Cigna Medical Coverage Policy

Subject **Continuous Passive Motion (CPM) Devices**

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Coverage Policy

Coverage for continuous passive motion (CPM) devices is subject to the terms, conditions and limitations of the applicable plan's Durable Medical Equipment (DME) benefit and schedule of copayments. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Under many benefit plans, coverage for DME is limited to the lowest-cost alternative.

If coverage for CPM devices is available, the following conditions of coverage apply.

CPM for Knee Conditions
Cigna covers a CPM device as medically necessary for up to 21 days in an individual in the early phase of rehabilitation (e.g., physical therapy, home exercise program) following total knee replacement, including revision, or revision of a worn component.

Cigna does not cover a CPM device for rehabilitation or treatment of any other knee indication, including but not limited to the following, because it is considered experimental, investigational, or unproven:

- following treatment of knee arthrofibrosis by manipulation under anesthesia and/or surgical release
- following anterior or posterior cruciate ligament (ACL, PCL) repair/reconstruction
- following an injury or surgical repair of the articular cartilage of the knee

CPM for Non-Knee Conditions

Cigna does not cover a CPM device for rehabilitation or treatment of ANY other joint, including but not limited to the shoulder, elbow, wrist, hand, or hip, or for any indication not listed above, including but not limited to the following, because it is considered experimental, investigational, or unproven:

- Dupuytren's contracture
- low back pain
- rheumatoid arthritis in the absence of a listed covered condition
- rotator cuff repair
- temporomandibular joint (TMJ) repair

Cigna does not cover a CPM device beyond 21 days because it is considered experimental, investigational or unproven.

General Background

Continuous passive motion (CPM) is a rehabilitation technique designed to assist in recovery of joint range of motion (ROM). CPM provides progressive passive ROM to an extremity through an externally applied force. The device contains two parts; a carriage for support of the extremity and a controller that can be programmed for ROM, speed, pause, and duration of treatment. During CPM therapy, the joint area is secured in the device, and it is programmed to flex and extend the joint passively. CPM use is based on the theory that recovery will be accelerated by decreasing soft tissue stiffness, increasing ROM, and promoting healing of joint surfaces in soft tissues, and preventing the development of adhesions. Motion and stress are important for the maintenance of normal connective tissue and the healing of injured connective tissue. Motion enhances blood flow and decreases pain. Passive motion involves movement of a joint without active contraction of muscle groups

CPM has been used in the rehabilitation period following surgery or injury to synovial joints or associated tissues. It is generally used as an adjunct to active physical therapy. Most of the published literature has evaluated CPM following total knee arthroplasty (TKA). CPM has also been used for other knee indications including rehabilitation following anterior cruciate ligament (ACL) reconstruction or repair, posterior cruciate ligament (PCL) repair; and following manipulation under anesthesia or surgical release of knee arthrofibrosis. Knee arthrofibrosis may occur following surgical procedures performed on the knee; and following an injury or surgical repair of the knee articular cartilage. CPM has been proposed for treatment of various other joints, including the shoulder, elbow, wrist, hand, ankle and hip, and temporomandibular joint. There is insufficient evidence to support the use of CPM for indications other than rehabilitation following total knee arthroplasty.

U.S. Food and Drug Administration (FDA)

CPM machines are considered Class II devices and are generally approved through the 510(k) process. CPM devices are most commonly used for the knee, but are available for many joints, including the elbow, hip, ankle, shoulder, and fingers.

Literature Review: Lower Extremity

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

A Cochrane systematic review evaluated CPM following total knee arthroplasty in people with arthritis (Harvey et al., 2010, updated 2014). Twenty-four randomized controlled trials met the inclusion criteria. The authors concluded that the effects of CPM on range of motion, pain, function and quality of life are too small to justify its use and costs but the effects of CPM on participants' global assessment of treatment effectiveness are unclear. This review provides very low-quality evidence that CPM reduces the risk of manipulation under anesthesia; but that these findings must be interpreted with caution because they are inconsistent with the moderate-quality

evidence indicating that CPM has no effect on knee ROM even though the main indication for manipulation under anesthesia is joint stiffness.

