Policy Title:	Policy – Mechanical Stretching (Dynamic Splinting) Devices for Treatment of Joint Stiffness and Contractures	Number & Version:	UM04 v.6
Functional Unit:	Utilization Management	Effective Date:	04/17/2024
Policy Owner (Title):	Senior Director, Utilization Management	Page Number:	1 of 5

I. POLICY STATEMENT and PURPOSE

In its administration of Medicare Advantage plans (Health Plans), the Company shall determine benefits in accordance with the requirements of the Centers for Medicare & Medicaid Services (CMS). Where CMS has established a national coverage policy on an item or service or a local Medicare contractor has done so as authorized by CMS, the Company follows the Medicare coverage policy. In the absence of fully established Medicare coverage criteria, the Company may develop and implement internal criteria based on current evidence in widely used treatment guidelines or clinical literature. Internal criteria are reviewed and approved by the Medical Management Committee and are made publicly accessible.

CMS has not established coverage criteria for Mechanical Stretching Devices (also known as **dynamic splinting systems**) for Treatment of Joint Stiffness and Contractures, therefore the Company has developed and implemented this coverage policy to ensure that patients receive clinically appropriate, medically necessary care at the appropriate level, which allows for the best clinical outcome and prevents harm such as inpatient acquired illness. The purpose of this policy is to describe the circumstances under which Mechanical Stretching Devices (also known as **dynamic splinting systems**) for Treatment of Joint Stiffness and Contractures would be considered medically necessary for members under the guidelines used for clinical review of organizational determinations.

II. BACKGROUND

Joint contractures refer to a decreased range of motion (ROM) that impairs function. Joint immobilization can cause contractures to develop (Wong, 2015). Different afflictions, including neurological conditions, joint trauma, or healing can contribute to contractures. They can also occur as a result of structural changes in muscle, tendons, ligaments, and/or skin that limit elasticity. Patients with joint contracture may appear with decreased ROM sufficient to impair daily activities such as dressing or walking. The clinical evaluation demonstrates limited joint mobility and a reduced joint ROM with or without limited passive motion (Harvey, 2017).

Restoring the ROM of the joint is the goal of treatment. Modalities to treat and prevent joint contractures can range from the invasive to the conservative (Farmer, 2001) (Pujol, 2015). Modalities provided by physical therapy may include the following: manual joint mobilization by a physical therapist, serial plastering or casting, dynamic bracing, static splinting, mechanical stretching devices, continuous device-assisted passive motion, massage, exercise, and electrical stimulation. Due to risks of complications with major operations, surgery is evolving to more minimally invasive procedures (AAPMR, 2020).

Mechanical stretching devices were devised to restore range of motion (ROM) by stretching joints. These devices provide adjustable degree passive stretching for a select time period over

multiple sessions. These devices provide stretching for longer periods than a physical therapist can, and the devices are generally used in addition to conventional physical therapy (PT). There are 3 main types of mechanical stretching devices described in the "DEFINITIONS" section below (Hayes, 2022).

III. SCOPE

This Policy applies to Mechanical Splinting Devices for Treatment of Joint Stiffness and Contractures.

IV. DEFINITIONS

Low-load prolonged-duration stretch (LLPS) devices - LLPS devices permit resisted active and passive motion (elastic traction) within a restricted range. LLPS devices use springs to maintain a set level of tension (Hayes, 2022). Dynamic splinting systems include, but are not limited to, such products as Advance Dynamic ROM, Dynasplint, EMPI Advance Dynamic ROM, LMB Pro-glide, Pro-glide Dynamic ROM, SaeboFlex, SaeboReach, Stat-A-Dyne, and Ultraflex.

Patient-actuated serial stretch (PASS) devices - PASS devices permit resisted active and passive motion (elastic traction) within a restricted range. Low- to high-level load to the joint is provided using pneumatic or hydraulic systems that can be adjusted by the patient (Hayes, 2022). Terms used to describe these systems include Extensionaters (ERMI Inc.) or hydraulic (lexionaters (ERMI Inc.).

Static progressive stretch (SPS) devices - SPS devices are designed to hold the joint in a fixed position but allow for manual modification of the joint angle. They may allow for active motion without resistance (inelastic traction). There is no stress on the tissue unless the joint angle is set at the maximum ROM (Hayes, 2022). Examples of static progressive stretch and stress relaxation devices include Joint Active Systems (JAS splints) and Air Cast.

Medically Necessary – Covered Services rendered by a Health Care Provider that the Plan determines are:

1) Safe and effective
2) Not experimental or investigational
3) Appropriate for patients,
    a) including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is—
        i) furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member,

ii) furnished in a setting appropriate to the patient's medical needs and condition,
iii) ordered and furnished by qualified personnel,
iv) one that meets, but does not exceed, the patient's medical need; and
v) is at least as beneficial as existing and available medically appropriate alternatives.

V. OWNERSHIP & TRAINING

The Sr. Director of Utilization Management is responsible for administration, oversight, and training regarding performance under this Policy.

