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Medical Policy

Subject:	Rehabilitative Devices with Remote Monitoring		
Document#:	DME.00047	**Publish Date:**	07/06/2022
Status:	New	**Last Review Date:**	05/12/2022

Description/Scope

This document addresses the use of rehabilitative devices with remote monitoring and adjustment capabilities intended to evaluate and improve muscle strength and range of motion while reporting session data to the individual's provider.

Note: Benefit exclusions regarding exercise equipment may apply.

Note: This document does not address mobile device-based health management applications. For more information regarding such service, please see:

- CG-ANC-08 Mobile Device-Based Health Management Applications
- CG-DME-10 Durable Medical Equipment

Position Statement

Investigational and Not Medically Necessary:

The use of rehabilitative devices with remote monitoring or adjustment capabilities (for example, ROMTech PortableConnect® and ROMTech AccuAngle®) is considered **investigational and not medically necessary** for all indications.

Rationale

No published studies have evaluated the effects of any rehabilitation therapy device with remote monitoring or adjustment capabilities on improving health outcomes. No nationally recognized published guidelines recommend the use of such devices for any medical purpose.

At this time, there is insufficient evidence to demonstrate that the use of rehabilitative devices with remote monitoring or adjustment capabilities provides any incremental health outcome benefit compared to the other widely accepted alternative therapies. Until such time, it is unclear if the use of this device provides any benefits beyond standard devices.

Background/Overview

Post-operative rehabilitation after knee arthroplasty

Although it is generally accepted that rehabilitation following knee arthroplasty is essential to achieve optimal results, no single rehabilitation protocol has been established as the standard of medical practice. Moderate quality evidence suggests that multi-disciplinary rehabilitation may improve treatment outcomes. Rehabilitation programs in this setting typically address range of motion, strengthening, gait, and modification of daily activities as needed. Unresolved questions remain about the optimal setting, intensity, and frequency of therapy sessions.

ROMTech PortableConnect®

The PortableConnect is a rehabilitative therapy device to increase range of motion. It is similar in appearance and function to a recumbent exercise bicycle. An adaptive pedal adjusts the turning radius to the individual's current range of motion. Used in conjunction with the ROMTech AccuAngle® (see below), the device shares data on time used, effort, and range of motion with a remote physician or therapist. The physician or therapist can remotely adjust settings such as active vs. passive motion, resistance, and pedal radius. The manufacturer asserts that the PortableConnect® improves recovered range of motion over a 3 to 6 week treatment course. No published scientific studies are available to verify this assertion.

The U.S. Food and Drug Administration (FDA) identifies the PortableConnect device as an isokinetic testing and evaluation system intended for medical purposes, such as to evaluate, measure, and increase the muscle strength and range of motion. The FDA classifies this type of devices as exempt from the premarket notification procedures.

ROMTech AccuAngle®

The AccuAngle measures knee extension and flexion and reports these data to the individual's app. It is placed on the side of the leg and uses Bluetooth technology to measure and report flexion and extension during each therapy session. It is used in conjunction with the PortableConnect® device.

The U.S. Food and Drug Administration (FDA) identifies the AccuAngle device as an AC-powered goniometer, a device intended to evaluate joint function by recording and measuring ranges of motion and forces exerted by a joint. The FDA classifies this type of devices as exempt from the premarket notification procedures.

At this time, there is no evidence published in the medical literature addressing the clinical utility of these device.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

HCPCS

E1399	Durable medical equipment, miscellaneous [when specified as a remote monitoring rehabilitative therapy device]

ICD-10 Diagnosis

All diagnoses

References

At this time there are no published, peer reviewed articles or recommendations from authoritative medical specialty organizations addressing rehabilitative devices with remote monitoring.

1. Minns Lowe CJ, Barker KL, Dewey M, et al. Effectiveness of physiotherapy exercise after knee arthroplasty for osteoarthritis: systematic review and meta-analysis of randomised controlled trials. BMJ. 2007 Oct 20;335(7624):812.
2. Mistry JB, Elmallah RD, Bhave A, et al. Rehabilitative Guidelines after Total Knee Arthroplasty: A Review. J Knee Surg. 2016 Apr;29(3):201-217.

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PortableConnect
AccuAngle

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
New	05/12/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.