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

Postel et al. (2007) performed a systematic review of the literature regarding the use of CPM after TKA in order to develop clinical practice guidelines. After analysis of 21 studies included in the review, the authors determined that CPM after TKA could have short-term beneficial influence on the speed of recovery of motion, early flexion, postoperative pain, knee swelling and length of hospital stay but found no long-term confirmation of the early benefit of CPM. The authors concluded that, although there is insufficient evidence to recommend substituting CPM for other modalities of rehabilitation following TKA, it can be used as an adjunctive option to accelerate short-term results. .

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

Anterior Cruciate Ligament (ACL) Reconstruction: Engstrom et al. (1995) reported on a prospective randomized study of 34 patients with unilateral anterior cruciate ligament ruptures randomized to either the early active motion group (n=17) or the active motion with CPM group (n=17). Outcome measurements included ROM and joint swelling, evaluated preoperatively and at six weeks post-operation. At six weeks follow–up, there was no difference in ROM between the two groups, and joint swelling was more pronounced in the early active motion group. The data suggests that CPM did not improve ROM.

McCarthy et al. (1993) evaluated the effect on pain when CPM is used immediately following ACL reconstruction. Thirty patients were randomized to a rehabilitation program with CPM (n=15) or without CPM (n=15). The CPM group used significantly less ($p<.05$) narcotics within the first postoperative 24 hours and used patient-controlled analgesia (PCA) less frequently ($p<.05$) compared to the no-CPM group. The CPM group also received significantly less ($p<.05$) oral medication on postoperative days two and three. There was no significant difference between the two groups regarding perceived pain. The study did not address whether these results affected functional outcome. .

Rosen et al. (1992) conducted a prospective study to examine the effects of CPM and supervised active ROM following ACL repair (n=75). Patients with ACL deficiencies treated with arthroscopic ACL autograft reconstruction were randomized into one of three groups. Group A (n=25), the active motion group, received PT three times a week. Group B (n=25) received PT and CPM. Group C (n=25) received CPM but no formal PT. Evaluations occurred at specific intervals for six months. The authors reported no statistically significant differences among the three groups in drain output, medication usage, hospital length of stay, or in any other outcome measures. The authors concluded that effects of CPM on ROM were similar to that of active motion and that neither protocol had deleterious effects on stability. .

Periosteal Transplantation: Alfredson et al. (1999) conducted a retrospective study of 57 consecutive patients with an isolated full-thickness cartilage defect of the patella and disabling knee pain of long duration. Patients were treated by autologous periosteal transplantation to the cartilage defect. The first 38 consecutive patients

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

Knee Arthrofibrosis: Arthrofibrosis and associated stiffness may occur following total knee arthroplasty (TKA), and other surgical procedures, including ACL reconstruction or total knee arthroplasty, and is associated with inflammation and scar tissue proliferation. Arthrofibrosis may also occur following traumatic injury of the knee. Treatment options for knee arthrofibrosis include physical therapy, manipulation under anesthesia (MUA), arthroscopic debridement, and open debridement. Open release of adhesions or revision surgery may be considered for refractory arthrofibrosis or in cases of component malposition or damage following TKA (Fitzsimmons et al., 2010).

Although CPM has been used as a component of rehabilitation for arthrofibrosis following MUA and/or surgical release, the impact of CPM as an individual variable has not been demonstrated in the published medical literature. There is insufficient evidence to determine whether the addition of CPM to standard rehabilitation programs improves outcomes.

Summary-Lower Extremity: Continuous passive motion (CPM) has been used following total knee arthroplasty (TKA) since the 1980's, despite a lack of robust evidence, and became widely accepted by some practitioners. There is general agreement that the addition of CPM to standard physical therapy rehabilitation following TKA has no impact on long-term knee flexion range of motion, although some evidence indicates that CPM may result in improved knee flexion range of motion in the immediate postoperative period, shorter hospitalization, and decreased need for subsequent knee manipulation. There is insufficient evidence in the published medical literature, however, to demonstrate that CPM when used alone or as a component of standard treatment or rehabilitation for other knee conditions results in improved outcomes.

Literature Review: Upper Extremity

Rotator Cuff Repair: Eckstein et al. (2011) conducted a systematic review to evaluate the effectiveness of CPM combined with usual physiotherapy management on increasing shoulder joint range of motion and muscle strength, and reducing pain in adults following rotator cuff repair. Three randomized controlled trials met the inclusion criteria. CPM was found to improve shoulder range of motion in two studies; one study found a decrease in pain in the intervention group, and one study found that CPM improved muscle strength. Inability to obtain raw data precluded critical analysis of the included studies, however. Additional limitations of the studies included varied outcome measurements, control group interventions, and duration of application of CPM.

An Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness review based on research conducted by the University of Alberta Evidence-Based Practice Center (Seida et al., 2010) compared the benefits and harms of nonoperative and operative interventions on clinically important outcomes in adults with rotator cuff repair. One of the questions addressed by the review was the following: "What is the comparative effectiveness of nonoperative interventions on improved health-related quality of life, decreased disability, reduced time to return to work/activities, higher rate of cuff integrity, less shoulder pain, and increased range of motion and/or strength?" Of the 11 postoperative rehabilitation studies (10 comparative, 1 uncontrolled), three compared CPM with physical therapy versus physical therapy alone. The three studies provided moderate evidence of no clinically important or statistically significant difference in function, but some evidence for earlier return to work with CPM. The authors stated that this suggests that CPM may affect the course of recovery over the short-term but not result in functional differences over the long-term. The trials were all at high risk of bias due to lack of blinding and inadequate allocation concealment.

Thien et al. (2004, updated 2008) conducted a Cochrane systematic review to determine the optimal rehabilitation strategy after surgery for flexor tendon injuries in the hand, based on evidence from randomized controlled trials. One trial compared CPM with controlled intermittent passive motion and found a significant difference in mean active motion in favor of CPM. Other trials compared various rehabilitation regimens, including active flexion with rubber band traction vs. early controlled active mobilization, early controlled active mobilization with early controlled passive mobilization and dynamic splinting vs. static splinting. The authors concluded that controlled mobilization regimens are widely employed in rehabilitation after flexor tendon repair in the hand, and that there is insufficient evidence from randomized controlled trials to define the best mobilization strategy.

Lastayo et al. (1998) conducted a randomized outcome study of 31 patients (32 rotator cuffs) who had rotator cuff repair. The patients were randomly assigned to CPM (n=17) or manual passive range-of-motion exercises (n=15). The Shoulder Pain and Disability Index was used to subjectively evaluate the treatment results, and there was no significant difference between the two groups (p=0.853). Using the Visual Analog Scale, the level of pain decreased in both groups, but there was no significant difference in the mean scores in each group (p=0.92). No significant difference in ROM (p>0.20) or strength (p>or = to 0.20) was reported. The data suggests that although both CPM and manual passive range-of-motion provided improvement in ROM, strength, function and pain relief, there was no significant difference between the two groups.

Garofalo et al. (2010) conducted a randomized controlled trial to evaluate the use of CPM following arthroscopic rotator cuff repair (n=100). Patients were randomized to a postoperative physical therapy regimen consisting of passive self-assisted range of motion exercise supervised by a physiotherapist (n=46, group A) or passive self-assisted ROM exercise associated with use of CPM for a total of two hours per day (n=54, group B) for four weeks. CPM was used in four 30-minute sessions. During weeks five through twelve, the same therapy (i.e., passive mobilization with the physiotherapist) was administered to both groups, and for weeks 13 through 28, active-assisted ROM exercises were added, along with progressive isometric reinforcement exercise. An independent examiner assessed patients at 2, 5, 6, and 12 months based on VAS, range of motion for abduction (ABD), forward flexion (FF) and external rotation in abduction (ER2). At 2.5 months, patients in group B had significantly better values for VAS (7.5 ± 0.1) (P< 0.01), FF (133 ± 21.1) (P<0.01), ABD (66.7 ± 14.5) (P<0.05) and ER2 (63.5 ± 15.4) (P<0.05) than group A: VAS (9.1 ± 0.2), FF (120.7 ± 20.6), ABD (60.1 ± 14) and ER2 (56 ± 14). At six months, however, there was no longer any significant difference in the VAS values, and at one year there were no statistically significant differences between the values for any of the parameters.

Raab et al. (1996) conducted a prospective, randomized controlled study on 26 patients who underwent rotator cuff repair and completed three-month follow-up. Patients were randomized to the control group (n=12) who received PT only or the study group (n=14) who received PT plus CPM. Outcomes were evaluated using a shoulder score questionnaire which consisted of four areas: function, pain, muscle strength and ROM. No significant difference in shoulder scores were reported at three month follow-up, although significant improvements in the study group were noted in specific subgroups, including: pain relief in female patients (p=0.00185), pain relief in patients age 60 or older (0.0364), and increased ROM (0.0138) in the study group.

