



Louisiana

Mechanical Stretch Devices for Joint Stiffness and Contractures

Policy # 00193

Original Effective Date: 02/23/2006

Current Effective Date: 07/08/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically. Note: Continuous Passive Motion (CPM) is addressed separately in medical policy 00020.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member’s contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider low-load prolonged-duration stretch (LLPS) (Dynamic Splinting) devices for use on the knee, elbow, and wrist or finger to be **eligible for coverage.****

Examples of LLPS devices include Dynasplint System^{®†} (Dynasplint Systems Inc.); Ultraflex (Ultraflex Systems Inc.); LMB Pro-Glide devices (DeRoyal Industries); Advance Dynamic ROM^{®†}, Saunders^{®†}, Pronex^{®†} (Empi).

Patient Selection Criteria

Coverage eligibility may be considered for low-load prolonged-duration stretch (LLPS) (Dynamic Splinting) devices for use on the knee, elbow, and wrist or finger when **ANY** of the following criteria are met:

- As an adjunct to physical therapy in members with documented signs and symptoms of significant motion stiffness/loss in the sub-acute injury or postoperative period (≥ 3 weeks but ≤ 4 months after injury or surgery); **OR**
- In the acute post-operative period for members who have a prior documentation of motion stiffness/loss in a joint and are having additional surgery or procedures done to improve motion in that joint; **OR**
- As an alternative to manipulation under anesthesia.

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Note:

Covered devices will be initially approved for monthly rental for up to four (4) months.

One-time additional monthly rental for up to four (4) months will be approved only when the following criteria are met and documented in medical records:

- *Persistent significant motion stiffness/loss*
- *Significant improvement after initial use*
- *Compliance with conventional therapy and daily device use.*

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

The use of low-load prolonged-duration stretch (LLPS) (Dynamic Splinting) devices when patient selection criteria are not met is considered to be **investigational***, including but not limited to:

- The management of chronic fixed contractures due to joint trauma, fractures, burns, brain and spinal cord injuries, rheumatoid arthritis, plantar fasciitis, multiple sclerosis, muscular dystrophy, cerebral palsy, or other chronic conditions; **OR**
- When conventional methods of treating stiff or contracted joints have not been attempted; **OR**
- If there is no significant improvement after four months of use: **OR**
- If initiated more than four months post-operatively (unless it is to be used as an alternative to manipulation under anesthesia); **OR**
- The use on any other joint not mentioned above.

Based on review of available data, the Company considers static progressive stretch devices, e.g. Joint Active Systems^{®‡} (JAS) Static Progressive Stretch devices (finger, wrist, elbow, shoulder, knee, ankle), JAS^{®‡} Pronation/Supination device, Static-Pro^{®‡} Knee, Stat-A-Dyne^{®‡}, AliMed^{®‡} Turnbuckle Orthosis, and Mayo Aircast^{®‡} to be **investigational.***

Based on review of available data, the Company considers patient-actuated serial stretch (PASS) devices, e.g. End Range of Motion Improvement ERMI Knee Extensionator, ERMI Knee/Ankle

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Flexionator, ERMI Shoulder Flexionator, ERMI MPJ Extensionator, and ERMI Elbow Extensionator to be **investigational**.*

Background/Overview

Range of Motion Impairments

Loss of full range of motion 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 range of motion compared with the normal contralateral side. Loss of knee range of motion can lead to impairments in walking, sitting, rising from a chair, and navigating stairs. In 2010, Stephenson et al 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. Manipulation under anesthesia is safest and most effective after total knee arthroplasty if performed within the first three postoperative months. 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 (ie, 6-8 hours or overnight). 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 sessions per day, and number of days per week that stretching is performed.

This medical policy 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

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due to decreased range of motion. We address 2 types of commercially available devices. Static progressive stretch devices (eg, 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 (eg, 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 range of motion is an intermediate outcome. In 2000, 1 small study by Rowe et al. correlated knee range of motion with functional parameters and concluded that 110° is considered the functional range of motion 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 a car, or tying one's shoes. This threshold of range of motion is therefore used as a measure of treatment success for individual patients. Loss of knee range of motion 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." Range of motion thresholds in joints other than the knee have been less clearly defined.

