Protocol

Continuous Passive Motion in the Home Setting

(10110)

Medical Benefit		**Effective Date**: 01/01/12	**Next Review Date**: 09/19
Preauthorization	Yes	**Review Dates**: 04/07, 01/08, 11/08, 03/09, 03/10, 09/10, 09/11, 09/12, 09/13, 09/14, 09/15, 09/16, 09/17, 09/18	

Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With total knee arthroplasty	Interventions of interest are: • Continuous passive motion in the home setting	Comparators of interest are: • Physical therapy alone • Standard of care, if unable to tolerate physical therapy	Relevant outcomes include: • Symptoms • Functional outcomes
Individuals: • With articular cartilage repair of the knee	Interventions of interest are: • Continuous passive motion in the home setting	Comparators of interest are: • Standard of care	Relevant outcomes include: • Symptoms • Functional outcomes
Individuals: • With musculoskeletal conditions other than total knee arthroplasty or knee cartilage repair requiring physical therapy	Interventions of interest are: • Continuous passive motion in the home setting	Comparators of interest are: • Standard of care	Relevant outcomes include: • Symptoms • Functional outcomes
Individuals: • Who have had a stroke requiring physical therapy	Interventions of interest are: • Continuous passive motion in the home setting	Comparators of interest are: • Standard of care	Relevant outcomes include: • Symptoms • Functional outcomes

DESCRIPTION

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

SUMMARY OF EVIDENCE

For individuals who have total knee arthroplasty (TKA) who receive CPM 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 CPM in the inpatient setting and are less relevant to today's practice patterns of short hospital stays followed by outpatient rehabilitation. Current postoperative rehabilitation protocols differ considerably from when the largest body of evidence was collected, making it dif-

ficult to apply available evidence to the present situation. For use of CPM after TKA, recent studies have suggested that institutional and home use of CPM has no benefit compared with standard PT. There were no studies evaluating CPM in patients who could not perform standard PT. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

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

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

POLICY

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:

- 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.
- 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 CPM in the home setting for all other conditions is considered **not medically necessary**.

POLICY GUIDELINES

This protocol only addresses CPM in the home setting (i.e., not the hospital setting).

Following TKA, CPM in the home setting will be allowable for up to 21 days after surgery while patients are immobile or unable to bear weight.

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

MEDICARE ADVANTAGE

CPM devices are devices **medically necessary** for patients who have received a total knee replacement.

To qualify for coverage:

- use of the device must commence within two days following surgery
- coverage is limited to that portion of the three-week period following surgery during which the device is used in the patient's home.

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, CPM devices have also been used. CPM 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. CPM 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 CPM 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 CPM 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 (ROM) and speed. The initial settings for ROM are based on a patient's level of comfort and other factors assessed intraoperatively. The ROM is increased by 3° to 5° per day, as tolerated. The speed and ROM can be varied, depending on joint stability. The use of the 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 one to two days. As a result, there has been a considerable shift in the rehabilitation regimen, moving from an intensive in-hospital program to a less intensive outpatient program. Some providers may want patients to continue CPM in the home setting as a means of duplicating services offered with a longer (seven-day) hospital stay.

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

REGULATORY STATUS

CPM devices are considered class I devices by the U.S. Food and Drug Administration (FDA) and are exempt from

510(k) requirements. This classification does not require submission of clinical data on efficacy but only notification of the FDA prior to marketing. Food and Drug Administration product code: BXB.

RELATED PROTOCOLS

Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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