Anthem

Clinical UM Guideline

Subject: Dynamic Low-Load Prolonged-Duration Stretch Devices
Guideline #: CG-DME-39
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Description

This document addresses dynamic low-load prolonged-duration stretch (LLPS) devices for the treatment of joint stiffness and contracture.

Dynamic LLPS (dynamic splinting) devices are designed to provide a low load, prolonged stretch to joints that have reduced range of motion secondary to immobilization, surgery, contracture, fracture, dislocation, or a number of additional non-traumatic disorders. The objective of stretch therapy is to improve range of motion without compromising the stability and quality of the connective tissue and joint.

For additional information, please see the following documents:

- CG-DME-05 Cervical Traction Devices for Home Use
- DME.00038 Static Progressive Stretch (SPS) and Patient-Actuated Serial Stretch (PASS) Devices
- SURG.00008 Mechanized Spinal Distraction Therapy

Clinical Indications

Medically Necessary:

Dynamic LLPS devices are considered **medically necessary** when criteria A., B and C below have been met:

A. For use in the following anatomical locations:
    1. Elbow; **or**
    2. Finger; **or**
    3. Knee; **or**
    4. Wrist;
    and
B. Clinical settings:
    1. During the subacute injury or post-operative period (greater than or equal to 3 weeks but less than or equal to 4 months after injury or operation); **and**
        a. As an addition to physical or occupational therapy in in individuals with signs and symptoms of persistent joint stiffness or contracture; **or**
        b. The individual's limited range of motion poses a meaningful (as judged by the physician) functional limitation, AND who has not responded to other therapy (including physical or occupational therapy); **or**
    2. During the acute post-operative period for individuals who have undergone additional surgery to improve the range of motion of a previously affected joint; **or**
    3. For individuals unable to benefit from standard physical or occupational therapy modalities because of an inability to exercise;
    and
C. Duration:
    1. For an initial period of up to 4 months;**or**
    2. After 4 months: for as long as improvement can continue to be demonstrated.

Dynamic LLPS devices for the postoperative management of tendon repair, referred to as "protected motion", to limit motion and protect the underlying surgical repair are considered **medically necessary.**

Replacement interface material used with the dynamic LLPS device is considered **medically necessary** when both the following criteria have been met:

A. The interface material is no longer functioning properly; **and**
B. The replacement material is requested for use during the time that the device is considered medically necessary.

Not Medically Necessary:

If there is no significant improvement after 4 months of use, dynamic LLPS devices are considered **not medically necessary** under any circumstance, including but not limited to for individuals unable to benefit from standard physical or occupational therapy modalities because of an inability to exercise.

Dynamic LLPS devices are considered **not medically necessary** for use on any other joint or for any other condition not listed above, including but not limited to the management of chronic joint stiffness or chronic or fixed contractures.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

HCPCS

E1399	Durable medical equipment, miscellaneous [when specified as a dynamic LLPS device, for example Carpal Tunnel Dynasplint System]
E1800	Dynamic adjustable elbow extension/flexion device, includes soft interface material
E1802	Dynamic adjustable forearm pronation/supination 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
E1820	Replacement soft interface material, dynamic adjustable extension/flexion device
E1825	Dynamic adjustable finger extension/flexion device, includes soft interface material

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

When services are also Not Medically Necessary:
For the following procedure codes, or when the code describes a procedure or situation designated in the Clinical Indications section as not medically necessary.

HCPCS

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

ICD-10 Diagnosis

All diagnoses

Discussion/General Information

Dynamic LLPS devices are spring-loaded, adjustable systems which provide a low-load prolonged stretch. Dynamic LLPS devices provide a sustained, set level of tension using integrated springs. These devices are set at a fixed joint angle and worn over long periods (6-8 hours/day or overnight). Dynamic LLPS units provide extension as well as flexion and are available for various joints including the elbows, wrists, fingers, knees, ankles, and toes. These devices are being marketed for the treatment of joint stiffness due to immobilization or limited range of motion (ROM) as a result of various conditions, including, but not limited to, fractures, dislocations, tendon and ligament repairs, joint arthroplasties, total knee replacements, burns, rheumatoid arthritis, hemophilia, tendon releases, head trauma, spinal cord injuries, cerebral palsy, multiple sclerosis, and other traumatic and non-traumatic disorders. The purpose of the dynamic LLPS device is to restore ROM to a joint without diminishing the stability and quality of the connective tissue and joint. Dynamic LLPS devices are frequently used during the post-operative period to prevent or treat motion stiffness or decreased ROM in the knee, elbow, wrist or finger. These devices are generally not used in other joints such as the hip, ankle or foot. Examples of this type of device include but are not limited to:

- Dynasplint® (Dynasplint Systems, Severna Park, MD); and
- JAS Dynamic (Joint Active Systems, Effingham, IL); and
- Pro-Glide™ (De Royal Industries, Powell, TN).

Rives and colleagues (1992) reported the results of a prospective, non-randomized study in which a total of 23 proximal interphalangeal joints that were severely contracted (approximately 45 degrees) as a result of Dupuytren's disease underwent operative correction and 6 months of dynamic extension splinting. Proximal interphalangeal joint extension was measured preoperatively and postoperatively at 3-month intervals for 1 year and at 6-month intervals thereafter. Mean follow-up was 2 years (minimum, 1 year). Overall, at 2 years, 44% improvement in proximal interphalangeal joint extension was noted. Mean improvement of 59% in proximal interphalangeal joint extension was noted in the participants who complied with the postoperative dynamic extension splinting program. Participants who were noncompliant demonstrated a 25% improvement in proximal interphalangeal joint extension. The difference in values between participants who were compliant and those who were not was statistically significant. Other factors such as the severity of contracture, the digit involved, and the necessity for capsular release were not significantly related to outcome. The authors concluded that soft tissue responds to continuous dynamic extension stresses and can be remodeled over time.