Low-load Prolonged-duration Stretch (LLPS) (Dynamic Splinting) Devices

LLPS devices permit resisted active and passive motion (elastic traction) within a limited range. LLPS devices maintain a set level of tension by means of incorporated springs. Most spring loaded dynamic splinting devices are designed to provide a low load, prolonged stretch to joints that have reduced range of motion secondary to immobilization, surgery, contracture, fracture, dislocation, or a number of additional non-traumatic disorders. Most of these devices are adjustable-tension controlled units that provide a continuous dynamic stretch while patients are asleep or at rest. Commonly time of use is continuously for 6 – 12 hours, which can be at night or can be two three-hour sessions during the day for less than four months. The objective of stretch therapy is to improve range of motion without compromising the stability and quality of the connective tissue and joint. Currently, dynamic splinting devices are available for but not limited to the elbow, wrist, knee, ankle, and toes. Examples of LLPS devices include Dynasplint System (Dynasplint SystemsInc.); Ultraflex

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(Ultraflex Systems Inc.); LMB Pro-Glide devices (DeRoyalIndustries); Advance Dynamic ROM, Saunders, Pronex (Empi).

Static Progressive Stretch Devices

Static progressive stretch 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 static progressive stretch devices are designed to be used for 15 to 30 minutes, in up to 8 sessions per day. Static progressive stretch devices are available for the knee, shoulder, ankle, wrist, and for pronation and supination. Patients are typically instructed to use them for 30 minutes, 3 times a day. During each session, patients adjust their device by turning a ratchet or turnbuckle 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 static progressive stretch include JAS (Joint Active Systems), Static-Pro (DeRoyal), Stat-A-Dyne (Ortho-Innovations), AliMed Turnbuckle Orthosis (AliMed), and Mayo Aircast (DJO).

Serial Stretch Devices

Serial stretch devices (e.g., ERMI) use hydraulics to alternate between periods of higher intensity stretch and relaxation.

Examples include End Range of Motion Improvement ERMI Knee Extensionator, ERMI Knee/Ankle Flexionator, ERMI Shoulder Flexionator, ERMI MPJ Extensionator, and ERMI Elbow Extensionator.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

The U.S. Food and Drug Administration (FDA) 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 FDA prior to marketing. FDA product code: ION

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Low-load Prolonged-duration Stretch (LLPS) (Dynamic Splinting) Devices

Evidence from five randomized controlled trials (RCTs) and two uncontrolled studies suggests that low-load prolonged-duration stretch (LLPS) for finger contractures following surgical extensor injury repair may increase range of motion (ROM) faster than static splinting. However, the treatment benefit is small and the final outcome is similar to that achieved with static splinting. Furthermore, LLPS did not significantly improve hand function and grip strength, indicating that the small short-term gains in ROM may not be clinically meaningful and that LLPS may not improve final outcomes. There was a paucity of studies investigating mechanical stretching devices for other applications, including contracture of the fingers following flexor injury or trauma, the hand, wrist, elbow, shoulder, and the knee. Because there were only one or two studies available for each device type, a systematic analysis of the evidence was not possible. No safety issues associated with mechanical stretching devices were identified in the reviewed studies.

Although there is inadequate data in the published peer reviewed literature to validate the effectiveness of dynamic splinting in improving joint range of motion, this technology is widely used in the Orthopedic and Physical Therapy communities for selected patient populations. On the basis of national community standards, dynamic splinting may be considered eligible for coverage with criteria in the clinical settings outlined under the coverage section of this document.

There is insufficient evidence in the published peer-reviewed literature to support the use of dynamic LLPS devices for the treatment of conditions such as, but not limited to, chronic joint stiffness or chronic fixed contractures caused by chronic medical conditions such as rheumatoid arthritis (RA), cerebral palsy, stroke, long term lack of motion in the joint, neuromuscular disease, or plantar fasciitis.

