

## Medical Policy



### Title: Continuous Passive Motion in the Home Setting

Professional	Institutional
Original Effective Date: June 10, 1986	Original Effective Date: March 8, 2010
Revision Date(s): June 21, 1990; May 16, 1991; July 16, 1996; December 4, 1996; January 1, 2000; August 1, 2002; May 3, 2004; May 14, 2004; July 6, 2005; December 28, 2006; April 19, 2007 March 8, 2010; March 7, 2012; September 17, 2013; September 29, 2015; September 16, 2016; April 12, 2017; April 11, 2018; April 24, 2019; June 7, 2021; May 4, 2022	Revision Date(s): September 29, 2015; September 16, 2016; April 12, 2017; April 11, 2018; April 24, 2019; June 7, 2021; May 4, 2022
Current Effective Date: June 7, 2021	Current Effective Date: June 7, 2021

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Populations	Interventions	Comparators	Outcomes
Individuals: • With total knee arthroplasty	Interventions of interest are:	Comparators of interest are: • Physical therapy alone	Relevant outcomes include: • Symptoms

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

**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.

**OBJECTIVE**

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

**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. 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 h/d). 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 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. As a result, there has been a considerable shift in the rehabilitation regimen, moving range of motion 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 the current review 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 range of motion 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.

**POLICY**

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

**POLICY GUIDELINES**

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

**Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

**RATIONALE**

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through December 20, 2021.

Evidence reviews 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 patients 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 patients with total knee arthroplasty is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of continuous passive motion improve the net health outcome in patients with total knee arthroplasty?

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

### REVIEW OF EVIDENCE

#### Systematic Reviews

This evidence review was informed by a TEC Assessment (1997) that concluded continuous passive motion met the TEC criteria as an adjunct to physical therapy (PT) in patients undergoing total knee arthroplasty.<sup>1</sup> Early studies of continuous passive motion 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 continuous passive motion devices were used. A critical study identified in the TEC Assessment was an RCT by McInnes et al (1992) that compared use of continuous passive motion initiated in the immediate postoperative period and continued through the 7-day hospital stay with standard rehabilitation alone.<sup>2</sup> 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.

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.<sup>3</sup> 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.<sup>4</sup> This Cochrane review was updated in 2010 and again in 2014.<sup>5,6</sup> The updated review included 24 RCTs with 1,445 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
continuous passive motion increases passive and active knee flexion range of motion (mean difference, 2), but the effects were too small to be clinically relevant	Moderate
continuous passive motion does not have clinically important short-term effects on pain (-0.4 points on a 10-point scale)	Low
continuous passive motion does not have clinically important medium-term effects on function or quality of life	Moderate
continuous passive motion may reduce the need for manipulation under anesthesia (25 fewer manipulations per 1000; RR=0.3)	Very low
continuous passive motion reduced the risk of adverse events (13 fewer adverse events per 1000, RR=0.9)	Low

Adapted from Harvey et al (2014).<sup>5</sup> continuous passive motion: continuous passive motion; QOE: quality of evidence; RR: relative risk.

Another 2014 Cochrane systematic review, which included 11 RCTs, found no evidence that continuous passive motion reduced venous thromboembolism after total knee arthroplasty.<sup>7</sup>

### **Randomized Controlled Trials**

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.<sup>8</sup> 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 four 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.<sup>9</sup> 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.<sup>10</sup> 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.<sup>11</sup> Patients assigned to passive flexion were discharged range of motion 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.<sup>12,13,14,15</sup> 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.<sup>12</sup> 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.<sup>14</sup> 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.<sup>15</sup>

### **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.<sup>16</sup> After an average length of stay of eight 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 (2000) randomized 51 patients in an inpatient rehabilitation service who had undergone total knee arthroplasty to conventional active physical therapy or to physical therapy plus continuous passive motion.<sup>17</sup> 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.<sup>18</sup> Outcomes following use of continuous passive motion were compared with those range of motion 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 h/d) 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 physical therapy in the home setting. At discharge, they randomized 80 patients undergoing total knee arthroplasty to home continuous passive motion (3 h/d for 10 days) or to active physical therapy.<sup>19</sup> Most studies have examined continuous passive motion as an adjunct to active physical therapy, while this study proposed continuous passive motion as an alternative to physical therapy. 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 physical therapy alone or physical therapy plus continuous passive motion in the home (4 h/d) until assessment on postoperative day 17.<sup>20</sup> Blinded assessment showed a trend for increased range of motion for the continuous passive motion group (e.g., 89 vs 84, respectively,  $p=0.07$ ), with no differences in function between groups, as measured by the Knee Society Score (function subscore 43 vs 40, respectively) and the Western Ontario and McMaster Universities Osteoarthritis Index difficulty score (49 vs 45, respectively). No differences were observed between groups in 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 physical therapy 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 patients 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 question addressed in this evidence review is: Does the use of continuous passive motion improve the net health outcome in patients with articular cartilage repair of the knee?