VI. PROTOCOLS / COVERAGE POLICY

A. Low-load prolonged-duration stretch (**LLPS**) for the knee, elbow, wrist, finger, or toe **are considered medically necessary** durable medical equipment (DME) if one of the following selection criteria is met:
   a) As an adjunct to physical therapy in members with documented signs and symptoms of significant motion stiffness/loss in the sub-acute injury or post-operative period (at least three (3) weeks but less than four (4) months after injury or surgery); or
   b) In the acute post-operative period for members who have a prior documented history of motion stiffness/loss in a joint and are having additional surgery or procedures done to improve motion to that joint; or
   c) The member is unable to perform and/or benefit from standard physical therapy modalities because of an inability to exercise or participate in the treatment program. In this instance, use of a dynamic device for as long as four (4) months with documented improvement, and then for as long as improvement can continue to be documented would be considered medically necessary.
   d) Only one device is covered per affected area, i.e., **separate devices for flexion and extension for the same area** is a **non-covered** benefit.

B. Low-load prolonged-duration stretch (**LLPS**) for any indications other than the above are NOT considered medically necessary. Patient-actuated serial stretch (**PASS**) devices and static progressive stretch (**SPS**) devices are also **NOT** considered medically necessary as the evidence for their use is considered low quality or inadequate at this time (Hayes, 2022).

NOTE: The LLPS device has been commonly used in the orthopedic and physical therapy communities for select patient population. Although there is inadequate data published in the peer reviewed medical literature regarding the effectiveness of dynamic splinting devices in improving range of motion, because of national community standards these devices may be approved as indicated in "A" above.

VII. SUMMARY of EVIDENCE

Published evidence defining joint contractures and stiffness with decreased range of motion (ROM) and evaluation of Mechanical splinting devices for treatment of said conditions indicates improved clinical outcomes in patients when mechanical splinting devices are used in combination with other treatment regimens.

VIII. REGULATORY REFERENCES / CITATIONS

CMS National Coverage Determinations (NCDs)	None
CMS Local Coverage Determinations (LCDs)	None
CMS Articles	None

IX. PROFESSIONAL REFERENCES / CITATIONS

1. American Academy of Physical Medicine and Rehabilitation (AAPMR). PM&R Knowledge Now. Medical Rehabilitation. Contractures. July 20, 2023. Accessed at: https://now.aapmr.org/contractures/ on April 17, 2024.

2. Farmer, S. E., & James, M. (2001). Contractures in orthopaedic and neurological conditions: a review of causes and treatment. *Disability and rehabilitation*, *23*(13), 549–558. https://doi.org/10.1080/09638280010029930. Accessed at: https://pubmed.ncbi.nlm.nih.gov/11451189/ on April 17, 2024.

3. Harvey, L. A., Katalinic, O. M., Herbert, R. D., Moseley, A. M., Lannin, N. A., & Schurr, K. (2017). Stretch for the treatment and prevention of contracture: an abridged republication of a Cochrane Systematic Review. *Journal of physiotherapy*, *63*(2), 67–75. https://doi.org/10.1016/j.jphys.2017.02.014. Accessed at: https://pubmed.ncbi.nlm.nih.gov/28433236/ on April 17, 2024.

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5. Pujol, N., Boisrenoult, P., & Beaufils, P. (2015). Post-traumatic knee stiffness: surgical techniques. *Orthopaedics & traumatology, surgery & research : OTSR*, *101*(1 Suppl), S179–S186. https://doi.org/10.1016/j.otsr.2014.06.026. Accessed at: https://pubmed.ncbi.nlm.nih.gov/25583236/ on April 17, 2024.

6. Wong, K., Trudel, G., & Laneuville, O. (2015). Noninflammatory Joint Contractures Arising from Immobility: Animal Models to Future Treatments. *BioMed research*

international, *2015*, 848290. https://doi.org/10.1155/2015/848290. Accessed at: https://pubmed.ncbi.nlm.nih.gov/26247029/ on April 17, 2024.

X. RELATED POLICIES / PROCEDURES

None

XI. ATTACHMENTS

None

APPROVALS:

	Printed Name	Signature
Senior Medical Officer, UM:	Michael Fusco, MD	
Corporate Chief Medical Officer (MMC Chair):	Debbie Zimmerman, MD	

VERSION HISTORY:

Version #	Date	Author	Purpose/Summary of Major Changes
01	09/11/2019	Bob Brault	Original
02	03/29/2021	Julie Braundmeier	General review; no substantive changes
03	06/08/2022	Gina Vehige	General review; no substantive changes
04	08/17/2022	Gina Vehige	General review; no substantive changes
05	1/3/2024	Gina Vehige	General review; updated reference; no substantive changes
06	04/17/2024	Sheila Gray / Kerrie Stehl	Addition to policy statement, reference checks; summary of evidence. Approved by MMC on 04/10/2024.