MEDICAL POLICY

POLICY TITLE	MECHANICAL STRETCHING DEVICES FOR CONTRACTURE AND JOINT STIFFNESS
POLICY NUMBER	MP-6.039

Original Issue Date (Created):	**7/1/2005**
Most Recent Review Date (Revised):	**9/30/2019**
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I. POLICY

Mechanical Stretching Devices

Dynamic Splinting Devices

Dynamic splinting devices for the knee, elbow, wrist or finger may be considered **medically necessary** for the following indications:

- As an adjunct to physical therapy when there are documented signs and symptoms of significant motion stiffness or loss in the sub-acute injury or post-operative period (i.e., at least three weeks after injury or surgery); or
- During the acute post-operative period where there is prior documented history of motion stiffness or loss in a joint when additional surgery or procedures are done to improve motion to that joint.

Continued use beyond an eight (8) week period will require medical director review.

Dynamic splinting devices for use in any other joint including the toes or any condition not listed above is considered **not medically necessary.**

The prophylactic use of dynamic splinting in the management of chronic contractures (no significant change in a motion for a four month period) and joint stiffness due to joint trauma, fractures, burns, head and spinal cord injuries, rheumatoid arthritis, multiple sclerosis, muscular dystrophy, or cerebral palsy is considered **not medically necessary.**

POLICY TITLE	MECHANICAL STRETCHING DEVICES FOR CONTRACTURE AND JOINT STIFFNESS
POLICY NUMBER	MP-6.039

Joint Active System splints are considered **investigational**, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these devices.

Extensionator and flexionator devices are considered **investigational**, as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these devices.

Continuous Passive Motion Device (CPM)
Use of continuous passive motion (CPM) in the home setting may be considered **medically necessary** as an adjunct to physical therapy in the following situations:

- During the non-weight bearing rehabilitation period following articular cartilage repair procedures of the knee (e.g., microfracture, osteochondral grafting, autologous chondrocyte implantation, treatment of osteochondritis dissecans, repair of tibial plateau fractures); **OR**
- Under conditions of low postoperative mobility or inability to comply with rehabilitation exercises following a total knee arthroplasty (TKA), TKA revision or other major knee surgery. This may include patients with complex regional pain syndrome (reflex sympathetic dystrophy), extensive arthrofibrosis or tendon fibrosis, or physical, mental, or behavioral inability to participate in active physical therapy.

Use of the CPM device should commence within two (2) days of surgery and the maximum benefit is usually obtained within fourteen (14) days from the start of therapy. Continued use beyond 6 weeks following surgery of any type is generally considered **not medically necessary** or appropriate; including following knee arthroscopy with microfracture.

The use of a CPM device for other joints including, but not limited to, major hip joint and shoulder surgery is considered **not medically necessary**.

II. PRODUCT VARIATIONS

Top

This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

POLICY TITLE	MECHANICAL STRETCHING DEVICES FOR CONTRACTURE AND JOINT STIFFNESS
POLICY NUMBER	MP-6.039

III. DESCRIPTION/BACKGROUND

Top

Mechanical Stretching Devices

Joint stiffness, contracture and diminished range of motion can result from surgery, illness, trauma, immobilization or congenital abnormalities. Prefabricated or custom fabricated devices worn across a stiff or contractured joint to provide incremented tension in one or both directions can increase range of motion. These devices are manually controlled by the patient and can be used alone or in conjunction with physical therapy.

A dynamic splint is a custom fit, spring-loaded device designed to provide low intensity stretch force. These devices provide a low-load, prolonged stretch to joints while an individual is asleep or at rest. Dynamic splinting devices are available for the elbow, wrist, finger, shoulder, knee, ankle and toes. Examples of available product names for dynamic splinting include: Dynasplint ™, Ultraflex ™, LMB Pro-glide™, Advanced Bio Mechanics™, and SaeboFlex.

The ERMI Shoulder Flexionater® is a device designed to isolate and treat decreased glenohumeral abduction and external rotation from excessive scar tissue. This is a customizable device with biomechanical and anatomically located pads, which focus treatment on the glenohumeral joint, without stressing the other shoulder joints. The shoulder flexionator can be used by the patient at home without assistance to perform serial stretching exercises. The knee/ankle flexionator (ERMI Knee/Ankle Flexionater®) is a self-contained device that aids recovery from decreased range of motion of the knee and/or ankle joints. The knee extensionator (ERMI Knee Extensionater®) and elbow extensionator (ERMI Shoulder Extensionater®) provide serial stretching, using a patient controlled pneumatic device that can deliver variable loads to the affected joint.