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

### ***Populations***

The relevant population(s) of interest are patients 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.

### **Review of Evidence**

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.<sup>21,22,23</sup> 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.<sup>24,25</sup>

Fazalare et al (2010) published a systematic review of continuous passive motion after knee cartilage defect surgery.<sup>26</sup> 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 range of motion 6 days to 8 weeks. Heterogeneity in the studies and outdated surgical techniques limited conclusions drawn range of motion 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.<sup>27</sup> 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 patients with musculoskeletal conditions other than total knee arthroplasty or knee cartilage repair requiring physical therapy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of continuous passive motion improve the net health outcome in patients with musculoskeletal conditions other than total knee arthroplasty or knee cartilage repair requiring physical therapy?

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

### ***Populations***

The relevant population(s) of interest are patients with musculoskeletal conditions other than total knee arthroplasty or knee cartilage repair requiring physical therapy.

### ***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 physical therapy: 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.

## **REVIEW OF EVIDENCE**

### **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 physical therapy with or without continuous passive motion for 48 hours postoperatively.<sup>28</sup> At the 48-hour assessment, the continuous passive motion group had significantly greater knee flexion (43 difference,  $p < 0.005$ ). 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, 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. The TEC Assessment (1997) concluded that continuous passive motion as an adjunct to conventional PT in the immediate postoperative period after anterior cruciate ligament repair offered no demonstrable advantage over conventional physical therapy alone.<sup>17</sup> In a systematic review of anterior cruciate ligament reconstruction rehabilitation, Wright et al (2008) discussed 6 RCTs on continuous passive motion published before 1996; no RCTs published after the 1997 TEC Assessment were identified.<sup>29</sup> 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.

### **Rotator Cuff Repair**

Du Plessis et al (2011) published a systematic review of continuous passive motion following rotator cuff repair.<sup>30</sup> 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.<sup>31,32</sup> 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 physical therapy control group, with no significant difference in pain between the 2 groups.<sup>33</sup>

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 h/d) or to manual passive elevation and rotation exercises.<sup>31</sup> No significant difference in outcomes was observed between the two approaches. Previously, Raab et al (1996) had randomized 26 patients to postoperative physical therapy alone or to physical therapy plus continuous passive motion.<sup>32</sup> 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.<sup>34</sup> 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. Range of motion weeks 5 to 28 post surgery, all patients underwent the same physical therapy protocol. range of motion and 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, and 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.<sup>35</sup> 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.

**Adhesive Capsulitis of the Shoulder**

Dundar et al (2009) compared continuous passive motion with physical therapy in a randomized trial of 57 patients with adhesive capsulitis (frozen shoulder).<sup>36</sup> Continuous passive motion or physical therapy was provided for 1 hour a day (5 d/wk) for 4 weeks. Pain and function levels were similar in the 2 groups at baseline, with visual analog scale scores for pain ranging range of motion 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 physical therapy (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 physical therapy regimen for this patient population.

An RCT by Ekim et al (2016) compared continuous passive motion (n=20) with physical therapy (n=21) for the treatment of adhesive capsulitis in patients who had diabetes.<sup>37</sup> Continuous passive motion or physical therapy 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 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 physical therapy 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 continuous passive motion 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).<sup>38</sup> 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, 4-10 months) and the final (range, 11-56 months) evaluations.

**Hand Repair**

In 1997, the TEC Assessment reviewed a multicenter study of continuous passive motion in patients who had undergone flexor tendon repair and found the data inadequate to permit scientific conclusions about continuous passive motion application.<sup>1</sup>

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.<sup>39</sup> 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.<sup>40</sup> Patients who received continuous passive motion improved total active motion by 40 (range, 137-177), while patients who did not improved total active motion by 32 (range, 152-184); this difference was not statistically significant.

### **Foot Repair**

One study (2005) has compared continuous passive motion with immobilization following surgical treatment of idiopathic club foot in 37 infants (50 feet).<sup>41</sup> The infants were randomized to continuous passive motion (4 h/d) 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.<sup>42</sup>

### **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.<sup>43</sup> Although patients treated with the device appeared to have improved outcomes on a numeric rating scale of back pain compared with waiting-list controls, the trial had significant methodologic problems. Patients who received other treatments were excluded, a large number of subjects dropped out, and control patients did not receive any conservative management.

