Medical Coverage Policy | Patient-Controlled End Range Stretching Motion Devices

EFFECTIVE DATE: 10|01|2015
POLICY LAST UPDATED: 09|20|2016

OVERVIEW

Patient-controlled stretching devices are mechanical devices that are used in the home to increase range of motion (ROM) in patients who have impaired functional status due to decreased ROM. There are 2 commercially available types of devices. Serial progressive stretch (SPS) devices (e.g., JAS, Static-Pro) provide low- to moderate-intensity stretching with a crank or ratchet that progressively increases the stretch within each session. Serial stretch devices (e.g., ERMI) devices use a hydraulic mechanism to alternate between brief periods of high-intensity stretch and periods of relaxation.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Patient-controlled end range motion stretching devices are considered not medically necessary due to insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND

Loss of full ROM occurs in a significant proportion of patients following surgical procedures around the joint, such as total knee arthroplasty (TKA) or anterior cruciate ligament (ACL) reconstruction. The most common cause for severe postoperative motion loss is the development of intra-articular or extra-articular arthrofibrosis. Arthrofibrosis, characterized by periarticular fibrosis and bands of scar tissue, is described as a painful loss of end range motion compared with the normal contralateral side. Loss of ROM of the knee can lead to impairments in walking, sitting down and rising from a chair, and navigating stairs. A 2010 publication estimated that given the annual rates of TKA and ACL reconstruction, the number of major knee surgery patients affected by arthrofibrosis in the United States would be at least 85,000 per year, and approximately 21,000 patients each year would be at risk of requiring additional surgery.

Treatment of arthrofibrosis may include physiotherapy, manipulation under anesthesia, arthroscopic or open lysis of adhesions, or revision surgery. Conservative treatment typically consists of postoperative physical therapy with pressure stretching techniques and home exercises. When traditional rehabilitation has failed, serial casting, static braces, or dynamic splints that provide low-load prolonged stretch may be used. Dynamic splints use spring loading or elastic bands to provide low-intensity tension (less than that exerted by a physical therapist) and are designed to be worn over relatively long periods (i.e., 6-8 hours or overnight). Dynamic splinting devices include the Advance Dynamic ROM, DeROM, Dynasplint, EMPI advance, LMB Pro-glide, Pro-glide Dynamic ROM, SaeboFlex, SaeboReach, and Ultraflex.

This policy focuses on patient-controlled mechanical devices that provide either moderate- to high-intensity stretch or static progressive stretch in the home. The efficacy of a stretching regimen to permanently remodel tissue is considered to be a function of the intensity, length of the session, number of times per day, and number of days per week that stretching is performed. Patient-controlled serial stretch devices in the home include the ERMI (ERMI Inc.) line. Other devices, such as the JAS (Joint Active Systems Inc.), provide a low- to moderate-intensity force to hold a joint at its end range and gradually increase the stretch (static progressive stretch). In contrast to the long periods of low-intensity stretch provided by dynamic splinting devices, patient-controlled serial stretch and SPS devices are designed to be used for periods of 15 to 30 minutes, in up to 8 sessions per day.

SPS devices are available for the knee, shoulder, ankle, wrist, and for pronation and supination. Patients are typically instructed to use the devices for 30 minutes, 3 times a day. During each session, patients adjust their device by turning a ratchet or turn-buckle to the maximum tolerated position of end range stretch. Each position is held for several minutes to allow for tissue relaxation to occur, and the device is then advanced to a new position of stretch (SPS). It is proposed that the systems unload the joint to reduce joint surface pressures during the stretch. Devices that provide SPS include JAS (Joint Active Systems), Static-Pro® (DeRoyal), Stat-A-Dyne® (Ortho-Innovations), AliMed® Turnbuckle Orthosis (AliMed), and Mayo Aircast® (DJO).

Specific ERMI devices are the Shoulder Flexionater, Knee Flexionater, Knee Extensionater, Elbow Extensionater, and the MPJ Extensionater. These are intended primarily to address excessive scar tissue around the joint using progressive stretching alternating with periods of relaxation, with torque similar to that applied by physical therapists that is near or at the pain threshold. The patient uses a hydraulic pump to control the load, which can range from a few ounces to 500 lbs. For example, to use the ERMI Knee/Ankle Flexionater, patients pull a lever to increase knee flexion angle, as well as the amount of torque being applied to the joint. The hydraulic system amplifies the force of the lever into a greater torque applied to the knee for about 5 to 10 minutes. Periods of flexion are interspersed by 5- to 10-minute recovery intervals where the knee is released back into extension.

Overall, the quality of evidence is poor for individuals who have functional limitations in ROM who receive serial progressive stretch devices in conjunction with physical therapy. The evidence is insufficient to determine the effects of the technology on health outcomes. Additionally, for individuals who have functional limitations in ROM who receive serial stretch devices in conjunction with physical therapy, the evidence is limited. The clinical significance of gains 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. Therefore, the service is considered not medically necessary.

CODING

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The following items are considered not medically necessary:

E1801
E1806
E1811
E1816
E1818
E1831
E1841

RELATED POLICIES

Preauthorization via Web-Based Tool for Durable Medical Equipment (DME)

PUBLISHED

Provider Update, December 2016
Provider Update, March 2016
Provider Update, January 2015
Provider Update, August 2013
Provider Update, July 2012
Provider Update, January 2012
Provider Update, October 2009

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