion to knee rehabilitation.

Other Musculoskeletal Conditions Requiring Physical Therapy

Clinical Context and Therapy Purpose

The purpose of continuous passive motion in the home setting in individuals with musculoskeletal conditions other than total knee arthroplasty or knee cartilage repair requiring PT 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 policy.

Populations

The relevant population of interest is individuals with musculoskeletal conditions other than total knee arthroplasty or knee cartilage repair requiring PT.

Interventions
The therapy being considered is continuous passive motion.

Comparators
The following therapies are currently being used for musculoskeletal conditions other than total knee arthroplasty or knee cartilage repair requiring PT: standard of care.

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.

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 continuous passive motion for 48 hours postoperatively. (29) At the 48-hour assessment, the continuous passive motion group had significantly greater knee flexion (43 difference; $p<.005$). However, 6 of 20 patients were unable to tolerate continuous passive motion and there was no benefit to adding 48 hours of continuous passive motion when assessed at any of the follow-up visits (2, 6, 12, and 24 weeks).

Anterior Cruciate Ligament Repair
This literature review did not identify any RCTs of continuous passive motion in the home setting after repair of the anterior cruciate ligament. However, the studies of continuous passive motion after anterior cruciate ligament 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. In a systematic review of anterior cruciate ligament reconstruction rehabilitation, Wright et al. (2008) discussed 6 RCTs on continuous passive motion published before 1996. (30) Reviewers found no substantial advantage for continuous passive motion use and concluded that continuous passive motion for anterior cruciate ligament rehabilitation could not be justified. Wright et al. (2008) also noted that most current anterior cruciate ligament rehabilitation protocols initiate 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. (31) This review identified 1 systematic review that included evidence for continuous passive motion by Gatewood et al. (2017). (32) 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. (33) 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 Repair

Du Plessis et al. (2011) published a systematic review of continuous passive motion following rotator cuff repair. (34) 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. (35, 36) 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. (37)

The trial by Lastayo et al. (1998) randomized 31 patients undergoing rotator cuff repair to a 4-week home program of continuous passive motion (average, 3 hours/day) or to manual passive elevation and rotation exercises. (35) 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 continuous passive motion. (36) Patients were evaluated with preoperative and 3 month postoperative shoulder scores that included pain, function, muscle strength, and range of motion. A statistically significant improvement was found in range of motion for those receiving continuous passive motion, although there was no significant improvement in overall shoulder score between groups. Both of these RCTs were likely under powered to show differences on important clinical outcomes.

Garofalo et al. (2010) reported on a randomized trial assessing the effects of continuous passive motion after rotator cuff repair. (38) During weeks 1 to 4 post surgery, all 100 patients underwent passive self-assisted range of motion exercise, with half of the patients also receiving continuous passive motion for 4, 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 post surgery, all patients underwent the same PT protocol. Visual analog scale ratings for pain were measured at 2.5, 6, and 12 months by an independent examiner. Between groups, visual analog scale ratings were slightly better for patients who received continuous passive motion 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. Range of

motion was significantly better in the group receiving continuous passive motion versus those who did not at 2.5-month follow-up (e.g., 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 continuous passive motion following rotator cuff surgery were identified in the English-language literature. Two of these trials reported short-term improvements in range of motion for patients undergoing continuous passive motion, 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, so the optimal comparator for continuous passive motion is not clear.

Hip Osteoarthritis
One older pilot study (1999) examined the use of continuous passive motion in patients with hip osteoarthritis in the absence of surgical intervention. (39) In this uncontrolled study, continuous passive motion 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.

Femoral Fracture
Olasinde et al. (2023) reported the results of a randomized trial that compared continuous passive motion to PT in patients who underwent retrograde femoral nailing for femoral fracture. (40) The 88 participants were randomized to continuous passive motion or conventional PT, each for 2 hours daily. Knee stiffness at weeks 1, 2, and 6 were significantly lower among patients who received continuous passive motion compared to patients who received conventional PT (all $p<.0001$). Pain scores (measured by visual analogue scale) were significantly lower for the first 7 days in the continuous passive motion group, and total arc of motion gained postoperatively was also significantly larger at postoperative weeks 1, 2, and 6 (all $p<.05$). Interpretation of these results is limited because the duration of the intervention was not clearly stated.

