FEP 1.03.05 Patient-Controlled End Range of Motion Stretching Devices

Effective Date: July 15, 2018

Related Policies: None

Patient-Controlled End Range of Motion Stretching Devices

Description

Patient-controlled stretching devices are used at home to increase range of motion (ROM) in patients who have impaired functional status due to decreased ROM. We address 2 types of commercially available devices. Static progressive stretch (SPS) devices (eg, JAS, Static-Pro) provide low- to moderate-intensity stretching with a crank or ratchet that progressively increases the stretch within each session, and serial stretch devices (eg, ERMI) use hydraulics to alternate between periods of higher intensity stretch and relaxation.

FDA REGULATORY STATUS

The U.S. Food and Drug Administration has determined that devices classified as “Exerciser, Non-Measuring” are considered class I devices and exempt from 510(k) requirements. This classification does not require submission of clinical data on efficacy, only notification to the Food and Drug Administration prior to marketing. Food and Drug Administration product code: ION.

POLICY STATEMENT

Patient-controlled end range of motion stretching devices are considered **investigational**.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who have functional limitations in ROM who receive SPS devices and physical therapy, the evidence includes RCTs, a systematic review, and case series. Relevant outcomes include symptoms, change in disease status, functional outcomes, and quality of life. Three RCTs have evaluated SPS devices, but comparators in each differed (physical therapy, a dynamic splint, and a serial stretch device). One RCT reported significant improvements in Disabilities of the Arm Shoulder and Hand questionnaire scores and shoulder ROM compared with physical therapy alone at the end of 4 weeks of treatment, with significant improvements maintained at the 2-year follow-up. A second RCT evaluating SPS in the elbow found similar improvements in most ROM outcomes compared with dynamic splinting, except better Disabilities of the Arm Shoulder and Hand scores in the SPS group at 6 months and better

flexion contracture in the dynamic splinting group at 12 months. A third RCT, which compared SPS with serial stretch devices, found greater improvements in Western Ontario and McMaster University Osteoarthritis Index and knee flexion scores with the serial stretch devices. A systematic review and meta-analysis of case reports and series found that similar clinical efficacy for increasing elbow ROM and flexion can be achieved using dynamic splints, SPS devices, and static braces. It is not known whether patient compliance is higher with SPS devices because results have indicated these devices improve ROM faster than comparators. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have functional limitations in ROM who receive serial stretch devices and physical therapy, the evidence includes an RCT and observational studies. Relevant outcomes include symptoms, change in disease status, functional outcomes, and quality of life. The best evidence consists of serial stretching with ERMI devices used to treat knee ROM. One small RCT and a larger retrospective comparative study have reported that high-intensity stretching with ERMI devices improved ROM more than lower intensity stretching devices in patients who were post injury or surgery. Other available data consist of retrospective case series that have demonstrated improved ROM in patients whose ROM had plateaued with physical therapy. The clinical significance of gains in this surrogate outcome measure is unclear. Further high-quality comparative trials are needed to determine whether these patient-controlled devices improve functional outcomes better than alternative treatments and identify the patient populations that might benefit. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY

Date	Action	Description
March 2015	New Policy	
December 2016	Update Policy	Policy updated with literature review through June 13, 2016; references 7-9 and 11-12 added. Policy title changed to “Patient-Controlled End Range of Motion Stretching Devices”.
March 2018	Update Policy	Policy updated with literature review through January 8, 2018; no references added. Policy statement unchanged.