

Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.



**BlueCross BlueShield
of Alabama**

Name of Blue Advantage Policy:

Patient-Controlled End Range of Motion Stretching Devices

Policy #: 578

Latest Review Date: April 2023

Category: DME

ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat the **use of bi-directional static progressive (SP) stretch devices** as a **non-covered benefit** and as **investigational**.

Blue Advantage will treat the **use of patient-actuated serial stretch (PASS) devices** as a **non-covered benefit** and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Patient-controlled stretching devices are used at home to increase range of motion in patients who have impaired functional status due to decreased range of motion. We address 2 types of commercially available devices. Static progressive stretch devices (e.g., Joint Active Systems, 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 (e.g., End Range of Motion Improvement [ERMI]) use hydraulics to alternate between periods of higher intensity stretch and relaxation.

Range of Motion Impairments

Loss of full range of motion (ROM) occurs in a significant proportion of patients following surgical procedures around a joint, such as total knee arthroplasty or anterior cruciate ligament reconstruction. The most common cause of 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 ROM compared with the normal contralateral side. Loss of knee ROM can lead to impairments in walking, sitting, rising from a chair, and navigating stairs. Stephenson et al (2010) estimated that, based on the annual rates of total knee arthroplasty and anterior cruciate ligament 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 designed to be worn over relatively long periods (i.e., 6-8 hours or overnight).

This evidence review focuses on patient-controlled mechanical devices that provide either moderate- to high-intensity stretch or static progressive stretch in the home. Patient-controlled stretching devices are used at home to increase range of motion in patients who have impaired functional status due to decreased range of motion. We address 2 types of commercially available devices. Static progressive stretch devices (e.g., Joint Active Systems ([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 (e.g., End Range of Motion Improvement ([ERMI])) use hydraulics to alternate between periods of higher intensity stretch and relaxation.

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 non-involved 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.” ROM thresholds in joints other than the knee have been less clearly defined.

For dynamic low load prolonged duration stretch (LLPS) devices, see Medical Policy 346-“Stretching and Splinting Devices for the Treatment of Joint Stiffness and Contractures”.

KEY POINTS:

The most recent literature update was performed through December 19, 2022.

Summary of Evidence:

For individuals who have functional limitations in range of motion who receive static progressive stretch 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 static progressive stretch devices but comparators in each differed (physical therapy, a dynamic splint, and a serial stretch device). The evidence on static progressive stretch devices does not currently support an improvement in pain and function with static progressive stretch compared to alternative treatments. One RCT found greater improvements in range of motion and WOMAC scores with serial stretch devices for the knee compared with static progressive stretch devices. Another RCT

evaluating static progressive stretch for shoulder adhesive capsulitis found significant differences in shoulder range of motion compared with physical therapy alone at the end of 4 weeks of treatment, with no difference in pain and function. A third RCT found comparable improvements in most outcomes for the static progressive stretch device compared with dynamic splinting, and a systematic review of case reports and series found similar clinical efficacy for increasing elbow range of motion between static progressive stretch devices and dynamic splints. Dynamic splints are used for 8 to 24 hours per day while static progressive stretch devices require several 30 minute sessions. It is not known whether patient compliance is higher with static progressive stretch devices. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements:

No guidelines or statements on patient-actuated end-range motion devices were identified.

U.S. Preventive Services Task Force Recommendations:

Not applicable.

KEY WORDS:

Bi-directional static progressive (SP) stretch devices, patient-actuated serial stretch (PASS) devices, FlexPro Knee Flexor, StaticPro® Knee, ERMI (End Range Motion Improvement), Joint Active Systems (JAS), patient-controlled mechanical devices, Stat-A-Dyne® (Ortho-Innovations), AliMed® Turnbuckle Orthosis (Alimed), and Mayo Aircast®, Advance Dynamic ROM, DeROM, Dynasplint, EMPI advance, LMB Pro-glide, Pro-glide Dynamic ROM, SaeboFlex, SaeboReach, Ultraflex.

APPROVED BY GOVERNING BODIES:

The FDA has determined that devices classified as “Exerciser, Non-Measuring” are class I devices by the U.S. Food and Drug Administration (FDA) and are exempt from 510(k)

requirements. This classification does not require submission of clinical data on efficacy, only notification to FDA prior to marketing.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

HCPCS

E1399	Durable Medical Equipment Miscellaneous
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
E1821	Replacement soft interface material/cuffs for bi-directional static progressive stretch device
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.

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POLICY HISTORY:

Adopted for Blue Advantage, September 2009

Available for comment October 3-November 18, 2009

Medical Policy Group, December 2010 – 2011 Code update
Medical Policy Group, April 2011;
Medical Policy Group, February 2012
Medical Policy Administration Committee, February 2012
Medical Policy Group, May 2013: Effective 05/1/2013: Active Policy but no longer scheduled for regular literature reviews and updates.
Medical Policy Group, September 2013
Medical Policy Group, August 2014
Medical Policy Group, January 2015
Medical Policy Group, July 2016
Medical Policy Group, March 2017
Medical Policy Group, April 2017
Medical Policy Group, April 2018
Medical Policy Group, March 2019
Medical Policy Group, March 2020
Medical Policy Group, March 2021
Medical Policy Group, March 2022
Medical Policy Group, April 2023
Medical Policy Group, November 2023: Archived effective 11/1/2023.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.