Joint Active Systems (JAS) Splints use static progressive stretch. The patient sets the device angle at the beginning of a session and every few minutes increases the angle. Sessions usually lasts thirty minutes and are repeated up to three times per day.

Continuous Passive Motion Devices

Physical therapy (PT) of joints following surgery focuses both on passive motion to restore mobility and on active exercises to restore strength. While passive motion can be administered by a therapist, continuous passive motion (CPM) devices have also been used. CPM is thought to improve recovery by stimulating the healing of articular tissues and the circulation of synovial fluid; reducing local edema; and preventing adhesions, joint stiffness or contractures, or cartilage degeneration. CPM has been investigated primarily in the knee, particularly after

total knee arthroplasty or ligamentous or cartilage repair. Acceptance of its use in the knee joint has created interest in CPM use for other weight-bearing joints (i.e., hip, ankle, metatarsals) as well as non-weight-bearing joints (i.e., shoulder, elbow, metacarpals, interphalangeal joints). Use of CPM in stroke and burn patients is also being explored.

The device used for the knee moves the joint (e.g., flexion and extension) without patient assistance, continuously for extended periods of time (i.e., up to 24 h/d). An electrical power unit is used to set the variable range of motion (ROM) and speed. The initial settings for ROM are based on a patient's level of comfort and other factors assessed intraoperatively. The ROM is increased by 3° to 5° per day, as tolerated. The speed and ROM can be varied, depending on joint stability. The use of the device may be initiated in the immediate postoperative period and then continued at home for a variable period of time.

Over time, hospital lengths of stay have progressively shortened and, in some cases, surgical repair may be done either as an outpatient or with a length of stay of 1 to 2 days. As a result, there has been a considerable shift in the rehabilitation regimen, moving from an intensive in-hospital program to a less intensive outpatient program. Some providers may want patients to continue CPM in the home setting as a means of duplicating services offered with a longer (7-day) hospital stay.

The focus of the current review is to examine the literature on the use of CPM in the home setting as it is currently being prescribed postoperatively. Relevant comparisons are treatment outcomes of CPM when used alone or with PT, compared with PT alone.

Regulatory Status
Continuous passive motion devices are considered 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 but only notification of FDA prior to marketing. FDA product code: BXB.

IV. Rationale

TOP

CPM

Summary of Evidence
For individuals who have total knee arthroplasty (TKA) who receive continuous passive motion (CPM) in the home setting, the evidence includes randomized clinical trials (RCTs), case series, and systematic reviews. Relevant outcomes are symptoms and functional outcomes. Early trials generally used CPM in the inpatient setting and are less relevant to today's practice patterns of short hospital stays followed by outpatient rehabilitation. Current postoperative rehabilitation protocols differ considerably from when the largest body of evidence was collected, making it

difficult to apply available evidence to the present situation. For use of CPM after TKA, recent studies have suggested that institutional and home use of CPM has no benefit compared to standard physical therapy (PT). There were no studies evaluating CPM in patients who could not perform standard PT. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have articular cartilage repair of the knee who receive CPM in the home setting, the evidence includes nonrandomized studies, case series, and studies with nonclinical outcomes (e.g., histology), and systematic reviews of these studies. Relevant outcomes are symptoms and functional outcomes. Systematic reviews of CPM for this indication have cited studies reporting better histologic outcomes in patients following CPM. A few studies have reported clinical outcomes, but inadequacies of these studies do not permit conclusions on efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have musculoskeletal conditions other than TKA or knee cartilage repair requiring PT who receive CPM in the home setting, the evidence includes RCTs for some conditions and case series for others. Relevant outcomes are symptoms and functional outcomes. Three small RCTs of CPM after rotator cuff surgery showed some evidence that CPM after this shoulder surgery improved short-term pain and range of motion (ROM); however, the trials were not high quality, and the small differences in outcomes may not be clinically important. Two trials reported short-term improvements in ROM for patients undergoing CPM, and 1 reported a short-term reduction in pain. None reported long-term improvements, and there are no reported benefits in functional status. Therefore, the clinical significance of the short-term improvements reported is uncertain. In addition, there is uncertainty about the optimal PT regimen following shoulder surgery such that the optimal treatment comparator for CPM is unclear. Two small RCTs compared CPM with conventional PT for treatment of adhesive capsulitis. One of the trials focused on diabetic patients with adhesive capsulitis. Both reported comparable improvements in ROM and functional ability between treatment groups. For other musculoskeletal conditions, RCTs do not exist; case series either did not show efficacy of CPM or had important methodologic flaws. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have had a stroke requiring PT who receive CPM in the home setting, the evidence includes 1 small RCT. Relevant outcomes are symptoms and functional outcomes. This trial reported a trend toward improved shoulder joint stability, but no statistical difference between CPM plus PT compared to PT alone. The trial was small and treatment lasted only 20 days. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY TITLE	MECHANICAL STRETCHING DEVICES FOR CONTRACTURE AND JOINT STIFFNESS
POLICY NUMBER	MP-6.039

