Continuous Passive Motion in the Home Setting

Introduction

A continuous passive motion (CPM) device moves or flexes a joint. This movement is done without the patient’s help. A continuous passive motion device has been used most often after certain knee surgeries to allow the knee joint to slowly bend. Using CPM was very common; however, newer studies show that it does not improve the outcomes of knee surgery except in some complex knee surgeries, or when people have prolonged bed rest due to some other problem after knee replacement. Continuous passive motion usually starts in the hospital. For those who need it at home after knee surgery it is usually covered for 21 days. There are a number of high quality studies showing that CPM is effective for specific types of knee surgery. There are not enough high quality studies to show how effective CPM is for other joints. This policy describes when CPM is considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
This policy only addresses continuous passive motion (CPM) in the home setting.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Medically Necessary Coverage Criteria</th>
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<tbody>
<tr>
<td>Continuous passive motion (CPM) in the home</td>
<td>The use of CPM may be considered medically necessary as an adjunct to physical therapy in the following situations:</td>
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<tr>
<td></td>
<td>Total Knee Arthroplasty (TKA) or TKA repair</td>
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<td>• The member is not able to ambulate or comply with rehabilitation exercises. Examples include:</td>
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<td>o Complex regional pain syndrome (reflex sympathetic dystrophy)</td>
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<td>o Extensive arthrofibrosis or tendon fibrosis</td>
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<td>o Physical, mental, or behavioral inability to participate in active physical therapy</td>
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<td></td>
<td>▪ 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.</td>
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<td>Articular cartilage repair (eg, microfracture, osteochondral grafting, autologous chondrocyte implantation, treatment of osteochondritis dissecans, repair of tibial plateau fractures)</td>
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<td>• During the non-weight-bearing rehabilitation period</td>
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<td>• For up to 6 weeks maximum</td>
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<td>The use of CPM in the home setting for all other conditions not listed in this medical policy is considered not medically necessary.</td>
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**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>HCPCS</td>
<td>Continuous passive motion exercise device for use on knee only</td>
</tr>
<tr>
<td>E0935</td>
<td>Continuous passive motion exercise device for use other than knee</td>
</tr>
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</table>
Background

Physical therapy (PT) of joints following surgery focuses both on passive motion to restore mobility and active exercises to restore strength. While passive motion can be administered by a therapist, Continuous passive motion (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 most thoroughly investigated in the knee, particularly after total knee arthroplasty (TKA) or ligamentous or cartilage repair, but its acceptance in the knee joint has created interest in extrapolating this experience to other weight-bearing joints (ie, hip, ankle, metatarsals) and non-weight-bearing joints (ie, shoulder, elbow, metacarpals, interphalangeal joints). Use of CPM in stroke and burn patients is also being explored.

The device moves the joint (ie, flexion/extension) continuously for extended periods of time (eg, up to 24 hours per day) without patient assistance. An electrical power unit is used to set the variable range of motion (ROM) and speed. The initial settings for ROM are based on a patient’s level of comfort and other factors that are assessed intraoperatively. The ROM is increased by 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 the past 10 to 20 years, hospital lengths of stay have progressively shortened, and in some cases surgical repair may be done either 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. Therefore, some
providers may want patients to continue CPM in the home as a means of duplicating the services offered with a longer (seven-day) hospital stay. The focus of the current review is to examine the literature on the use of postoperative CPM in the home setting. Relevant comparisons are treatment outcomes of CPM when used alone or with PT, compared with PT alone.