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Patient-controlled End Range of Motion Stretching Devices

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 (eg, 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 (eg, End Range of Motion Improvement ERMI)) use hydraulics to alternate between periods of higher intensity stretch and relaxation.

For individuals who have functional limitations in range of motion who receive static progressive stretch devices and physical therapy, the evidence includes randomized controlled trials (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 Western Ontario and McMaster University Osteoarthritis Index 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 range of motion who receive serial stretch devices and physical therapy, the evidence includes a 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 End Range of Motion Improvement (ERMI) devices used to treat knee range of motion. One small RCT and a larger retrospective comparative study have

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reported that high-intensity stretching with ERMI devices improved range of motion 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 range of motion in patients whose range 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.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

Ongoing and Unpublished Clinical Trials

A search of [ClinicalTrials.gov](https://clinicaltrials.gov) in January 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

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| 01/04/2006 | Medical Director review |
| 01/17/2006 | Medical Policy Committee |
| 02/23/2006 | Quality Care Advisory Council approval |
| 05/02/2007 | Medical Director review |
| 05/23/2007 | Medical Policy Committee approval. Coverage eligibility unchanged. |
| 11/05/2008 | Medical Director review |
| 11/18/2008 | Medical Policy Committee approval. Changed title of policy to “Dynamic Range of Motion Devices”. Removed 1st investigational statement, “The use of dynamic range of motion when the above patient selection criteria are not met is considered investigational.*”. Rationale updated. |
| 10/01/2009 | Medical Policy Committee review |
| 10/14/2009 | Medical Policy Implementation Committee approval. No change to coverage. |
| 10/14/2010 | Medical Policy Committee review |
| 10/20/2010 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged. |

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10/06/2011	Medical Policy Committee review
10/19/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2012	Medical Policy Committee review
02/15/2012	Medical Policy Implementation Committee approval. Coverage for static progressive stretch devices and low-load prolonged-duration stretch (LLPS) added. Title changed from Dynamic Range of Motion to Mechanical Stretch Devices for Joint Stiffness and Contractures.
03/07/2013	Medical Policy Committee review
03/20/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/06/2014	Medical Policy Committee review
03/19/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/25/2015	Medical Policy Committee review
07/15/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/30/2016	Medical Policy Committee review
07/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis codes
07/06/2017	Medical Policy Committee review
07/19/2017	Medical Policy Implementation Committee approval. Added “the treatment of joint stiffness” and “the joint does not have chronic or fixed contractures and” to coverage statement and deleted the last criteria bullet “the joint does not have chronic or fixed contractures”.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/03/2019	Medical Policy Committee review
07/18/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/02/2020	Medical Policy Committee review

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07/08/2020 Medical Policy Implementation Committee approval. Added “physical” to the third criteria bullet before “inability to exercise” for clarification. Coverage eligibility unchanged.

05/06/2021 Medical Policy Committee review

05/12/2021 Medical Policy Implementation Committee approval. Coverage section completely revised.

06/02/2022 Medical Policy Committee review

06/08/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

06/01/2023 Medical Policy Committee review

06/14/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

06/06/2024 Medical Policy Committee review

06/12/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

12/11/2024 Coding update

03/25/2025 Coding update

Next Scheduled Review Date: 06/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Louisiana

Mechanical Stretch Devices for Joint Stiffness and Contractures

Policy # 00193

Original Effective Date: 02/23/2006

Current Effective Date: 07/08/2024

medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	E1800, E1801, E1802, E1803, E1804, E1805, E1806, E1807, E1808, E1810, E1811, E1812, E1813, E1814, E1815, E1816, E1818, E1820, E1821, E1822, E1823, E1825, E1826, E1827, E1828, E1829, E1830, E1831, E1840, E1841 Add codes effective 04/01/2025: E1832
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with technology evaluation center(s);

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2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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