



MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 02/06/14
LAST REVIEW DATE: 03/05/19
LAST CRITERIA REVISION DATE: 02/24/15
ARCHIVE DATE:

MECHANICAL STRETCHING DEVICES FOR TREATMENT OF JOINT STIFFNESS AND CONTRACTURES

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

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.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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.

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

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:* Advance® Dynamic ROM, DeROM, Dynasplint®, EMPI advance, LMB Pro-glide, Pro-Glide®, Pro-glide Dynamic ROM, SaeboFlex, SaeboMas, SaeboReach, and Ultraflex®.

Serial Stretch Devices:

Individual-controlled serial stretch devices in the home include the ERMI line of flexionators and extensionators.

Flexionators and Extensionators:

The shoulder flexionator (ERMI Shoulder Flexionator®) 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 Flexionator®) 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 Extensionator®) and elbow extensionator (ERMI Elbow Extensionator®) II provide serial stretching, by the individual controlling a pneumatic device that can deliver variable loads to the affected joint.

The metatarsophalangeal joint (MPJ) extensionator (ERMI MPJ Extensionator®) can be configured to promote both extension and flexion by mimicking the position of the foot and toe while walking to restore lost motion.

Static Progressive Stretch (SPS) Devices:

SPS devices provide a low- to moderate-intensity force to hold a joint at its end range and gradually increase the stretch. SPS devices are designed to be used for 15 to 30 minutes, in up to 8 sessions per day.

SPS devices are available for the knee, shoulder, ankle, wrist and for pronation and supination. Individuals are typically instructed to use the SPS device for 30 minutes, 3 times per day. During each session, individuals 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 SPS include JAS® (Joint Active Systems), Static-Pro® (DeRoyal), Stat-A-Dyne® (Ortho-innovations), AliMed® Turnbuckle Orthosis (AliMed) and Mayo Aircast® (DJO).



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Description: (cont.)

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.

Joint Active Systems (JAS) EZ Splints:

JAS EZ systems (e.g. JAS EZ Ankle, JAS EZ Elbow, JAS EZ Finger, JAS EZ Knee-Ext, JAS EZ Knee-Flex, JAS EZ Pro/Sup, JAS EZ Shoulder, JAS EZ Toe, JAS EZ Wrist) use full-range, bi-directional ROM therapy in a single-patient device.

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.

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 chronic¹ 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



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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
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Criteria: (cont.)

Flexionators and Extensionators:

- Knee/ankle flexionator, shoulder flexionator, 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) and JAS EZ Splints:

- JAS splints and JAS EZ splints 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.

- ¹ 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.



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Resources:

Literature reviewed 04/03/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 1.03.05 Blue Cross Blue Shield Association Medical Policy Reference Manual. Patient-Controlled End Range of Motion Stretching Devices. Re-issue date 03/08/2018, issue date 01/15/2015.
2. Bonutti PM, Marulanda GA, McGrath MS, Mont MA, Zywiell 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.
3. 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.
4. Clinical Trials.Gov. Rehabilitation With or Without Static Progressive Splinting for Wrist Stiffness. Accessed 2/6/14.
5. 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.
6. 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.
7. 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.
8. UpToDate.com. Proximal Phalanx Fractures. 03/15/2018, 02/02/2016.



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

