Continuous Passive Motion Device (CPM) in the Home Setting

MEDICAL POLICY NUMBER: 93

| Effective Date: 3/1/2024 | COVERAGE CRITERIA | 2 |
|----------------------------|---|---|
| Last Review Date: 2/2024 | POLICY CROSS REFERENCES | 2 |
| Next Annual Review: 2/2025 | POLICY GUIDELINES | 2 |
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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

PLAN PRODUCT AND BENEFIT APPLICATION

☑ Commercial ☑ Medicaid/OHP* ☐ Medicare**

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

PHP follows Guideline Notes 172 and 173 of the OHP Prioritized List of Health Services for guidance on New and Emerging Technology. In the absence of OHP guidance, PHP will follow this policy.

**Medicare Members

This <u>Company</u> policy may be applied to Medicare Plan members only when directed by a separate <u>Medicare</u> policy. Note that investigational services are considered "not medically necessary" for Medicare members.

COVERAGE CRITERIA

<u>Note</u>: This medical policy does not address in-facility use of continuous passive motion devices. Use of continuous passive motion devices in a facility, such as a hospital or ambulatory care center, is not separately reimbursable.

 Use of a continuous passive motion device in the home setting is considered **not medically** necessary for all indications, including, but not limited to use in post-operative rehabilitative therapy for the shoulder, hip, knee, ankle, or foot.

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

Continuous passive motion (CPM) is intended to restore and maintain range of motion by providing movement of the synovial fluid. This is thought to help promote lubrication of the joint, stimulate healing, prevent joint stiffness, and reduce swelling. CPM uses a motorized device that moves the joint through a prescribed range of motion without any muscle contraction. The joint area is secured in the device and the device is pre-programmed for a set range of motion and duration. The device is intended to be used as an adjunct to physical therapy to complement or replace some physical therapy sessions by providing frequent and consistent joint mobilization. CPM devices are available for several joints, including the knee, ankle, jaw, hip, elbow, shoulder, and finger.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of continuous passive motion devices in the home setting for post-surgical rehabilitation. Below is a summary of the available evidence identified through January 2024.

CPM Following Cartilage Repair Surgery

In 2018 (archived), the ECRI Institute conducted an evidence review to evaluate continuous passive motion (CPM) devices for aiding recovery following cartilage repair surgery. The review identified four systematic reviews evaluating the use of CPM after cartilage repair surgery. The ECRI review concluded the following:

"Evidence from four systematic reviews is insufficient to determine whether use of CPM devices improves cartilage healing after cartilage repair surgery. CPM protocols were poorly described in the identified studies, and all cited a need for high-quality randomized controlled trials (RCTs) examining CPM and cartilage defect repair. However, no RCTs have been published since the publication of these systematic reviews."²

CPM Following Knee Surgery

Systematic Reviews

 In 2013, Karnes and colleagues published a systematic review of the evidence assessing CPM use following cartilage restoration procedures of the knee.³ Included studies reported CPM outcomes after autologous chondrocyte implantation (63 studies), autologous chondrocyte transplantation, microfracture (28 studies), marrow-stimulation technique, mosaicplasty, osteochondral autograft (13 studies), and osteochondral allograft (15 studies). Overall, a total of 107 studies (n=5723) were included in the review and the grade or quality of included studies varied. Authors concluded evidence regarding CPM use was of low quality due to a lack of standardized reporting. Authors noted, "(t)he majority of studies did not describe common variables such as the duration of CPM therapy, the initiation of CPM therapy, and the initial range of motion used."³

• In 2022, Hayes conducted a review of reviews evaluating continuous passive motion (CPM) devices for knee indications. The evidence review identified one systematic review assessing 24 RCTs and 5 randomized controlled trials (RCTs) evaluating CPM following total knee arthroplasty (TKA) and 3 RCTs evaluating CPM following anterior cruciate ligament (ACL) repair. The sample sizes included 1,445 patients in the systematic review and 462 patients in subsequently published RCTs. Follow-up times varied from 2 days to more than 6 months. The outcome measures included manipulation under anesthesia, range of motion (ROM), function, quality of life (QOL), pain, strength, and swelling.

Very-low-quality evidence suggested that CPM following TKA may be associated with a decreased incidence of manipulation under anesthesia compared to physical therapy alone. However, moderate-quality evidence suggests no benefit in ROM, function, or QOL with CPM. Low-quality evidence suggests no benefit in ROM with CPM after ACL repair surgery. The Hayes review concluded with the following ratings:

- D1 (no proven benefit) for continuous passive motion for prevention of contracture after total knee arthroplasty surgery.
- D2 (insufficient evidence)—for continuous passive motion for prevention of contracture after anterior cruciate ligament repair.
- o D2 (insufficient evidence) —for continuous passive motion for all other knee indications.

