Anthem

Medical Policy

Subject: Rehabilitative Devices with Remote Monitoring
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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 (ROM) 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 is considered**investigational and not medically necessary** for all indications.

Rationale

Limited published studies have evaluated the effects of any rehabilitation therapy device with remote monitoring or adjustment capabilities (for example, ROMTech PortableConnect®, ROMTech AccuAngle®, and Sensoria Health Diabetic Foot Ulcer Boot) on improving health outcomes. No nationally recognized published guidelines recommend the use of such devices for any medical purpose.

Summers and colleagues (2023) evaluated outcomes of a home-based, remote clinician-controlled physical therapy device compared to standard physical therapy after total knee arthroplasty. The study included individuals following a primary total knee arthroplasty for primary or secondary osteoarthritis and excluded bilateral total knee arthroplasty, previous surgery on the ipsilateral knee, or deformity requiring higher level of implant constraint. (n=270). Individuals who had had bilateral total knee arthroplasty, previous surgery on the ipsilateral knee, or deformity requiring higher level of implant constraint were excluded. The study was a retrospective review of outcomes for a consecutive series of individuals from a single surgeon's practice in 6 months before and the 6 months after the practice adopted use of the home-based therapy device. The standard therapy group (n=135) were those who received arthroplasty in the 6 months before the adoption. The intervention group was comprised of those treated in the 6 months after the practice adopted the home-based, clinician-controlled therapy system (n=135). The standard therapy group received a minimum of 4 weeks of in person, outpatient therapy sessions 2-3 times per week. The home-based, clinician-controlled therapy system group received the in-home, remote physical therapy device and no additional physical therapy. The home-based, clinician-controlled therapy system group accumulated more therapy sessions than the standard therapy protocol group, averaging 2.9 sessions per day compared to 2-3 times per week. The home-based, clinician-controlled therapy system group had less pain after 2 weeks (6.2 versus 7.7), 6 weeks (3.6 versus 5.2), and 12 weeks (1.4 versus 2.9) compared to the standard therapy group (all with $P < .0001$). Knee ROM was greater in the home-based, clinician-controlled therapy system group. After 2 weeks of therapy, total knee ROM was 97 degrees (range 69-122) in the home-based group compared to 83 degrees (range 45-102) in the standard therapy group ($P < .0001$). At the 6 weeks follow up, the total knee ROM was 114.9 (range 88-131) in the home-based group compared to 98.1 (range 73-124) in the standard therapy group ($P < .0001$). At 12 weeks, total knee ROM was 125.2 (range 103-135) in the home-based group compared to 117.6 (range 102-132) in the standard therapy group ($P < .0001$). This study had multiple limitations. The asynchronous nature of the study and control interventions may have introduced confounding factors relating to treatment differences or external factors, including the COVID-19 pandemic occurring during the study period. A therapist met with each individual in the home-based group during the 2-, 6-, 12-week visits to measure their knee ROM with a goniometer. Therefore, the home-based, clinician-controlled therapy system group was not strictly telerehabilitation. Furthermore, the therapists who measured outcomes were not blinded to the rehabilitation protocols. The preoperative knee ROM was estimated visually by the surgeon and may not have been an accurate comparison with the postoperative measurements by goniometry. Results from this single-surgeon study may not be generalizable to broader practice. The authors concluded home-based, clinician-controlled therapy system group was superior to standard protocol therapy. Prospective randomized studies are needed to verify their conclusions.

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 ROM, 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 ROM. It is similar in appearance and function to a recumbent

exercise bicycle. An adaptive pedal adjusts the turning radius to the individual's current ROM. Used in conjunction with the ROMTech AccuAngle ® (see below), the device shares data on time used, effort, and ROM 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 ROM 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 ROM. 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.

Mechanical Offloading for Diabetic Foot Ulcer

Reducing pressure by mechanical offloading benefits ulcers subjected to frequent pressure and stress. Various types of offloading devices include shoe modifications, cast walkers, total contact cast and other devices aiding ambulation. Cast walkers are prefabricated brace designed to provide offloading capability and maintain contact fit.

Sensoria Health Diabetic Foot Ulcer Boot

The Sensoria diabetic foot ulcer boot monitors an individual's compliance to the clinician's prescribed stabilization and mechanical offloading rehabilitation protocol. Real-time updates on the individual's activities and for how long the boot is taken off is provided to the clinician.

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

1. Elraiyah T, Prutsky G, Domecq JP, et al. A systematic review and meta-analysis of off-loading methods for diabetic foot ulcers. J Vasc Surg. 2016 Feb;63(2 Suppl):59S-68S.e1-2.
2. 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.
3. 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.
4. 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. 2023 Mar;38(3):497-501.

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PortableConnect
AccuAngle
Sensoria Health Diabetic Foot Ulcer Boot

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.

History

Status	Date	Action
Revised	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Removed list of examples from Position Statement section. Updated Rationale, Background, References and Index sections.
New	05/12/2022	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax #

818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.