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

EFFECTIVE DATE: 10|01|2015
POLICY LAST UPDATED: 10|16|2018

OVERVIEW

Patient-controlled stretching devices 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. Static 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 hydraulics to alternate between periods of higher intensity stretch and relaxation.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare

Patient-controlled end range of motion stretching devices are not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Patient-controlled end range of motion stretching devices are considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

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

BACKGROUND

RANGE OF MOTION IMPAIRMENTS

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 of 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 based on 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

Treatment of arthrofibrosis may include physical therapy, 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 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).

Static Progressive Stretch Devices

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 session per day, and number of days per week that stretching is performed. SPS devices provide a low- to moderate-intensity force to hold a joint at its end range and gradually increase the 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. 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).

Serial Stretch Devices

Patient-controlled serial stretch devices in the home include the ERMI (ERMI Inc.) line. Specific ERMI devices are the Shoulder Flexionater, Knee Flexionater, Knee Extensionater, Elbow Extensionater, and the MPJ Extensionater. They are intended primarily to address excessive scar tissue around the joint by alternating progressive stretching with periods of relaxation, at a 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, and 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.

Outcome Measures

Improvement in functional outcomes, such as the ability to perform activities of daily living, is the primary goal of this intervention. Joint ROM is an intermediate outcome. One small study (2000) correlated knee ROM with functional parameters and concluded that 110° is considered the functional ROM necessary to allow patients to perform common activities of daily living such as navigating stairs, rising from a low chair or commode, entering or exiting from a car, or tying one's shoes. This threshold of ROM is therefore used as a measure of treatment success for individual patients. Loss of knee ROM of more than 15°, which occurs in about 1% to 2% of patients after anterior cruciate ligament reconstruction, has been associated with loss of quadriceps muscle strength and the development of osteoarthritis. According to the knee examination form developed by the International Knee Documentation Committee (2000), an extension deficit of 6° to 10° or a flexion deficit of 16° to 25° when compared with the noninvolved knee is categorized "abnormal," and an extension deficit of more than 10° or a flexion deficit of more than 25□ when compared with the noninvolved knee is categorized "severely abnormal."5 ROM thresholds in joints other than the knee have been less clearly defined.

For individuals who have functional limitations in ROM who receive SPS devices and physical therapy, 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 is insufficient to determine the effects of the technology on health outcomes.

CODING

The following HCPCS codes are not covered for BlueCHiP for Medicare and not medically necessary for Commercial Products:

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
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

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, January 2019
Provider Update, January 2018
Provider Update, December 2016
Provider Update, March 2016
Provider Update, January 2015

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