BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

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MECHANICAL STRETCHING DEVICES FOR TREATMENT OF JOINT STIFFNESS AND CONTRACTURES

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Dynamic Splinting Devices:
Dynamic splinting devices are spring-loaded, adjustable devices designed to provide low-load prolonged stretch (LLPS) while an individual is asleep or at rest. Units for both flexion and extension are available for elbow, wrist, finger, shoulder, knee, ankle and toe. These devices are used as an adjunct to physical therapy. The unit can restore motion in a joint that is stiff or to prevent stiffness. Device names include, *but are not limited to*: Dynasplint®, Advance® Dynamic ROM, SaeboFlex, SaeboMas, SaeboReach, Pro-Glide® and Ultraflex®.

MECHANICAL STRETCHING DEVICES FOR TREATMENT OF JOINT STIFFNESS AND CONTRACTURES (cont.)

Description: (cont.)

Flexionators and Extensionators:
The shoulder flexionator (ERMI Shoulder Flexionater®) is designed to isolate and treat decreased glenohumeral abduction and external rotation in individuals with excessive scar tissue.

The knee/ankle flexionator (ERMI Knee/Ankle Flexionater®) is a self-contained device that facilitates recovery from decreased range of motion (ROM) of the knee and/or ankle joints in individuals with arthrofibrosis (excessive scar tissue and around the joint).

The knee extensionator (ERMI Knee Extensionater®) and elbow extensionator (ERMI Shoulder Extensionater®) provide serial stretching, by the individual controlling a pneumatic device that can deliver variable loads to the affected joint.

The Elite Seat® is a portable knee hyper-extension rehabilitation device that is used to correct the loss of knee extension, increase ROM, decrease knee pain and improve function.

Joint Active Systems (JAS) Splints:
JAS systems (e.g., JAS Elbow, JAS Shoulder, JAS Ankle, JAS Knee, JAS Wrist, and JAS Pronation-Supination) use static progressive stretch (SPS). SPS is a technique using the biomechanical principle of stress relaxation to restore ROM.

MECHANICAL STRETCHING DEVICES FOR TREATMENT OF JOINT STIFFNESS AND CONTRACTURES (cont.)

Criteria:

Dynamic Splinting Devices:

- Dynamic splinting devices for the knee, elbow, wrist, finger, or toe are considered ***medically necessary*** with documentation of **ONE** of the following:

  1. As an adjunct to physical therapy in individuals with documented signs and symptoms of significant motion stiffness/loss in the sub-acute injury or post-operative period (i.e., at least 3 weeks after injury or surgery)
  2. Individual with a prior documented history of motion stiffness/loss in a joint and surgery or procedure performed to improve motion to that joint and are in the acute post-operative period following a second or subsequent surgery or procedure

- Prophylactic use of dynamic splinting devices for the treatment of chronic* (see note below) contractures (no significant change in motion for a 4-month period) and joint stiffness as a result of the following conditions is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

  These conditions include, *but are not limited to:*

  - Burns
  - Cerebral palsy
  - Fractures
  - Head and spinal cord injuries
  - Joint trauma
  - Multiple sclerosis
  - Muscular dystrophy
  - Rheumatoid arthritis

* If surgery is being performed for a “chronic” condition, the use of a dynamic splinting device may be considered medically necessary if the individual meets the medically necessary criteria stated above.

MECHANICAL STRETCHING DEVICES FOR TREATMENT OF JOINT STIFFNESS AND CONTRACTURES (cont.)

Criteria: (cont.)

Dynamic Splinting Devices: (cont.)

- Dynamic splinting devices for all other indications not previously listed or if above criteria not met are considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

  These indications include, *but are not limited to:*

  - Carpel tunnel syndrome
  - Cerebral palsy
  - Foot drop associated with neuromuscular diseases
  - Head and spinal cord injuries
  - Injuries of the ankle and shoulder
  - Multiple sclerosis
  - Muscular dystrophy
  - Plantar fasciitis
  - Rheumatoid arthritis
  - Stroke
  - Trismus

- The SaeboMas dynamic mobile arm support system is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

MECHANICAL STRETCHING DEVICES FOR TREATMENT OF JOINT STIFFNESS AND CONTRACTURES (cont.)

Criteria: (cont.)

Flexionators and Extensionators:

- Knee/ankle flexionator, shoulder flextionator, knee extensionator, knee extension devices (e.g., Elite Seat) and the elbow extensionator for the treatment of contractures or joint stiffness is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

Joint Active Systems (JAS) Splints:

- JAS splints (e.g., JAS Elbow, JAS Shoulder, JAS Ankle, JAS Knee, JAS Wrist, and JAS Pronation-Supination) for the treatment of contractures or joint stiffness is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

MECHANICAL STRETCHING DEVICES FOR TREATMENT OF JOINT STIFFNESS AND CONTRACTURES (cont.)

Resources:

1. Bonutti PM, Marulanda GA, McGrath MS, Mont MA, Zywiel MG. Static progressive stretch improves range of motion in arthrofibrosis following total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc.* Feb 2010;18(2):194-199.

2. Branch TP, Karsch RE, Mills TJ, Palmer MT. Mechanical therapy for loss of knee flexion. *Am J Orthop (Belle Mead NJ).* Apr 2003;32(4):195-200.

3. Clinical Trials.Gov. Rehabilitation With or Without Static Progressive Splinting for Wrist Stiffness. Accessed 2/6/14.

4. Glasgow C, Tooth LR, Fleming J, Peters S. Dynamic splinting for the stiff hand after trauma: predictors of contracture resolution. *J Hand Ther.* Jul-Sep 2011;24(3):195-205; quiz 206.

5. Larson D, Jerosch-Herold C. Clinical effectiveness of post-operative splinting after surgical release of Dupuytren's contracture: a systematic review. *BMC Musculoskelet Disord.* 2008;9:104.

6. Lindenhovius AL, Doornberg JN, Brouwer KM, Jupiter JB, Mudgal CS, Ring D. A prospective randomized controlled trial of dynamic versus static progressive elbow splinting for posttraumatic elbow stiffness. *J Bone Joint Surg Am.* Apr 18 2012;94(8):694-700.