In a descriptive study, Nuismer and colleagues (1997) retrospectively evaluated a convenience sample of subjects at multiple sites using LLPS orthoses for contracture management. The records of 17 participants from skilled nursing facilities, hand clinics, and hospitals were reviewed. There were a total of 18 contractures (2 wrists, 12 elbows, 4 knees) secondary to neurological and orthopedic causes. Chart review focused on participant demographic information, ROM, functional outcomes, and wear schedules. The authors found that the use of LLPS orthoses significantly increased ROM for the whole sample, mean 28.61 degrees (range, -10-66, $p<0.001$), which in turn significantly improved the participants' functional outcomes. When the sample was divided into two pathology groups to compare a predominately geriatric population with neurological pathologies to a somewhat younger population with a history of musculoskeletal pathology, both groups showed a significant gain in ROM with the use of the LLPS orthoses. The authors concluded that the use of LLPS orthoses for contracture management can mediate the losses in ROM and function that occur with joint contractures.

Lindenhovius and colleagues (2012) compared the use of dynamic and static progressive (turnbuckle) splints to help stretch a contracted elbow capsule and regain motion after elbow trauma. In a prospective randomized controlled trial the authors tested the null hypothesis that there is no difference in improvement of motion and Disabilities of the Arm, Shoulder and Hand (DASH) scores between static progressive and dynamic splinting. A total of 66 subjects with posttraumatic elbow stiffness were enrolled in a prospective randomized trial: 35 in the static progressive and 31 in the dynamic cohort. Elbow function was measured at enrollment and at 3, 6, and 12 months later and the DASH questionnaire at enrollment and at the 6- and 12-month evaluation. A total of 3 participants asked to be switched to static progressive splinting. The analysis was done according to intention-to-treat principles and with use of mean imputation for missing data. There were no significant differences in flexion arc at any time point. Improvement in the arc of flexion (dynamic versus static) averaged 29 degrees versus 28 degrees at 3 months ($p=0.87$), 40 degrees versus 39 degrees at 6 months ($p=0.72$), and 47 degrees versus 49 degrees at 12 months after splinting was initiated ($p=0.71$). The average DASH score (dynamic versus static) was 50 versus 45 points at enrollment ($p=0.52$), 32 versus 25 points at 6 months ($p<0.05$), and 28 versus 26 points at 12 months after enrollment ($p=0.61$). The authors concluded that posttraumatic elbow stiffness can improve with exercises and dynamic or static splinting over a period of 6 to 12 months, and patience is warranted. There were no significant

differences in improvement in motion between static progressive and dynamic splinting protocols.

Although there is limited data from controlled trials in the published peer reviewed literature, this technology is widely used by orthopedists as well as occupational and physical therapists for selected populations. Additional input from medical practitioners practicing in relevant clinical areas support the role of dynamic splinting in the clinical settings outlined under the Clinical Indications section of this document.

Definitions

Protected motion: A clinical concept which recognizes the importance of protecting damaged tissues as well as the benefits of controlled motion during the early stages of connective tissue repair.

References

Peer Reviewed Publications:

1. Hepburn GR. Case studies: contracture and stiff joint management with Dynasplint. J Orthop Sports Phys Ther. 1987; 8(10):498-504.
2. Lindenhovius AL, Doornberg JN, Brouwer KM, et al. A prospective randomized controlled trial of dynamic versus static progressive elbow splinting for posttraumatic elbow stiffness. J Bone Joint Surg Am. 2012; 94(8):694-700.
3. MacKay-Lyons M. Low-load, prolonged stretch in treatment of elbow flexion contractures secondary to head trauma: a case report. Phys Ther. 1989; 69(4):292-296.
4. Nuismer BA, Ekes AM, Holm MB. The use of low-load prolonged stretch devices in rehabilitation programs in the Pacific Northwest. Am J Occup Ther. 1997; 51(7):538-543.
5. Richard RL, Jones LM, Miller SF, Finley RK Jr. Treatment of exposed bilateral Achilles tendons with use of the Dynasplint. A case report. Phys Ther. 1988; 68(6):989-991.
6. Rives K, Gelberman R, Smith B, Carney K. Severe contractures of the proximal interphalangeal joint in Dupuytren's disease: results of a prospective trial of operative correction and dynamic extension splinting. J Hand Surg. 1992; 17(6):1153-1159.
7. Steffen TM, Mollinger LA. Low-load, prolonged stretch in the treatment of knee flexion contractures in nursing home residents. Phys Ther. 1995; 75(10):886-895.

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Reformatted Clinical Indications, updated review date and History sections.
Reviewed	05/12/2022	MPTAC review. Updated review date and History section.
Reviewed	05/13/2021	MPTAC review. Updated Discussion/General Information and History sections. Reformatted Coding section.
Reviewed	05/14/2020	MPTAC review. Updated History section.
Revised	06/06/2019	MPTAC review. Updated the Discussion/General Information and Index sections. References to the “Elite Seat” device moved to DME.00038 Static Progressive Stretch (SPS) and Patient-Actuated Serial Stretch (PASS) devices to align with the proper classification of the device. In the Not Medically Necessary Position Statement, changed “four” to “4”. Updated Coding section to add E1399 NOC code.
Reviewed	03/21/2019	MPTAC review. Updated the Discussion/General Information and Index sections.
Reviewed	03/22/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.”
Reviewed	05/04/2017	MPTAC review. Updated formatting in the Clinical Indications section.
New	05/05/2016	MPTAC review. Initial document development.