Medical Coverage Policy | Patient-Actuated End Range Motion Stretching Devices (former policy title: Dynamic Splinting)

EFFECTIVE DATE: 05|01|2016
POLICY LAST UPDATED: 12|15|2015

OVERVIEW
Patient-actuated stretching devices are mechanical devices that are used in the home to increase range of motion (ROM) in patients who experience impairments in functional status due to decreased ROM. There are 2 commercially available types of devices. Serial progressive stretch devices (e.g., Joint Active Systems, JAS, Static-Pro) provide moderate-intensity stretching with a crank or ratchet that progressively increases the stretch within each session. End Range Motion Improvement (ERMI) devices use a hydraulic mechanism to create brief periods of high-intensity stretch alternating with periods of relaxation.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Patient-actuated 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-actuated mechanical devices that provide either 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.[2] Devices that provide high-intensity stretching in the home are ERMI (ERMI Inc.) devices. Other devices, such as the JAS (Joint Active Systems Inc.), provide a moderate-intensity force to hold a joint at its end range and gradually increase the stretch (static progressive stretch). The Static-Pro (DeRoyal) is another brace design that applies a static progressive stretch. In contrast to the long periods of low-intensity stretch provided by dynamic splinting devices, ERMI, JAS, and Static-Pro devices are designed to be used for brief periods of 15 to 30 minutes, in up to 8 sessions per day.

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.

Joint Active Systems include the JAS Elbow, JAS Shoulder, JAS Ankle, JAS Knee, JAS Wrist, and JAS Pronation-Supination. Patients are instructed to use the JAS devices for 30 minutes, 3 times a day. During each 30-minute session, patients adjust their device by turning a ratchet to the maximum tolerated position of end range stretch. Each position is held for 5 minutes to allow for tissue relaxation to occur, and the device is then advanced to a new position of stretch (static progressive stretch). It is proposed that the JAS systems unload the joint to reduce joint surface pressures during the stretch. Other devices that provide static progressive stretch include Static-Pro Knee, Static-Pro Wrist, and Static-Pro Elbow. Static-Pro devices provide moderate torque by turning a knob and combine static stretching with stress relaxation.

There is a small body of evidence on patient-actuated ERMI devices. Further high-quality comparative trials are needed to determine whether these patient-actuated devices improve functional outcomes compared with alternative treatments and to better define the patient population that might benefit. Therefore, use of patient-actuated end range motion stretching devices is considered not medically necessary.

CODING

BlueCHiP for Medicare and Commercial Products

The following items are considered not medically necessary **(Effective 5/1/2016)**:

E1801 Static progressive stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1806 Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
E1811 Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1816 Static progressive stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
E1818 Static progressive stretch forearm pronation/supination device, with or without range of motion adjustment, includes all components and accessories

The following codes are not medically necessary

E1831 Static progressive stretch toe device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1841 Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories
E1830 Dynamic adjustable toe extension/flexion device, includes soft interface material
E1840 Dynamic adjustable shoulder flexion/abduction/rotation device, includes soft interface material

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

PUBLISHED
Provider Update, March 2016
Provider Update, January 2015
Provider Update, August 2013
Provider Update, July 2012
Provider Update, January 2012
Provider Update, October 2009
Provider Update, October 2008

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