JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Medical Policy Manual** **Medical Policy**	*Policy Number*	CMS19.07
		Effective Date	11/01/2023
		Approval Date	08/15/2023
	Subject **Dynamic Splinting for the Treatment of Joint Stiffness and Contracture**	*Supersesedes Date*	11/01/2022
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This document applies to the following Participating Organizations:

EHP	Johns Hopkins Advantage MD	Johns Hopkins Health Plan of Virginia Inc. (JHHPVA)	Priority Partners
US Family Health Plan			

Keywords: Contracture, Dynamic Splinting, Joint Stiffness

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I. ACTION

	New Policy	
X	Revising Policy Number	CMS19.07
	Superseding Policy Number	
	Archiving Policy Number	
	Retiring Policy Number	

II. POLICY DISCLAIMER

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

III. POLICY

For Advantage MD, refer to: Medicare Coverage Database

- Local Coverage Determination (LCD) L33686 Ankle-Foot/Knee-Ankle-Foot Orthosis
- National Coverage Determination (NCD) 280.1 Durable Medical Equipment Reference List

For Employer Health Programs (EHP) refer to:

- Plan specific Summary Plan Descriptions (SPDs)

For Johns Hopkins Health Plan of Virginia Inc. (JHHPVA) refer to: Medicare Coverage Database (*Effective 1/1/2024*)

- Local Coverage Determination (LCD) L33686 Ankle-Foot/Knee-Ankle-Foot Orthosis
- National Coverage Determination (NCD) 280.1 Durable Medical Equipment Reference List

For Priority Partners (PPMCO) refer to: Code of Maryland Regulations

- Code of Maryland Regulations (COMAR) 10.67.06.13 Benefits - Disposable Medical Supplies and Durable Medical Equipment

For US Family Health Plan (USFHP) refer to: Tricare Policy Manuals

- TRICARE Policy Manual 6010.63-M, April 1, 2021 Chapter 8, Section 2.1 Durable Equipment (DE): Basic Program

IV. POLICY CRITERIA

A. When benefits are provided under the member's contract, JHHP considers low-load prolonged-duration stretch (LLPS)/ dynamic splinting devices for use on the knee, elbow, wrist or finger medically necessary durable medical equipment when *one* of the three(3) following conditions *and* documentation requirements are met:
   1. As an adjunct to physical therapy in the sub-acute injury or post-operative period (> 3 weeks but < 4 months after injury or operation) in patients with signs and symptoms of persistent joint stiffness, OR;
   2. In the acute post-operative period for patients who are undergoing additional surgery to improve the range of motion of a previously affected joint, OR;
   3. As an adjunct to botulinum toxin injections for treatment of spasticity (on a case-by-case basis), AND;
   4. Documentation requirements:
      a. Current prescription from the physician
      b. A clinical note indicating all of the following:
         i. The affected joint
         ii. The date of injury/surgery/established diagnosis
         iii. Previous treatment attempted
         iv. Treatment plan, including proposed duration of use.

B. Unless specific benefits are provided under the member's contract, JHHP considers the use of LLPS/dynamic splinting devices for the following indications experimental and investigational, as they do not meet the Technology Evaluation Criteria (TEC) as defined in CMS01.00 Medical Policy Introduction:
   1. The management of chronic joint stiffness and/or chronic or fixed contractures.
   2. For use on shoulders or any other condition not listed above.
   3. For prophylactic use
   4. For continued use if there is no significant improvement in range of motion after 4 (four) months of use
   5. Carpal tunnel syndrome
   6. Cerebral palsy (except as noted in A.3. above)
   7. Foot drop secondary to neuromuscular disease
   8. Head and spinal cord injuries

9. Injuries to the ankle or shoulder
10. Multiple sclerosis (except as noted in A.3. above)
11. Muscular dystrophy
12. Plantar fasciitis
13. Rheumatoid arthritis
14. Stroke (except as noted in A.3. above)
15. Trismus
16. Hallux Valgus

C. Requests for continued dynamic splinting beyond 4 months for any conditions listed in A above may receive individual consideration when accompanied by medical records, a plan of care and supporting peer-reviewed medical literature.

D. Unless specific benefits are provided under the member's contract, JHHP considers use of patient-actuated serial stretch (PASS) devices (e.g., ERMI Knee/Ankle flexionator or ERMI Shoulder flexionator; ERMI Elbow extensionator or ERMI Knee extensionator) and static progressive stretch (SPS) devices (e.g., JAS SPS Systems; Stat-A-Dyne™ static splints; Static-Pro® devices) for treatment of joint stiffness experimental and investigational, as they do not meet Technology Evaluation Criteria (TEC).

V. DEFINITIONS

Dynamic Splinting: Dynamic splinting is also referred to as low-load prolonged-duration stretch (LLPS) devices. These devices are intended to restore a range of motion by stretching joints. LLPS devices permit resisted active and passive motion (elastic traction) within a limited range. LLPS devices maintain a set level of tension by means of incorporated springs (Hayes, 2020).

VI. BACKGROUND

Joint stiffness or contractures may be caused by immobilization following surgery, disease, or trauma. Mechanical stretching devices are intended to restore ROM by stretching joints. Devices provide passive stretching to an adjustable degree for a selected duration for multiple sessions. The devices, which are commonly used in addition to conventional physical therapy, can provide stretching for longer periods than therapists, who may only be able to apply manual stretching for a few minutes at a time (Harvey et al., 2017).

