BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Stretching and Splinting Devices for the Treatment of Joint Stiffness and Contractures

Policy #: 346
Latest Review Date: December 2023
Category: DME

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *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;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **dynamic low-load prolonged-duration stretch (LLPS) devices** for use on the ankle, knee, elbow, wrist, finger or jaw as a **covered** benefit for a period of up to four months in the following clinical setting:

- As a treatment for loss of motion from a contracture as part of a formal rehabilitation program or when a formal rehabilitative program is not feasible or has failed to provide benefit.

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.

Blue Advantage will treat the **use of dynamic LLPS devices for any other joint or condition including, but not limited to** toe, foot, shoulder and forearm disorders, chronic joint stiffness, chronic or fixed contractures, rheumatoid arthritis or plantar fasciitis as a **non-covered** benefit and as **investigational**.

Blue Advantage will treat **dynamic LLPS devices** as a **non-covered benefit when used as a part of post-operative care.**

Blue Advantage will treat the **use of dynamic, extension/flexion devices with active resistance control** as a **non-covered** benefit and as **investigational**.

Blue Advantage will treat the **use of carpal tunnel dynamic splinting** as a **non-surgical rehabilitative modality for the treatment of carpal tunnel syndrome** as a **non-covered** benefit and as **investigational**.

For bi-directional static progressive (SP) stretch devices and patient-actuated serial stretch (PASS) devices, please refer to ***Medical Policy 578-Patient-actuated End Range Motion Stretching Devices.***

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Mechanical stretching devices differ from continuous passive motion devices in that they are nonmotorized and include the following types: low-load prolonged-duration stretch (LLPS) devices. Mechanical stretching devices are generally proposed as an adjunct treatment to PT and/or exercise.

LLPS devices, also referred to as dynamic splinting, permit active and passive motion with elastic traction within a limited range and maintain a set level of tension by means of incorporated springs. Examples of LLPS devices include, but may not be limited to, Advance Dynamic ROM, Dynasplint, EMPI Advance Dynamic ROM, Proglide Advance Dynamic ROM, LMB Pro-Glide, SaeboFlex, SaeboReach, Stat-A-Dyne and Ultraflex.

Jaw mobility mechanical stretching devices are suggested for use in the treatment of temporomandibular joint (TMJ) disorders, trismus or other conditions in which jaw movement is limited. Examples of this type of mechanical stretching device include, but may not be limited to, TheraBite Jaw Motion Rehabilitation System, Dynasplint Trismus System or Orastretch.

KEY POINTS:

Literature review through December 5, 2023.

Summary of Evidence:

The use of low-load prolonged stretch (LLPS) splinting devices are proven for improvement of range of motion after surgery or injury when physical therapy alone has not been effective. The use is limited to joints of the jaw, ankle, knee, elbow, finger, and wrist. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

The use of low-load prolonged stretch (LLPS) splinting devices in joints other than those mentioned above and prophylactic use has not been proven at this time. Effectiveness with chronic or long-term fixed contractures has not been proven at this time. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

KEY WORDS:

Joint stiffness, contracture, dynamic low-load prolonged-duration stretch (LLPS) devices, plantar fasciitis, Dynasplint System, Dynasplint Trismus System, EMPI Advance Dynamic ROM, LMB Pro-Glide,TheraBite®, OraStretch™

APPROVED BY GOVERNING BODIES:

Mechanical stretching devices are classified by the FDA as Class 1 medical devices. Class 1 devices have the least amount of regulatory control; manufacturers of these devices are exempt from premarket notification procedures and are not required to provide safety and effectiveness data prior to marketing. Numerous mechanical stretch devices have been developed and are generally categorized as static progressive (SP) stretch devices, low-load, prolonged-duration stretch (LLPS) devices, and patient-actuated serial stretch (PASS) devices.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:
HCPCS:

E1700	Jaw motion rehabilitation system
E1701	Replacement cushions for jaw motion rehabilitation system, pkg. of 6
E1702	Replacement measuring scales for jaw motion rehabilitation system, pkg. of 200
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
E1815	Dynamic adjustable ankle extension/flexion device, includes soft interface material
E1820	Replacement soft interface material, dynamic adjustable extension/flexion device
E1825	Dynamic adjustable finger 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

REFERENCES:

1. Aspinall SK, Bamber ZA, Hignett SM, et al. Medical stretching devices are effective in the treatment of knee arthrofibrosis: A systematic review. J Orthop Translat. 2021;27:119-131.