Adhesive Capsulitis of the Shoulder
Systematic Review
Baradaran et al. (2023) conducted a systematic review of continuous passive motion compared to PT in patients with primary adhesive capsulitis (Tables 2 through 4). (41) A total of 5 studies were included in the meta-analysis, but the conclusions were limited by heterogeneity. The authors concluded that continuous passive motion may be slightly effective in the short-term, but that long-term efficacy is still unknown.

Table 2. Trials/Studies Included in Systematic Review and Meta-Analysis

Study	Baradaran et al. (2023) (41)
Azizi et al. (2018)	●
Ekim et al. (2016)	●

Chung et al. (2015)	●
Chen et al. (2009)	●
Dundar et al. (2009)	●

Table 3. Systematic Review and Meta-Analysis Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Baradaran et al. (2023) (41)	2009-2018	5	224	16-80	RCT	4-24 weeks

N: number; RCT: randomized controlled trial.

Table 4. Systematic Review and Meta-Analysis Results

Study	Pain at movement	Pain at rest	SPADI score	Constant functional shoulder score
Baradaran et al. (2023) (41)				
Total N	114	114	178	128
Pooled effect (95% CI)	Short-term[1]: -1.277 (-2.146 to -0.407) Long-term[2]: -1.222 (-2.224 to -0.220)	Short-term[1]: -0.872 (-1.784 to 0.040) Long-term[2]: -0.816 (-1.704 to 0.073)	Short-term[1]: -5.196 (-12.995 to 2.602) Long-term[2]: -4.561 (-12.976 to 3.855)	Short-term[1]: 4.117 (-1.622 to 9.857) Long-term[2]: 4.790 (0.376 to 9.204)
p	Short-term[1]: .004 Long-term[2]: .017	Short-term[1]: .061 Long-term[2]: .072	Short-term[1]: .192 Long-term[2]: .288	Short-term[1]: .160 Long-term[2]: .033

CI: confidence interval; N: number; SPADI: shoulder pain and disability index.

[1] Short-term was defined as outcomes at week 4.

[2] Long-term was defined as outcomes at week 12, or pooled outcomes from weeks 8 and 24 (depending on the study).

Randomized Controlled Trials

Dundar et al. (2009) compared continuous passive motion with PT in a randomized trial of 57 patients with adhesive capsulitis (frozen shoulder). (42) Continuous passive motion or PT was provided for 1 hour a day (5 days/week) for 4 weeks. Pain and function levels were similar in the 2 groups at baseline, with visual analog scale 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, continuous passive motion 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 range of motion or function. This trial provided modest support for the inclusion of continuous passive motion in a PT regimen for this patient population.

An RCT by Ekim et al. (2016) compared continuous passive motion (n=20) with PT (n=21) for the treatment of adhesive capsulitis in patients who had diabetes. (43) Continuous passive motion or PT was provided for 1 hour a day (5 days/week) 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 range of motion (active and passive). Pain decreased significantly in both treatment groups, though patients in the continuous passive motion group reported a larger improvement in pain scores than those in the PT group. Range of motion improved significantly in both treatment groups as well. Patients in the continuous passive motion group reported larger improvements in abduction and flexion measures than patients in the PT group, while external and internal rotation improvements were similar across groups.

Elbow Contracture

Postoperative management of open elbow contracture release with continuous passive motion was assessed in a matched cohort study by Lindenhovius et al. (2009). (44) Sixteen patients who had used continuous passive motion after open contracture release and 16 patients who had not were matched by age, sex, diagnosis, range of motion, and radiographic appearance. Improvements in range of motion did not differ between groups at the early (range, 4 to 10 months) and the final (range, 11 to 56 months) evaluations.

Hand Repair

Ring et al. (1998) conducted a randomized trial that examined the role of continuous passive motion in patients undergoing silicone interposition arthroplasty of the metacarpophalangeal joints secondary to rheumatoid arthritis. (45) Patients were randomized to a 6-week protocol of continuous passive motion (10 hands [40 joints]) or to a standard dynamic splint protocol (15 hands [60 joints]). The trial did not show better outcomes in the continuous passive motion group.

In 2008, a retrospective chart review compared 15 patients who had received continuous passive motion after tenolysis with 21 who did not. (46) Patients who received continuous passive motion improved total active motion by 40 (range, 137 to 177), while patients who did not improved total active motion by 32 (range, 152 to 184); this difference was not statistically significant.

