DRAFT Medical Coverage Policy | Continuous Passive Motion with Remote Monitoring or Adaptive Capabilities

EFFECTIVE DATE: 12|01|2026
POLICY LAST REVIEWED: 08|19|2026

OVERVIEW
This policy addresses the use of continuous passive motion devices that include remote monitoring or adaptive capabilities.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
The use of devices or systems featuring continuous passive motion with remote monitoring or adaptive capabilities is considered investigational and is considered not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
The use of devices or systems featuring continuous passive motion with remote monitoring or adaptive capabilities is considered investigational and.is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND
Continuous passive motion devices are considered class 1 devices by the U.S. Food and Drug Administration and are exempt from 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. The telerehabilitation and remote monitoring features of rehabilitation systems such as ROMTech PortableConnect® system are noninvasive and exempt from premarket notification requirements.3, Use of the ROMTech PortableConnect® system is often coupled with digitally transmitted measures of knee extension and flexion captured with the ROMTech AccuAngle® goniometer. The ROMTech PortableConnect® device features an adaptive pedal technology that offers active, active-assisted, and resistance modes in addition to passive motion.

Telerehabilitation systems may offer continuous passive motion physical intervention with telehealth conferencing interfaces, remote monitoring, and remote adjustment. Evidence on these devices is limited in quality. Remote monitoring rehabilitative systems are typically reported with HCPCS E1399 as currently there is no specific code.

Summers and colleagues (2023) retrospectively compared standard physical therapy (n=135) to a home-based clinician-controlled therapy system (n=135) among consecutive patients following total knee arthroplasty for primary or secondary knee osteoarthritis at a single surgical practice.24, The cohorts were asynchronous with the home-based cohort recruited following adoption of home-based protocol by the practice. The standard physical therapy group received a minimum of 4 weeks of in-person, outpatient therapy sessions 2 to 3 times

weekly. For the home-based group, a pedal-based device with telehealth conferencing and remote monitoring capabilities (ROMTech PortableConnect) was delivered for use, with patients averaging 2.9 treatment sessions per day. The device features an adaptive pedal technology that offers active, active-assisted, and resistance modes in addition to passive motion. No additional physical therapy was assigned to the home-based group. Patient dashboards were monitored remotely by a physical therapist, and patients were contacted as needed at the discretion of the surgeon and/or therapist. Patients were automatically contacted if a VAS pain score >8 was reported on two consecutive sessions. Treatment durations ranged from 3 to 6 weeks depending on clinician protocols and patient speed of recovery. The study reported statistically and clinically significant improvements in pain and function with the home-based telerehabilitation intervention over standard physical therapy at 2-, 6-, and 12-weeks postoperatively. However, generalizability of these outcomes is limited by the retrospective study design, non-blinded outcome assessment, and lack of protocol standardization. Additionally, both treatment and communication intensity was greater in the home-based telerehabilitation group. Home-based patients received 84 total monitored therapy sessions compared to 19 in the physical therapy group. Home-based participants received additionally counseling and assessment of range of motion at unblinded 2-, 6-, and 12-week appointments which does not reflect the marketed intended use of the platform with the companion ROMTech AccuAngle wearable digital goniometer.

CODING

Medicare Advantage Plans and Commercial Products

There is not a specific code(s) for this service. Claims must be filed with the following unlisted code(s):

E1399 Durable medical equipment, miscellaneous

RELATED POLICIES

Unlisted Procedures

PUBLISHED

Provider Update, October 2026

REFERENCES

1. Food and Drug Administration (FDA). Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring: Guidance for Industry and Food and Drug Administration Staff. October 19, 2023. https://www.fda.gov/media/136290/download. Accessed on February 2, 2026.
2. Summers SH, Nunley RM, Slotkin EM. A Home-Based, Remote-Clinician-Controlled, Physical Therapy Device Leads to Superior Outcomes When Compared to Standard Physical Therapy for Rehabilitation After Total Knee Arthroplasty. J Arthroplasty. Mar 2023; 38(3): 497-501. PMID 36252744

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