



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Mechanical Stretch Devices for Joint Stiffness and Contractures

**Policy #** 00193

**Original Effective Date:** 02/23/2006

**Current Effective Date:** 03/19/2014

*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 considered 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 static progressive stretch devices and low-load prolonged-duration stretch (LLPS) devices for use on the knee, elbow, and wrist or finger to be **eligible for coverage**.

### Patient Selection Criteria

Coverage eligibility will be considered for the above devices for use on the knee, elbow, wrist or finger when any of the following criteria are met:

- Motion stiffness in the subacute injury or post-operative period of at least three weeks; or
- Acute post operative period for patients with history of motion stiffness of a joint and having additional surgery done to improve motion of that joint; or
- Unable to benefit from standard physical therapy due to the inability to exercise; or
- The joint does not have chronic or fixed contractures

### **When Services Are Considered Investigational**

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

The use of static progressive stretch and low-load prolonged-duration stretch (LLPS) devices on the knee, elbow, wrist or finger when the above patient selection criteria are not met is considered **investigational**.\*

Based on review of available data, the Company considers patient-actuated serial stretch (PASS) devices (flexionators and extensionators) to be **investigational**.\*

Based on review of available data, the Company considers the use of static progressive stretch devices and low-load prolonged-duration stretch (LLPS) for all other indications to be **investigational**.\*

Based on review of available data, the Company considers the use of mechanical stretch devices for all other indications to be **investigational**.\*



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## **Background/Overview**

### **Low-Load Prolonged-Duration stretch (LLPS) Devices/Dynamic Splinting Devices**

Dynamic splinting devices are spring-loaded devices designed to provide a low load, prolonged stretch to joints that have reduced range of motion due to immobilization, surgery contracture, fracture, dislocation or a number of additional non-traumatic disorders. Dynamic splinting is used in the post-operative period for the prevention of motion stiffness in the knee, elbow, wrist or finger. It is not used in such joints as the hip, ankle or foot. Most of these devices are adjustable-tension controlled units which provide continuous dynamic stretch while patients are at rest. Time of use is continuously for 6 to 12 hours. Some examples of available devices are the Dynasplint, Ultraflex and Advance Dynamic ROM device.

### **Static Progressive Stretch Devices**

Bidirectional static progressive stretch devices concept of static progressive stretching applies to a different principle than the spring loaded dynamic splinting device of low load prolonged stress technique. The stretch is increased every few minutes by the patient to increase range of motion during the period of brace utilization. The period of use is 30 minutes used 2 to 3 times per day. Some examples of static progressive stretch and stress relaxation devices include Joint Active Systems (JAS splints) and Air Cast.

### **Patient-Actuated Serial Stretch (PASS) Devices**

Patient-Actuated Serial Stretch (PASS) Devices- These devices provide a low to high level load to the joint using pneumatic or hydraulic systems that are adjusted by the patient. They are custom-fitted and used for the ankle, elbow, knee and shoulder. Available devices are the ERMI Knee Extensionator, ERMI Knee/Ankle Flexionator, ERMI Shoulder Flexionator, ERMI MP J Extensionator, and the ERMI Elbow Extensionator.

## **FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

Numerous devices have been developed to provide mechanical passive joint stretch or continuous device-assisted passive motion (CPM). The FDA refers to these as exempted Class I devices, which include static devices, dynamic devices and patient-actuated serial devices. Premarket notification and approval are not required. Continuous device-assisted passive motion machines are approved by the FDA as Class II devices. Class II devices meet both the General Control requirements and Performance Standards established by the FDA. A large number of CPM devices, including bed-mounted stationary units and portable units, have been approved by the FDA over the past 15 years. These devices are produced and/or marketed by Electrobionics Corp., Danninger Medical Technology Inc., Sutter Corp., Jace Systems Inc., Ormed Inc., Thera-kinetics and OrthoLogic Corp., among others.  
Centers for Medicare & Medicaid Services (CMS)

The CMS has not issued a national coverage decision for the use of mechanical stretching devices for the treatment of joint contractures. Continuous device-assisted passive motion devices are covered in patients who have undergone total knee arthroplasty (TKA) if CPM is commenced within two days post surgery. Coverage is limited to a three week time frame following surgery, during which the device is used in the patient's home.

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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. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

## References

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## Coding

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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, E1805, E1806, E1810, E1811, E1812, E1815, E1816, E1818, E1820, E1821, E1825, E1830, E1831, E1840, E1841
ICD-9 Diagnosis	All relative diagnoses
ICD-9 Procedure	No codes

### **Policy History**

Original Effective Date: 02/23/2006  
Current Effective Date: 03/19/2014

01/04/2006 Medical Director review  
01/17/2005 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.  
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.  
Next Scheduled Review Date: 03/2015

\*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:



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1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
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.

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