Foot Repair

One study (2005) has compared continuous passive motion with immobilization following surgical treatment of idiopathic club foot in 37 infants (50 feet). (47) The infants were randomized to continuous passive motion (4 hours/day) or to casting during days 10 to 42 following surgery. Blinded analysis showed improvements in the Dimeglio Clubfoot Score with continuous passive motion (range of motion, 9.7 to 3.1) that were significantly greater than those in the control group (range of motion, 10.3 to 4.2) through 12 months (97% follow-up). Between 12 and 18 months, this trend reversed and by 48 months post-surgery, there was no significant difference between groups. Another study (2007) by the same group reported low compliance with this treatment. (48)

Back Pain

An RCT by Gavish et al. (2015) evaluated a continuous passive motion device for treatment of chronic low back pain in 36 patients. (49) 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.

Humeral Fractures

An RCT by Tille et al. (2024) evaluated a continuous passive motion device after plate osteosynthesis of proximal humeral fractures. (50) A total of 95 patients were enrolled with 48 assigned to continuous passive motion and 47 without. Physical therapy was provided for all patients starting on day 7 postoperatively. Continuous passive motion was utilized 2 to 3 times daily for 6 weeks after surgery. After 6 weeks, there was a significantly better range of motion for forward flexion (90° with continuous passive motion vs. 80° in control; p=.035), adduction (30° with continuous passive motion vs. 30° with control; p=.049), and abduction (80° with continuous passive motion vs. 70° with control; p=.048) in the continuous passive motion group. There was no difference in other planes of motion. At 3 and 12 months of follow-up, the results between treatment groups were similar.

Section Summary: Other Musculoskeletal Conditions Requiring Physical Therapy

There is a wide range of studies assessing the use of continuous passive motion for musculoskeletal conditions other than total knee arthroplasty 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 continuous passive motion after rotator cuff surgery showed some evidence that continuous passive motion 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 continuous passive motion, 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 continuous passive motion is unclear. A systematic review and two small RCTs compared continuous passive motion with conventional PT for treatment of adhesive capsulitis. The systematic review was limited by heterogeneity but concluded that continuous passive motion may be effective in the short-term. 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. One small RCT in humeral fractures also found short-term benefits of continuous passive motion, but by 3 months there was no significant difference between

groups. For other musculoskeletal conditions, RCTs do not exist; case series either did not show efficacy of continuous passive motion or had important methodologic flaws.

Stroke

Clinical Context and Therapy Purpose

The purpose of continuous passive motion in the home setting in individuals with stroke 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 policy:

Populations

The relevant population of interest is individuals with stroke.

Interventions

The therapy being considered is continuous passive motion.

Comparators

The following therapies are currently being used for stroke: standard of care.

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.

Continuous passive motion has been 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 continuous passive motion device (25 minutes) or to daily group therapy sessions consisting of self-directed shoulder range of motion for poststroke rehabilitation. (51) 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 continuous passive motion group (n=17; p=.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, 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. (52) All patients received standard-of-care occupational therapy and 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 who receive continuous passive motion in the home setting, the evidence includes randomized controlled trials (RCTs), case series, and systematic reviews. Relevant outcomes are symptoms and functional outcomes. Early trials generally used continuous passive motion 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 continuous passive motion after total knee arthroplasty, recent studies have suggested that institutional and home use of continuous passive motion has no benefit compared with standard physical therapy (PT). There were no studies evaluating continuous passive motion in patients who could not perform standard PT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have articular cartilage repair of the knee who receive continuous passive motion in the home setting, the evidence includes nonrandomized studies, case series, and studies with nonclinical outcomes (e.g., histology), and systematic reviews of these studies. Relevant outcomes are symptoms and functional outcomes. Systematic reviews of continuous

passive motion for this indication have cited studies reporting better histologic outcomes in patients following continuous passive motion. A few studies have reported clinical outcomes, but inadequacies of these studies do not permit conclusions on efficacy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have musculoskeletal conditions other than total knee arthroplasty or knee cartilage repair requiring PT who receive continuous passive motion in the home setting, the evidence includes systematic reviews and/or RCTs for some conditions and case series for others. Relevant outcomes are symptoms and functional outcomes. Three small RCTs of continuous passive motion after rotator cuff surgery showed some evidence that continuous passive motion 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 continuous passive motion, 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 continuous passive motion is unclear. A systematic review and two small RCTs compared continuous passive motion with conventional PT for treatment of adhesive capsulitis. The systematic review concluded that continuous passive motion may be effective in the short-term. 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. 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. One small RCT in humeral fractures also found short-term benefits of continuous passive motion, but by 3 months there was no significant difference between groups. For other musculoskeletal conditions, RCTs do not exist; case series either did not show efficacy of continuous passive motion or had important methodologic flaws. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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.