2. Berner SH, Willis FB and Martinez J. Treating carpal tunnel syndrome with dynamic splinting: A randomized, controlled trial. The Journal of Medicine, December 2008, Vol. 1, Issue 1.
3. Canale & Beaty: Campbell's Operative Orthopedics, 11th edition, Mosby 2007.
4. Finger E and Willis FB. Dynamic Splinting for Knee Flexion Contracture Following Total Knee Arthroplasty: A Case Report. Cases Journal 2008; I: 421.
5. Furia JP, Willis FB, Shanmugam R, Curran SA. Systematic review of contracture reduction in the lower extremity with dynamic splinting. Adv Ther. 2013;30(8):763-770.
6. Hayes Directory. (2013, February 20). Mechanical stretching devices and continuous passive motion for joints of the extremities. Retrieved from http://www.hayesinc.com. John MM, Willis FB and Portillo A. Dynamic Splinting for Runner's Toe. A Case Report with Gait Analysis. Journal of the American Podiatric Medical Association, July/August 2009, Vol. 99, No. 4, pp. 367-370.
7. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.
8. Kalish SR and Willis FB. Hallux Limitus and Dynamic Splinting: A Retrospective Series. The Foot and Ankle Online Journal 2009, Vol. 2, No. 4.
9. Lai JM, Jones M and Willis FB. Efficacy of Dynamic Splinting on Plantar-Flexion Tone and Contracture Seen in CVA and TBI Patients: A Controlled Cross-Over Study. Proceedings of the 16th European Congress of Physical and Rehabilitation Medicine 2008; 106-109.
10. Larson D and Jerosch-Herold C. Clinical Effectiveness of Post-Operative Splinting After Surgical Release of Dupuytren's Contracture: A Systematic Review. BMC Musculoskeletal Disorders 2008; 9: 104.
11. 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.
12. Lundequan P and Willis FB. Dynamic splinting home therapy for toe walking: A case report. Cases Journal 2009; 2: 188.
13. McPoil TG, et al. Heel Pain – Plantar Fasciitis: clinical practice guidelines linked to the international classification of functioning, disability, and health from the Orthopedic section of the American Physical Therapy Association. J. Orthop. Sports Phys. Ther. 2008; 38(4):A1-A18.
14. Mowlavi A, et al. Dynamic versus static splinting of simple zone V and zone VI extensor tendon repairs: A prospective, randomized, controlled study. Plastic Reconstructive Surgery, February 2005; 115(2): 482-487.
15. Plaass C, Karch A, Koch A, et al. Short term results of dynamic splinting for hallux valgus - A prospective randomized study. Foot Ankle Surg. 2020;26(2):146-150.
16. Ring D, et al. Hinged elbow external fixation for severe elbow contracture. Am Journal Bone Joint Surgery, June 2005; 87(6): 1293-1296.
17. Roos E, et al. Foot orthoses for the treatment of plantar fasciitis. Foot Ankle International, August 2006; 27(8): 606-611.

18. Sheridan L, Lopez A, et al. Plantar Fasciopathy treated with dynamic splinting. Journal of the American Podiatric Medical Association 2010; 100(3):161-165.
19. Stubblefield MD et al. A preliminary report on the efficacy of a dynamic jaw opening device (dynasplint trismus system) as part of the multimodal treatment of trismus in patients with head and neck cancer. Arch Phys Med Rehabil. 2010;91(8): 1278-1282.
20. Thomas JL, et al. The diagnosis and treatment of heel pain: a clinical practice guideline – revision 2010. The Journal of Food and Ankle Surgery 2010; 49:S1-S19.
21. U.S. Food and Drug Administration (FDA): Centers for Devices and Radiologic Health. www.accessdata.fda.gov/scripts/cdrh/cfdocs/search/search.cfm?db=CFR&id-890.3475.
22. Veltman ES, Doornberg JN, Eygendaal D, et al. Static progressive versus dynamic splinting for posttraumatic elbow stiffness: A systematic review of 232 patients. Arch Orthop Trauma Surg. 2015;135(5):613-617.
23. Verdugo RJ, Salinas RA, Castillo JL and Cea JG. Surgical versus non-surgical treatment for carpal tunnel syndrome. Cochrane Database Syst Rev 2008; CD001552.

POLICY HISTORY:

Adopted for Blue Advantage, September 2009
Available for comment October 3-November 18, 2009
Medical Policy Group, December 2010 – 2011 Code update
Medical Policy Group, April 2011;
Medical Policy Group, February 2012
Medical Policy Administration Committee, February 2012
Medical Policy Group, May 2013: Effective 05/1/2013: Active Policy but no longer scheduled for regular literature reviews and updates.
Medical Policy Group, September 2013
Medical Policy Group, August 2014
Medical Policy Group, January 2015
Medical Policy Group, January 2020
Medical Policy Group, January 2021
Medical Policy Group, January 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, December 2022
Medical Policy Group, December 2023
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.