### **Section Summary: Other Musculoskeletal Conditions Requiring 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. 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 physical therapy regimen following shoulder surgery such that the optimal treatment comparator for continuous passive motion is unclear. Two small RCTs compared continuous passive motion with conventional physical therapy for treatment of adhesive capsulitis. One of the trials focused on diabetic patients with adhesive capsulitis. Both reported comparable improvements in range of motion and functional ability between treatment groups. For other musculoskeletal conditions, RCTs do not exist; case series either did not show efficacy of 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 patients with stroke is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of continuous passive motion improve the net health outcome in patients stroke?

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

### ***Populations***

The relevant population(s) of interest are patients 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.

### **Review of Evidence**

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 continuous passive motion (25 minutes) or to daily group therapy sessions consisting of self-directed range of motion for poststroke rehabilitation.<sup>44</sup> 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=0.06) compared with the control group (n=15). No statistically significant differences were found for measures of motor impairment. This trial had a small sample size and short follow-up period.

### **Section Summary: Stroke**

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

### **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 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. Two small RCTs compared continuous passive motion with conventional PT for treatment of adhesive capsulitis. One of the trials focused on diabetic patients with adhesive capsulitis. Both reported comparable improvements in range of motion and functional ability between treatment groups. For other musculoskeletal conditions, RCTs do not exist; case series either did not show efficacy of 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 a small RCT. Relevant outcomes are symptoms and functional outcomes. This trial reported a trend toward improved shoulder joint stability but no statistical difference between continuous passive motion plus PT and PT alone. The trial was small and treatment lasted only 20 days. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### **SUPPLEMENTAL INFORMATION**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### **Clinical Input Range of Motion Physician Specialty Societies and Academic Medical Centers**

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

#### **2016 Input**

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

#### **2010 Input**

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

#### **2008 Input**

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

### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### **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.<sup>45</sup>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."

### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

### **Ongoing and Unpublished Clinical Trials**

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

**Table 2. Summary of Key Trials**

<b>NCT No.</b>	<b>Trial Name</b>	<b>Actual Enrollment</b>	<b>Completion Date</b>
<i>Unpublished</i>			
NCT01420887	Preservation of Joint Function Using Postoperative Continuous Passive Motion (continuous passive motion): A Pilot Study	6 0	May 2020

NCT: national clinical trial.

**CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.**

**Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

**The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.**

<b>CPT/HCPCS</b>	
E0935	Continuous passive motion exercise device for use on knee only
E0936	Continuous passive motion exercise device for use other than knee
E1399	Durable medical equipment, miscellaneous

<b>ICD-10 DIAGNOSES</b>	
M07.641	Enteropathic arthropathies; right hand
M07.642	Enteropathic arthropathies; left hand
M07.661	Enteropathic arthropathies, right knee
M07.662	Enteropathic arthropathies, left knee
M07.671	Enteropathic arthropathies, right ankle and foot
M07.672	Enteropathic arthropathies, left ankle and foot
M12.541	Traumatic arthropathy; right hand
M12.542	Traumatic arthropathy; left hand
M12.561	Traumatic arthropathy, right knee
M12.562	Traumatic arthropathy, left knee
M12.571	Traumatic arthropathy, right ankle and foot
M12.572	Traumatic arthropathy, left ankle and foot
M12.841	Other specific arthropathies, not elsewhere classified; right hand
M12.842	Other specific arthropathies, not elsewhere classified; left hand
M12.861	Other specific arthropathies, not elsewhere classified, right knee
M12.871	Other specific arthropathies, not elsewhere classified, right ankle and foot
M12.872	Other specific arthropathies, not elsewhere classified, left ankle and foot
M17.0-M17.9	Osteoarthritis of knee, code range
M18.0	Bilateral primary osteoarthritis of first carpometacarpal joints
M18.11	Unilateral primary osteoarthritis of first carpometacarpal joint; right hand
M18.12	Unilateral primary osteoarthritis of first carpometacarpal joint; left hand
M19.041	Primary osteoarthritis; right hand
M19.042	Primary osteoarthritis; left hand
Z96.621	Presence of right artificial elbow joint

<b>ICD-10 DIAGNOSES</b>	
Z96.622	Presence of left artificial elbow joint
Z96.631	Presence of right artificial wrist joint
Z96.632	Presence of left artificial wrist joint
Z96.651-Z96.659	Presence of artificial knee joint, code range
Z96.661	Presence of right artificial ankle joint
Z96.662	Presence of left artificial ankle joint