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers
Clinical input supports the use of CPM under the following circumstances:

- Under conditions of low postoperative mobility or inability to comply with rehabilitation exercises following a total knee arthroplasty or total knee arthroplasty revision; or
- During the non-weight-bearing rehabilitation period following articular cartilage repair of the knee.

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. (53) 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 Orthopaedic Surgeons
In 2015, the American Academy of Orthopaedic Surgeons (AAOS) published evidence-based guidelines on the surgical management of osteoarthritis of the knee. (54) The AAOS identified 2 high-quality studies and 5 moderate-quality studies that evaluated the use of continuous passive motion. In one high-quality study, continuous passive motion was used for about 2 weeks after discharge. The 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. (55)

Medicare National Coverage
In 2005, the Centers for Medicare & Medicaid Services issued a national coverage determination on durable medical equipment reference, which stated:

“Continuous passive motion devices are devices 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.” (56)

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this policy are listed in Table 5.

Table 5. Summary of Key Trials

NCT Number	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

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	E0935, E0936, E1399

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/01/2025	Document updated with literature review. The following changes were made to Coverage: 1) Removed “Use of the CPM device must begin within 48 hours of the surgical procedure (or on discharge from facility following the procedure) and may continue for ONLY up to 21 days postoperatively, OR” from the conditional coverage statement regarding continuous passive

	motion device use following a total knee arthroplasty or total knee arthroplasty revision; 2) Removed “and for reconstruction of the anterior cruciate ligament (ACL)” from the conditional coverage statement regarding continuous passive motion device use following articular cartilage repair procedures of the knee and 3) Specified that focus of the policy is for continuous passive motion in the home setting. Added references 40, 41, and 50; others updated. Title changed from “Continuous Passive Motion (CPM) Device”.
07/15/2024	Reviewed. No changes.
12/01/2023	Document updated with literature review. Coverage unchanged. Added references 1, 2, 31-33, 49, 50 and 52.
07/15/2022	Reviewed. No changes.
07/01/2021	Document updated with literature review. Coverage unchanged. No new references added.
07/15/2020	Reviewed. No changes.
10/01/2019	Document updated with literature review. Coverage unchanged. Added reference 33.
07/15/2018	Reviewed. No changes.
11/15/2017	Document updated with literature review. Coverage has changed for the second bullet under the Continuous Passive Motion (CPM) device may be considered medically necessary for use postoperatively as an adjunct to conventional physical therapy in the following situations ONLY statement and reflects the following: For up to 6 weeks during the non-weight bearing rehabilitation period following knee surgery for microfracture, osteochondral grafting, autologous chondrocyte implantation, treatment of osteochondritis dissecans, repair of tibial plateau fractures, and for reconstruction of the anterior cruciate ligament (ACL).
07/15/2016	Document updated with literature review. Coverage unchanged.
08/15/2015	Reviewed. No changes.
12/01/2014	Document updated with literature review. The following changes were made to the first bullet listed under the conditions considered medically necessary in the coverage section: Total knee arthroplasty (TKA) or TKA revision changed to knee arthroplasty or knee arthroplasty revision. The following clarification was made to the example section listed in the coverage section: From (e.g., microfracture, osteochondral grafting, autologous chondrocyte implantation, treatment of osteochondritis dissecans, repair of tibial plateau fractures, reconstruction of the anterior cruciate ligament [ACL]). To: (e.g., microfracture, osteochondral grafting, autologous chondrocyte implantation, treatment of osteochondritis dissecans, repair of tibial plateau fractures), and for reconstruction of the anterior cruciate ligament (ACL).
01/01/2012	Document updated with literature review. The following changes were made: 1) Following intra-articular cartilage repair procedures of the knee, CPM may be allowed for up to six (6) weeks during non-weight-bearing

	rehabilitation; 2) “This document is no longer scheduled for routine literature review and update.” was removed.
04/15/2009	Revised/updated entire document
02/15/2008	Revised/updated entire document. This policy is no longer scheduled for routine literature review and update.
03/15/2006	Revised/updated entire document
04/01/2002	Revised/updated entire document
03/01/1998	Revised/updated entire document
05/01/1996	Revised/updated entire document
03/01/1996	Revised/updated entire document
10/01/1994	Revised/updated entire document
07/01/1992	Revised/updated entire document
09/01/1990	New Medical Document