

Dynamic Splinting Devices

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. *Please refer to individual product lines certificates of coverage for possible exclusions of benefit.*

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not reasonable and necessary.

Suppliers are to follow The Health Plan requirements for precertification, as applicable.

Dynamic splinting devices require precertification and physician face-to-face.

National Coverage Determination Policy	None
Local Coverage Determination Policy	None
Effective Date	11/09/07
Review/Revisions Date	01/19, 10/18, 06/2018, 12/07/17, 03/09/17, 02/01/16, 03/01/15, Previous review 01/01/15, 05/01/14
The Health Plan	<p>Commercial plans will follow The Health Plan guidelines</p> <p>West Virginia Medicaid will follow THP guidelines for Codes E1800, E1802, E1805, E1810, E1812, E1815, E1820, &E1825.</p> <p>Medicare plans will follow Medicare Local Coverage Determinations for coverage pertaining to the ankle and knee. All plans will follow The Health Plan guidelines for all other joints as there is no local or national coverage determination for these joints</p>

DESCRIPTION

Dynamic splinting systems are spring-loaded, adjustable devices designed to provide low-load, prolonged stretching while the patient is asleep or at rest. Dynamic splinting units, both extension (bring the distal portion of a joint in parallel with the long axis of the proximal portion), and flexion (the act of flexing or bending a joint) are available for the elbow, wrist, fingers, knee, ankle, and toes. These units are being marketed for the treatment of joint stiffness due to immobilization or limited range of motion (ROM) as a consequence of fracture, dislocation, tendon and ligament repair, joint arthroplasty surgery. The goal being to restore as much as possible, the integrity and function of a joint, total knee replacement, burn, rheumatoid arthritis, hemophilia, tendon release, head trauma, spinal cord injury, cerebral palsy, multiple sclerosis, and other traumatic and non-traumatic disorders.

NOTE: At this time, due to lack of evidence of the effectiveness of some of these devices and of the application of the devices to some areas of the body, as well as for chronic physical conditions, there are narrow guidelines as to when the devices may be considered medically necessary. There are a limited number of codes, models, and diagnoses (conditions) for which the devices may be covered. *See below.*

COVERAGE GUIDELINES

- Dynamic splinting is commonly used in the postoperative period for the prevention or treatment of motion stiffness/loss of range of motion in the knee, elbow, wrist, or fingers. It is not generally used in other joints such as the hip, ankle, or foot.
- Dynamic splinting devices may be covered for the, knee, elbow, wrist, or fingers for a period of up to four months after surgery/injury to one of these joints for the following:
 1. As an adjunct to physical therapy in members with documented signs and symptoms of significant motion stiffness/loss in the sub-acute injury or postoperative period (at least three weeks after injury or surgery); or
 2. In the acute postoperative 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
 3. As a treatment for joint stiffness when a formal rehabilitation program is not feasible or has failed to provide benefits.
 4. Medicare is allowing coverage of dynamic splinting of the ankle; code E1815, if the above guidelines are met and as long as the device is not being used as an assistive function to joint plantar or dorsiflexion motion of the ankle. *See Ankle Foot/Knee Ankle Foot Orthoses Policy.*

NONCOVERAGE STATEMENT

- Dynamic splinting would be considered experimental and investigational because of lack of scientific evidence regarding effectiveness for the following conditions:
 1. Prophylactic use of dynamic splinting in the management of chronic contractures (no significant change in motion for a four-month period) and joint stiffness due to joint trauma, fractures, burns, head and spinal cord injuries, rheumatoid arthritis, multiple sclerosis, muscular dystrophy, or cerebral palsy.
 2. In the management of joint injuries of the shoulder, ankle, and toe(s) to prevent stiffness or restore range of motion.
 3. Joint Active Systems splints (e.g., JAS elbow, shoulder, ankle, and knee, wrist and JAS pronation-supination) are not covered. They are considered experimental and investigational due to lack of sufficient evidence in peer-reviewed published medical literature to support their effectiveness.
 4. Static Progression Stretch (SPS) knee device, extension/flexion with or without range of motion adjustment, includes cuff (E1811), is not covered for Commercial or Medicaid plans.
 5. The devices ERMI Extensionater and Flexionater.
 6. Jaw dynasplint device.
 7. No matter which code is used – the Elite seat is not covered.