Distal Radial Fracture: Handoll et al. (2003) conducted a Cochrane systematic review to assess the effectiveness of rehabilitation interventions with conservatively or surgically treated distal radial fractures. The 12 studies reviewed involved a total of 601 older female patients with fractures of the distal radius treated with rehabilitation interventions, such as active and passive mobilization exercises. There were no difference in outcomes between supervised and unsupervised exercises and no clinical significance between passive mobilization and whirlpool and no exercise. An update to this review (2006) determined that there continues to be insufficient evidence to determine which form of rehabilitation results in the best outcomes for patients with wrist fractures. .

Metacarpophalangeal (MCP) Joint Arthroscopy/Arthroplasty: Massy-Westropp et al. (2008) conducted a Cochrane systematic review to compare the effectiveness of postoperative therapy regimes for increasing hand function after MCP arthroplasty in adults with rheumatoid arthritis. The majority of evidence for various splinting and exercise regimes consisted of case series and case reports. Only one randomized controlled trial, considered to be poor quality, met the inclusion criteria. Results from this trial suggested that the use of continuous passive motion is not effective in increasing motion or strength after MCP arthroplasty.

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

Professional Societies/Organizations
The 2011 American College of Occupational and Environmental Medicine (ACOEM) practice guideline section on knee disorders states that CPM is not recommended for routine use for postoperative rehabilitation in arthroplasty patients. It may be useful for select, substantially physically inactive patients postoperatively. A procedure classified as level C, not recommended, denotes a recommendation against routinely providing the intervention and the existence of at least intermediate evidence that harms and costs exceed benefits based on limited evidence.

The 2011 ACOEM practice guideline section on shoulder disorders includes continuous passive motion in conjunction with a home exercise program in a list of recommended treatments for adhesive capsulitis. This is a C level recommendation, indicating that the intervention is recommended for appropriate patients. There is limited evidence that the intervention may improve important health and functional benefits.

Summary
The evidence supporting the use of continuous passive motion is not robust. There is adequate evidence, however, that CPM may improve health outcomes in the early postoperative phase (21 days post-operation) in patients who have undergone total knee arthroplasty (TKA). There is adequate evidence that CPM used as an adjunct to active physical therapy may decrease knee swelling, improve flexion and decrease the need for knee manipulation following these procedures. There is insufficient evidence in the published medical literature, however, to demonstrate that CPM when used alone or as a component of standard treatment or rehabilitation for other knee conditions results in improved outcomes. CPM has also been proposed for rehabilitation of other joints such as the shoulder, elbow, wrist, hand, ankle, knee, or hip, and for treatment of numerous conditions, including degenerative joint conditions and diseases (e.g., rheumatoid arthritis, Dupuytren's contracture). There is insufficient evidence in the medical literature evaluating the use of CPM for these conditions. Evidence published to date has failed to demonstrate that the use of CPM for conditions other than post-total knee arthroplasty results in improved outcomes (i.e., decreased pain or improved range of motion) compared to an active physical therapy program.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement
3) ICD-10-CM Diagnosis Codes are for informational purposes only and are not effective until 10/01/2015.

Continuous passive motion (CPM) for knee:

Covered when medically necessary:

HCPCS Codes	Description
E0935	Continuous passive motion exercise device for use on knee only

ICD-9-CM Diagnosis Codes	Description
V43.65	Organ or issue replaced by other means, joint, knee

ICD-10-CM Diagnosis Codes (Effective 10/01/2015)	Description
Z96.651-Z96.659	Presence of artificial knee joint

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
	All other codes

ICD-10-CM Diagnosis Codes (Effective 10/01/2015)	Description
	All other codes

Continuous passive motion (CPM) for joint other than knee:

Experimental/Investigational/Unproven/Not Covered:

E0936	Continuous passive motion exercise device for use on other than knee

ICD-9-CM Diagnosis Codes	Description
	All codes

ICD-10-CM Diagnosis Codes (Effective 10/01/2015)	Description
	All codes

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