V. DEFINITIONS

Top

AUTOLOGOUS CHONDROCYTE TRANSPLANTATION (ACT) is a surgical treatment aimed at repairing the damaged hyaline cartilage by transplanting regenerated hyaline-like cartilage to restore usable function.

OSTEOCHONDRAL refers to bone and cartilage.

PASSIVE MOTION is a therapeutic exercise technique used to move patients' joints through ROM without patient effort. This type of therapy is accomplished by a physical therapist or with the assistance of equipment, such as a CPM device.

IMMEDIATE POSTOPERATIVE PERIOD is a time period within one week of the surgical procedure. This period may be extended up to thirty days after the surgery, given individual circumstances.

VI. BENEFIT VARIATIONS

Top

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

Top

Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

POLICY TITLE	MECHANICAL STRETCHING DEVICES FOR CONTRACTURE AND JOINT STIFFNESS
POLICY NUMBER	MP-6.039

VIII. CODING INFORMATION

Top

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered, joint active system splints (static progressive stretch):

HCPCS Codes	Description
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

Not medically necessary; therefore, not covered, dynamic splinting devices:

HCPCS Codes	Description
E1802	Dynamic adjustable forearm pronation/supination device, includes soft interface material
E1815	Dynamic adjustable ankle extension/flexion device, includes soft interface material
E1830	Dynamic adjustable toe extension/flexion device, includes soft interface material
E1840	Dynamic adjustable shoulder flexion/abduction/rotation device, includes soft interface material

Covered when medically necessary, dynamic splinting devices

CPT Codes®								
29126	29131							

POLICY TITLE	MECHANICAL STRETCHING DEVICES FOR CONTRACTURE AND JOINT STIFFNESS
POLICY NUMBER	MP-6.039

HCPCS Codes	Description
E1800	Dynamic adjustable elbow extension/flexion device, includes soft interface material
E1805	Dynamic adjustable wrist extension/flexion device, includes soft interface material
E1810	Dynamic adjustable knee extension/flexion device, includes soft interface material
E1812	Dynamic knee, extension/flexion device with active resistance control
E1825	Dynamic adjustable finger extension/flexion device, includes soft interface material

ICD-10-CM Diagnosis Codes	Description
M24.521	Contracture, right elbow
M24.522	Contracture, left elbow
M24.531	Contracture, right wrist
M24.532	Contracture, left wrist
M24.561	Contracture, right knee
M24.562	Contracture, left knee
M25.621	Stiffness of right elbow, not elsewhere classified
M25.622	Stiffness of left elbow, not elsewhere classified
M25.631	Stiffness of right wrist, not elsewhere classified
M25.632	Stiffness of left wrist, not elsewhere classified
M25.661	Stiffness of right knee, not elsewhere classified
M25.662	Stiffness of left knee, not elsewhere classified

Not medically necessary; therefore, not covered, continuous passive motion device (CPM):

HCPCS Codes	Description
E0936	Continuous passive motion exercise device for use other than knee

Covered when medically necessary; continuous passive motion device (CPM):

HCPCS Code	Description
E0935	Continuous passive motion exercise device for use on knee only