CPM after Total Knee Arthroplasty (TKA)

- In 2014, He and colleagues published an updated a Cochrane systematic review of evidence regarding the use of CPM to prevent venous thromboembolism (VTE) after total knee arthroplasty (TKA).⁴ Eleven randomized trials, with 808 participants, met inclusion criteria and were reviewed. Overall, the quality of the evidence was rated as low due to variability in methodological design of studies and a lack of reporting of predefined outcome measures. Only five studies, with 405 participants, reported on the incidence of deep vein thrombosis (DVT). Results indicated a slightly higher rate of DVT in the CPM group (n=36/205, %18) compared to the control group (n=29/200, %15). Analysis further suggested that CPM had no effect on preventing (VTE) after TKA (RR 1.22, 95% CI 0.84 to 1.79).
- In 2014, Harvey and colleagues updated a Cochrane systematic review of evidence regarding the use of CPM following TKA in patients with arthritis. A total of 24 randomized trials, with 1445 participants, were included in the review. Primary outcomes included the following: active knee flexion ROM, pain, quality of life, function, participants' global assessment of treatment effectiveness, incidence of manipulation under anesthesia and adverse events. Authors concluded, "CPM does not have clinically important effects on active knee flexion ROM, pain, function or quality of life to justify its routine use. There was very low-quality evidence to indicate that CPM reduces

the risk of manipulation under anesthesia; risk of manipulation in the control group was 7.2%, risk of manipulation in the experimental group was 1.6%, CPM decreased the risk of manipulation by 25 fewer manipulations per 1000 (95% CI 9 to 64) or absolute risk reduction of -4% (95% CI -8% to 0%)."

CPM after Knee Arthroscopy

In 2016, Gatewood and colleagues conducted a systematic review of evidence regarding the use of postoperative devices following knee arthroscopy. Primary study outcomes included: muscle strength, range of motion, swelling, blood loss, pain relief, narcotic use, knee function evaluation and scores, patient satisfaction and length of hospital stay. Authors concluded, "CPM is not warranted in postoperative protocols following arthroscopic knee surgery because of its limited effectiveness in returning knee range of motion."

CPM for Shoulder Indications

In 2022, Hayes conducted a systematic review evaluating continuous passive motion devices for shoulder indications. Searching the literature through April 2018, Hayes included 6 RCTs evaluating a range of 26 to 100 shoulders undergoing rotator cuff repair and adults with adhesive capsulitis. Outcomes of interest included range of motion (ROM), pain, shoulder scores, should pain and disability, strength, rate of recurrent tear and complications. Follow-up ranged from 2 weeks to 22 months.

Low-quality evidence suggested that at least 3 weeks of CPM as an adjunct to PT rehabilitation was associated with similar or superior short-term improvements in ROM compared to standard PT only. Very-low-quality evidence reported that 4 weeks of CPM improved patients pain compared to PT alone for patients with adhesive capsulitis, and similar to improved outcomes for ROM and function. Hayes nonetheless called for additional, long-term studies using uniform rehabilitation protocols that establish whether observed short-term improvements are clinically meaningful. The Hayes review concluded with the following ratings:

- C (potential but unproven benefit) for continuous passive motion as an adjunct to physical therapy in the immediate postoperative rehabilitation of rotator cuff repair for prevention of shoulder joint contracture.
- D2 (insufficient evidence) for CPM as an adjunct to PT in patients with shoulder joint contracture.

CPM for Other Conditions

There is less evidence regarding the clinical utility of CPM to improve overall health outcomes for non-knee indications. Systematic evidence reviews were identified regarding CPM use as a rehabilitative intervention for other non-knee procedures and conditions of the shoulder, ^{6,8,9} hand, ¹⁰ wrist, ¹¹ and foot. ¹² These reviews either noted no long-term differences in outcomes between groups or were limited by a lack of standardized protocol for CPM application and duration of use. Overall, there is insufficient evidence to determine the benefits of CPM when used alone or in conjunction with standard treatment therapies for non-knee conditions.

CLINICAL PRACTICE GUIDELINES

American Academy of Orthopaedic Surgeons (AAOS)

The AAOS published clinical practice guidelines based on a systematic review of the current evidence (through January of 2015) regarding the use of CPM in patients after surgical management of osteoarthritis of the knee.¹³ The AAOS indicated there was strong evidence against the use of CPM after knee arthroplasty due to a lack of improved outcomes.

No evidence-based clinical practice guidelines were identified regarding the use of CPM for non-knee conditions.

American Physical Therapy Association (APTA)

In 2017, the APTA published evidence based guidelines assessing knee stability and movement coordination impairments. ¹⁴ On the basis of "weak evidence," authors concluded that clinicians may use continuous passive motion in the immediate postoperative period to decrease postoperative pain after ACL reconstruction.

EVIDENCE SUMMARY

Evidence is sufficient to recommend against the use of continuous passive motion (CPM) devices in the home setting for the treatment of knee indications. Evidence remains insufficient to support the use of CPM for all other indications (e.g. shoulder, hand, wrist and foot). The available evidence does not demonstrate that CPM in the home setting improves post-surgical rehabilitation and patient health outcomes. Additionally, the American Academy of Orthopedic Surgeons does not recommend the use of CPM after knee arthroplasty, while the American Physical Therapy Association recommend CPM for patients post-ACL reconstruction patients on the basis of "weak evidence."

BILLING GUIDELINES AND CODING

| CODES* | | |
|--------|-------|---|
| HCPCS | E0935 | Continuous passive motion exercise device for use on knee only |
| | E0936 | Continuous passive motion exercise device for use other than knee |

*Coding Notes:

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this
 policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for
 medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential
 utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code
 is submitted for non-covered services addressed in this policy then it will be denied as not covered. If an unlisted
 code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, prior
 authorization is recommended.
- See the non-covered and prior authorization lists on the Company <u>Medical Policy</u>, <u>Reimbursement Policy</u>, Pharmacy Policy and Provider Information website for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP)
 bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for

Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

| DATE | REVISION SUMMARY |
|--------|-----------------------------------|
| 2/2023 | Converted to new policy template. |
| 3/2023 | Annual update, no changes. |
| 3/2024 | Annual update, no changes. |
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