<b>REVISIONS</b>	
03-08-2010	<p>In Policy Section:</p> <ul style="list-style-type: none"> <li>▪ Revised wording in C. From: "The use of a CPM device for any primary or adjunct therapeutic application other than those listed above is considered investigational/ not medically necessary."</li> <li>To: "The use of a CPM device for any primary or adjunct therapeutic application other than those listed above is considered experimental / investigational."</li> <li>▪ Revised wording in A., third paragraph from: "CPM is approved without review-for a rental period no longer than 21 days from date of first application."</li> <li>To: "If CPM is approved, allow for a rental period no longer than 21 days from date of first application."</li> </ul> <p>In Coding Section:                      Added HCPCS Code: E0936 (effective 01-01-07)                      Added Rationale Section                      Updated References</p>
03-07-2012	<p>In the Policy section:</p> <ul style="list-style-type: none"> <li>▪ In Item A, #1, removed "TKA" at the end to read "or revision."</li> <li>▪ In Item A, added "#2. Partial knee arthroplasty (27446)</li> <li>▪ In Item A, added the following:                             <ul style="list-style-type: none"> <li>○ "6. Osteochondral grafting</li> <li>○ 7. Treatment of osteochondritis dissecans</li> <li>○ 8. Repair of tibial plateau fractures"</li> </ul> </li> </ul> <p>Updated the Rationale section.                      Updated the Reference section.</p>
09-17-2013	<p>In Coding section:</p> <ul style="list-style-type: none"> <li>▪ Added ICD-10 Diagnosis codes (<i>Effective October 1, 2014</i>)</li> </ul> <p>Updated Rationale section.                      Updated Reference section.</p>
09-29-2015	<p>Policy title revised from "Continuous Passive Motion for Home Use"</p> <p>Updated Description section.                      Updated Rationale section.                      Updated References section.</p>
09-16-2016	<p>Updated Description section.</p> <p>In Policy section:</p> <ul style="list-style-type: none"> <li>▪ Policy language previously stated, " A.Continuous passive motion (CPM) is considered medically necessary for the following surgeries:                             <ol style="list-style-type: none"> <li>1. Total knee arthroplasty (TKA) or revision</li> <li>2. Partial knee arthroplasty</li> <li>3. Anterior cruciate ligament (ACL) repair</li> <li>4. Autologous chondrocyte implantation (ACI)</li> <li>5. Microfracture of the knee</li> </ol> </li> </ul>

<b>REVISIONS</b>	
	<p>6. Osteochondral grafting                      7. Treatment of osteochondritis dissecans                      8. Repair of tibial plateau fractures</p> <p>Continuous passive motion (CPM) will be reviewed for medical necessity for the following surgeries:</p> <p>1. Ankle                      2. Elbow                      3. Wrist                      4. Hand</p> <p>If CPM is approved, allow for a rental period no longer than 21 days from date of first application.</p> <p>B. Continuous passive motion (CPM) is denied not medically necessary for the following surgeries:</p> <p>1. Shoulder                      2. Interphalangeal joints of lower extremities to include the great toe</p> <p>C. The use of a CPM device for any primary or adjunct therapeutic application other than those listed above is considered experimental / investigational."</p> <ul style="list-style-type: none"> <li>▪ Current policy language states, " A.Use of continuous passive motion (CPM) in the home setting may be considered medically necessary as an adjunct to physical therapy in the following situations:                             <ol style="list-style-type: none"> <li>1. Under conditions of low postoperative mobility or inability to comply with rehabilitation exercises following a total knee arthroplasty (TKA) or TKA revision. This may include patients with complex regional pain syndrome (reflex sympathetic dystrophy); extensive arthrofibrosis or tendon fibrosis; or physical, mental, or behavioral inability to participate in active physical therapy.</li> <li>2. 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.</li> </ol> </li> </ul> <p>B. Use of CPM in the home setting for all other conditions is considered not medically necessary.</p> <p>Policy Guidelines</p> <p>1. If CPM is approved, allow for a rental period no longer than 21 days from date of first application."</p>
	Updated Rationale section.
	Updated References section.
04-12-2017	Updated Description section.
	Updated Rationale section.
	Updated References section.
04-11-2018	Updated Description section.
	Updated Rationale section.
	In Coding section:
	▪ Removed ICD-9 codes.
	Updated References section.
04-24-2019	Updated Rationale section.
	Updated References section.
06-07-2021	Updated Description section.
	Updated Policy Guidelines

<b>REVISIONS</b>	
	<ul style="list-style-type: none"> <li>• Removed "If CPM is approved, allow for a rental period no longer than 21 days from date of first application"</li> <li>• Added Policy Guideline 1 and 2.</li> </ul>
	Updated Rationale section.
	Updated References section.
05-04-2022	Updated Description Section
	Updated Rationale Section
	Updated Coding Section <ul style="list-style-type: none"> <li>▪ Converted ICD-10 Codes to ranges</li> </ul>
	Updated References Section

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