There are 3 main types of mechanical stretching devices:

- Low-load prolonged-duration stretch (LLPS) devices (also referred to as dynamic splinting): LLPS devices permit resisted active and passive motion (elastic traction) within a limited range. LLPS devices maintain a set level of tension by means of incorporated springs. Examples of LLPS devices include the Dynasplint® Systems (Dynasplint Systems Inc.); Stat-A-Dyne™ dynamic splints (Lantz Medical Inc.); Ultraflex (Ultraflex Systems Inc.); Pro-Glide and DeROM devices (DeRoyal Industries Inc.); JAS Advance Dynamic Splints (Joint Active Systems Inc.).
- Static progressive stretch (SPS) devices: SPS devices hold the joint in a set position but allow for manual modification of the joint angle and may allow for active motion without resistance (inelastic traction). This type of device itself does not exert stress on the tissue unless the joint angle is set at the maximum ROM. Examples of this type of device are: Stat-A-Dyne™ static splints (Lantz Medical Inc.); Static-Pro® devices (DeRoyal Industries Inc.) JAS SPS Systems (Joint Active Systems Inc.).
- Patient-actuated serial stretch (PASS) devices: PASS devices permit resisted active and passive motion (elastic traction) within a limited range. PASS devices provide a low- to high-level load to the joint using pneumatic (extensionators) or hydraulic (flexionators) systems that can be adjusted by the patient. Examples of PASS devices include the ERMI Knee/ Elbow Extensionaters, ERMI Knee/Ankle Flexionater, and ERMI Shoulder Flexionater (ERMI Inc.) (Hayes, 2020).

Mechanical stretching devices are commonly used in the post-operative period, following an injury or when addressing joint stiffness in the knee, ankle, toe, shoulder, elbow, wrist, or finger. Peer reviewed studies investigating mechanical stretching devices are limited. The best evidence is available in studies evaluating LLPS when used for the knee, elbow, wrist, and following extensor tendon injuries of the finger. Despite limited evidence, experts recommend static or dynamic elbow and wrist-hand orthoses in children with spasticity to improve function and to prevent hand and finger flexion deformities (Hayes, 2020; Harvey et al., 2017; NICE, 2016; Morris et al., 2011).

Although limited, high-level evidence still exists to address the efficacy of LLPS interventions. A variety of randomized control trials, observational studies, case series, and medical community acceptance confirms the benefits of dynamic LLPS devices for the knee, elbow, wrist, and fingers when used to relieve persistent joint stiffness that can occur after injury or surgery. While additional evidence is emerging, there is insufficient evidence in the published peer reviewed literature to support the use of dynamic LLPS for other joints, including the foot, ankle, and shoulder. There is insufficient evidence in the published medical literature to demonstrate the safety, efficacy, and long-term outcomes of the use of PASS or SPS devices for treatment of joint stiffness (Aspinall et al, 2021; Ferrari et al., 2021; Hayes, 2020; Pace et al,, 2018; Patel et al, 2020; Plaass et al, 2020; Roll & Hardison, 2017).

Several systematic reviews found that casting and dynamic splinting improved spasticity when used concurrently with botulinum toxin A injections. Casting was more effective than taping or electrical stimulation and stretching. Published guidelines recommend that orthoses not be routinely used in patients with neurological disorders for the treatment of spasticity except when combined with botulinum toxin injections (Mills et al., 2016; Demetrios et al., 2013; COT, 2015); Rudd et al, 2017).

VII. CODING DISCLAIMER

Note: The following CPT/HCPCS codes are included below for informational purposes and may not be all inclusive. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member's specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply.

Note: All inpatient admissions require pre-authorization.

Adherence to the provisions in this policy may be monitored and addressed through post-payment data analysis and/or medical review audits
Advantage MD: Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Employer Health Programs (EHP): Specific Summary Plan Descriptions (SPDs) supersedes JHHP Medical Policy. If there are no criteria in the SPD, apply the Medical Policy criteria.

Johns Hopkins Health Plan of Virginia Inc. (JHHPVA): Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Priority Partners (PPMCO): Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria.
US Family Health Plan (USFHP): Regulatory guidance supersedes JHHP Medical Policy. If there are no TRICARE policies, or other regulatory guidelines, apply the Medical Policy criteria.

VIII. CODING INFORMATION

HCPCS CODES ARE FOR INFORMATIONAL PURPOSES ONLY	
HCPCS CODES	**DESCRIPTION**
E1800	Dynamic adjustable elbow extension/flexion device, includes soft interface material
E1801	Static progressive stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1802	Dynamic adjustable forearm pronation/supination device, includes soft interface material
E1805	Dynamic adjustable wrist extension/flexion device, includes soft interface material
E1806	Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
E1810	Dynamic adjustable knee extension/flexion device, includes soft interface material
E1811	Static progressive stretch knee device, extension, and/or flexion, with or without range of motion adjustment, includes all components and accessories
E1812	Dynamic knee, extension/flexion device with active resistance control
E1815	Dynamic adjustable ankle extension/flexion device, includes soft interface material
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 of forearm pronation/supination device, with or without range of motion adjustment, includes all components and accessories
E1820	Replacement soft interface material, dynamic adjustable extension/flexion device
E1821	Replacement soft interface material/cuffs for bi-directional static progressive stretch device
E1825	Dynamic adjustable finger extension/flexion device, includes soft interface material
E1830	Dynamic adjustable toe extension/flexion device, includes soft interface material
E1831	Static progressive stretch toe device extension and/or flexion, with or without range of motion adjustment, includes all components or accessories
E1840	Dynamic adjustable shoulder flexion/abduction/rotation device, includes soft interface material

E1841	Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories

IX. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins Health PlansLLC (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

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XI. APPROVALS

Historical Effective Dates: 10/21/2006, 06/25/2008, 06/04/2009, 04/02/2010, 01/07/2011, 12/06/2013, 09/04/2015, 09/01/2017, 10/01/2019, 05/01/2020, 11/01/2021, 08/16/2022, 11/01/2022, 11/01/2023