Summary of Evidence

For individuals who have total knee arthroplasty (TKA) and receive continuous passive motion (CPM) in the home setting, the evidence includes randomized clinical trials (RCTs), case series, and systematic reviews. Relevant outcomes are symptoms and functional outcomes. Early trials generally used CPM in the inpatient setting and are less relevant to today’s practice patterns of short hospital stays followed by outpatient rehabilitation. Current postoperative rehabilitation protocols differ considerably from when the largest body of evidence was collected, making it difficult to apply available evidence to the present situation. For use of CPM after TKA, recent studies have suggested that institutional and home use of CPM has no benefit compared to standard physical therapy (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 (eg, 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 (ROM); however, the trials were not high quality, and the small differences in outcomes may not be clinically important. Two trials reported short-term improvements in ROM for patients undergoing CPM, and 1 reported a short-term reduction in pain. None reported long-term improvements, and there are no reported benefits in functional status. Therefore, the clinical significance of the
short-term improvements reported is uncertain. In addition, there is uncertainty about the optimal PT regimen following shoulder surgery such that the optimal treatment comparator for CPM is unclear. Two small RCTs compared CPM with conventional PT for treatment of adhesive capsulitis. One of the trials focused on diabetic patients with adhesive capsulitis. Both reported comparable improvements in ROM and functional ability between treatment groups. For other musculoskeletal conditions, RCTs do not exist; case series either did not show efficacy of CPM or had important methodologic flaws. 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 1 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 compared to 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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td><strong>Ongoing</strong></td>
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<tr>
<td>NCT01420887</td>
<td>Preservation of Joint Function Using Postoperative Continuous Passive Motion (CPM): A Pilot Study</td>
<td>50</td>
<td>Dec 2018</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers

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

2008 Input

In response to requests, input was received from one physician specialty society and two academic medical centers while this policy was under review in 2008. The three reviewers interpreted the existing literature as providing support for the use of CPM for the knee for at least 7 days postoperatively, whether in the hospital or home, and suggested that longer use of CPM would be warranted for special conditions.

2010 Input

In response to requests, input was received from 2 physician specialty societies and 5 academic medical centers while this policy was under review in 2010. Overall, clinical input supported the use of CPM under conditions of low postoperative mobility or inability to comply with rehabilitation exercises following a TKA or TKA revision. It also supported the use of CPM during the non-weight-bearing rehabilitation period following intra-articular cartilage repair procedures of the knee. Support was limited for use of CPM in joints other than the knee, or in situations/conditions other than those described in this policy.

2016 Input

In response to requests for input on the use of CPM following knee intra-articular repair procedures, input was received from two physician specialty societies and one academic medical center while this policy was under review in 2016. Input agreed that CPM is considered medically necessary as an adjunct to PT during the non-weight-bearing rehabilitation period following articular cartilage repair procedures of the knee. One reviewer referred to the 2015 American Academy of Orthopaedic Surgery guidelines on the surgical management of osteoarthritis of the knee, which concluded that there was strong evidence that CPM after knee arthroplasty does not improve outcomes.
Practice Guidelines and Position Statements

American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons (AAOS) published evidence-based guidelines on the surgical management of osteoarthritis of the knee in 2015. AAOS identified two high-quality studies and five moderate-quality studies that evaluated the use of CPM. In one high-quality study, CPM was used for about two weeks after discharge. AAOS concluded that, “the combined results provide strong evidence that the surgical outcomes for those who used continuous passive motion are not better than for those who did not use continuous passive motion.”

French Physical Medicine and Rehabilitation Society

Clinical practice guidelines from the French Physical Medicine and Rehabilitation Society conclude that evidence is not sufficient to recommend substituting CPM for other rehabilitation techniques aimed at early mobilization after TKA. The evidence review found no positive effect of CPM over intermittent early mobilization, at short- or long-term follow-up.

Medicare National Coverage

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

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

Continuous passive motion 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 FDA prior to marketing.

FDA product code: BXB.

References

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Continuous Passive Motion as an Adjunct to Physical Therapy for Joint Rehabilitation. TEC Assessments. 1997;Volume 12(Tab 20).


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/11/15</td>
<td>New Policy. Add to Durable Medical Equipment section. In the Policy Guidelines, plan specific language allows using the device for up to 21 days. Literature current through June 3, 2015.</td>
</tr>
<tr>
<td>10/01/16</td>
<td>Interim Update, approved September 13, 2016. Clinical input reviewed; reference 43 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
<td>03/24/17</td>
<td>Policy moved into new format; no change to policy statements.</td>
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<tr>
<td>07/01/17</td>
<td>Interim review, approved June 22, 2017. The word &quot;intra-&quot; removed from the second bullet point of the first policy statement and from the text. Policy statements otherwise unchanged; rewritten for improved clarity.</td>
</tr>
</tbody>
</table>

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  - Qualified interpreters
  - Information written in other languages

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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