POLICY TITLE	MECHANICAL STRETCHING DEVICES FOR CONTRACTURE AND JOINT STIFFNESS
POLICY NUMBER	MP-6.039

ICD-10-CM Diagnosis Codes	Description
G90.521	Complex regional pain syndrome I of right lower limb
G90.522	Complex regional pain syndrome I of left lower limb
G90.523	Complex regional pain syndrome I of lower limb, bilateral
G90.59	Complex regional pain syndrome I of other specified site
M23.211	Derangement of anterior horn of medial meniscus due to old tear or injury, right knee
M23.212	Derangement of anterior horn of medial meniscus due to old tear or injury, left knee
M23.221	Derangement of posterior horn of medial meniscus due to old tear or injury, right knee
M23.222	Derangement of posterior horn of medial meniscus due to old tear or injury, left knee
M23.231	Derangement of other medial meniscus due to old tear or injury, right knee
M23.232	Derangement of other medial meniscus due to old tear or injury, left knee
M23.241	Derangement of anterior horn of lateral meniscus due to old tear or injury, right knee
M23.242	Derangement of anterior horn of lateral meniscus due to old tear or injury, left knee
M23.251	Derangement of posterior horn of lateral meniscus due to old tear or injury, right knee
M23.252	Derangement of posterior horn of lateral meniscus due to old tear or injury, left knee
M23.261	Derangement of other lateral meniscus due to old tear or injury, right knee
M23.262	Derangement of other lateral meniscus due to old tear or injury, left knee
M23.311	Other meniscus derangements, anterior horn of medial meniscus, right knee
M23.312	Other meniscus derangements, anterior horn of medial meniscus, left knee
M23.321	Other meniscus derangements, posterior horn of medial meniscus, right knee
M23.322	Other meniscus derangements, posterior horn of medial meniscus, left knee
M23.331	Other meniscus derangements, other medial meniscus, right knee
M23.332	Other meniscus derangements, other medial meniscus, left knee
M23.341	Other meniscus derangements, anterior horn of lateral meniscus, right knee
M23.342	Other meniscus derangements, anterior horn of lateral meniscus, left knee
M23.351	Other meniscus derangements, posterior horn of lateral meniscus, right knee
M23.352	Other meniscus derangements, posterior horn of lateral meniscus, left knee
M23.361	Other meniscus derangements, other lateral meniscus, right knee
M23.362	Other meniscus derangements, other lateral meniscus, left knee
M23.8X1	Other internal derangements of right knee
M23.8X2	Other internal derangements of left knee
M24.661	Ankylosis, right knee
M24.662	Ankylosis, left knee

POLICY TITLE	MECHANICAL STRETCHING DEVICES FOR CONTRACTURE AND JOINT STIFFNESS
POLICY NUMBER	MP-6.039

ICD-10-CM Diagnosis Codes	Description
M93.261	Osteochondritis dissecans, right knee
M93.262	Osteochondritis dissecans, left knee
S83.211A	Bucket-handle tear of medial meniscus, current injury, right knee, initial encounter
S83.211D	Bucket-handle tear of medial meniscus, current injury, right knee, subsequent encounter
S83.212A	Bucket-handle tear of medial meniscus, current injury, left knee, initial encounter
S83.212D	Bucket-handle tear of medial meniscus, current injury, left knee, subsequent encounter
S83.221A	Peripheral tear of medial meniscus, current injury, right knee, initial encounter
S83.221D	Peripheral tear of medial meniscus, current injury, right knee, subsequent encounter
S83.222A	Peripheral tear of medial meniscus, current injury, left knee, initial encounter
S83.222D	Peripheral tear of medial meniscus, current injury, left knee, subsequent encounter
S83.231A	Complex tear of medial meniscus, current injury, right knee, initial encounter
S83.231D	Complex tear of medial meniscus, current injury, right knee, subsequent encounter
S83.232A	Complex tear of medial meniscus, current injury, left knee, initial encounter
S83.232D	Complex tear of medial meniscus, current injury, left knee, subsequent encounter
S83.241A	Other tear of medial meniscus, current injury, right knee, initial encounter
S83.241D	Other tear of medial meniscus, current injury, right knee, subsequent encounter
S83.242A	Other tear of medial meniscus, current injury, left knee, initial encounter
S83.242D	Other tear of medial meniscus, current injury, left knee, subsequent encounter
S83.251A	Bucket-handle tear of lateral meniscus, current injury, right knee, initial encounter
S83.251D	Bucket-handle tear of lateral meniscus, current injury, right knee, subsequent encounter
S83.252A	Bucket-handle tear of lateral meniscus, current injury, left knee, initial encounter
S83.252D	Bucket-handle tear of lateral meniscus, current injury, left knee, subsequent encounter
S83.261A	Peripheral tear of lateral meniscus, current injury, right knee, initial encounter
S83.261D	Peripheral tear of lateral meniscus, current injury, right knee, subsequent encounter
S83.262A	Peripheral tear of lateral meniscus, current injury, left knee, initial encounter
S83.262D	Peripheral tear of lateral meniscus, current injury, left knee, subsequent encounter
S83.271A	Complex tear of lateral meniscus, current injury, right knee, initial encounter
S83.271D	Complex tear of lateral meniscus, current injury, right knee, subsequent encounter
S83.272A	Complex tear of lateral meniscus, current injury, left knee, initial encounter
S83.272D	Complex tear of lateral meniscus, current injury, left knee, subsequent encounter
S83.281A	Other tear of lateral meniscus, current injury, right knee, initial encounter
S83.281D	Other tear of lateral meniscus, current injury, right knee, subsequent encounter
S83.282A	Other tear of lateral meniscus, current injury, left knee, initial encounter

POLICY TITLE	MECHANICAL STRETCHING DEVICES FOR CONTRACTURE AND JOINT STIFFNESS
POLICY NUMBER	MP-6.039

ICD-10-CM Diagnosis Codes	Description
S83.282D	Other tear of lateral meniscus, current injury, left knee, subsequent encounter
S83.32XA	Tear of articular cartilage of left knee, current, initial encounter
Z47.1	Aftercare following joint replacement surgery
Z47.33	Aftercare following explantation of knee joint prosthesis
Z96.651	Presence of right artificial knee joint
Z96.652	Presence of left artificial knee joint
Z96.653	Presence of artificial knee joint, bilateral

IX. REFERENCES

Top

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POLICY TITLE	MECHANICAL STRETCHING DEVICES FOR CONTRACTURE AND JOINT STIFFNESS
POLICY NUMBER	MP-6.039

Continuous Passive Motion Devices

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X. POLICY HISTORY

Top

MP 6.039	**CAC 2/22/05**
	CAC 3/28/06
	CAC 3/27/07
	CAC 5/27/08
	CAC 5/26/09

POLICY TITLE	MECHANICAL STRETCHING DEVICES FOR CONTRACTURE AND JOINT STIFFNESS
POLICY NUMBER	MP-6.039

CAC 5/25/10 Consensus
CAC 9/28/10 Adopted BCBSA criteria language regarding CPM use for conditions of low postoperative mobility or inability to comply with rehabilitation exercises. Revised CPM statement for other joints from "investigational" to "not medically necessary". Adopted BCBSA "not medically necessary" statement for the use of a CPM device for all other conditions not specified in medically necessary criteria.
CAC 10/25/11 Consensus Review. Reference to FEP medical policy added.
10/23/12- Codes reviewed
CAC 3/26/13 Consensus Review--. References updated. Added BCBSA Background/Description for Continuous Passive Motion Devices.
05/13/13 Admin code review.
CAC 1/28/14 Consensus review. References updated. No changes to the policy statements. Codes reviewed.
CAC 1/27/15 Consensus review. References updated. Added rationale. No change to policy statements. 12/30/2014 Coding reviewed. Updated the ICD 9 ranges
CAC 1/26/16 Consensus review. No changes to the policy statements. References and rationale updated**.** Coding reviewed and updated.
Administrative Update 11/10/16 - Variation reformatting
CAC 3/28/17 Consensus review. No changes to the policy statements. References and rationale updated. Coding reviewed.
12/29/17 Consensus review. The word "intra-" removed from the second bullet point of the first policy statement and from the text. Intent of policy statements unchanged. References, background and rationale updated.
11/27/18 Consensus review. No change to policy statements. References and background updated. Rationale condensed.
9/30/2019 Consensus review. No change to policy statements. References updated.

Top

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