The following Hayes ratings are assigned: published February, 28 2014. Updated May, 09 2018

C – For LLPS as an adjunct to physical therapy for rehabilitation of finger extensor injury.

D1- For use of low-load prolonged-duration stretch (LLPS) mechanical stretching devices for treatment of finger joint contractures following extensor injury and repair.

D2 – For use of LLPS, static progressive stretch (SPS) or patient-actuated serial stretch (PASS) mechanical stretching devices for treatment of other types of contractures of the finger joint.

D2 –For use of LLPS, SPS, or PASS mechanical stretching devices for treatment of contractures in any other joint for any indication.

Per Hayes review: “Mechanical stretching devices may not provide any long-term benefit in the treatment of joint contractures of the extremities.”

REPAIR, REPLACEMENT, AND REASONABLE USEFUL LIFETIME

Dynamic splinting is covered as a rental device and repair or replacement will be included in the monthly rental

CODING INFORMATION

HCPCS codes: Codes covered if the above criteria are met.

HCPCS MODIFIERS

FA	LEFT HAND, THUMB
F1	LEFT HAND, SECOND DIGIT
F2	LEFT HAND, THIRD DIGIT
F3	LEFT HAND, FOURTH DIGIT
F4	LEFT HAND, 5 TH DIGIT
F5	RIGHT HAND, THUMB
F6	RIGHT HAND, SECOND DIGIT
F7	RIGHT HAND, THIRD DIGIT
F8	RIGHT HAND, FOURTH DIGIT
F9	RIGHT HAND, FIFTH DIGIT

HCPCS CODES

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
E1811	STATIC PROGRESSION STRETCH (SPS) KNEE DEVICE, EXTENSION/FLEXION W/OR W/O RANGE OF MOTION ADJUSTMENT, INCLUDES CUFF (CMS DECISION 5/03/07 TO REVISE THE DESCRIPTION OF THE CODE AND TO COVER IT). This code is to be used for ELITE SEAT by KNEEBORNE THERAPEUTICS as determined by CMS 06/05/12 and not covered in that capacity- see below
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 – MEMBER OWNED DEVICE ONLY

E1825	DYNAMIC ADJUSTABLE FINGER EXTENSION/FLEXION DEVICE, INCLUDES SOFT INTERFACE MATERIAL
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Codes not covered:

E1801	STATIC PROGRESSION STRETCH (SPS) ELBOW DEVICE W/ OR W/O RANGE OF MOTION ADJUSTMENT, INCLUDES CUFF
E1806	BI-DIRECTIONAL STATIC PROGRESSIVE STRETCH WRIST DEVICE, W/RANGE OF MOTION ADJUSTMENT INCLUDES CUFFS
E1811	STATIC PROGRESSION STRETCH (SPS) KNEE DEVICE, EXTENSION/FLEXION W/OR W/O RANGE OF MOTION ADJUSTMENT, INCLUDES CUFF. This code is to be used for ELITE SEAT by KNEEBORNE THERAPEUTICS as determined by CMS 06/05/12
E1816	BI-DIRECTIONAL STATIC PROGRESSIVE STRETCH ANKLE DEVICE, W/RANGE OF MOTION ADJUSTMENT INCLUDES CUFFS
E1818	BI-DIRECTIONAL STATIC PROGRESSIVE STRETCH FOREARM PRONATION/SUPINATION DEVICE, W/RANGE OF MOTION ADJUSTMENT INCLUDES CUFFS
E1821	REPLACEMENT SOFT INTERFACE MATERIAL/CUFFS FOR BI-DIRECTIONAL STATIC PROGRESSIVE STRETCH DEVICE
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 AND ACCESSORIES
E1840	DYNAMIC ADJUSTABLE TOE EXTENSION/FLEXION DEVICE, INCLUDES SOFT INTERFACE MATERIAL
E1841	STATIC PROGRESSIVE STRETCH SHOULDER DEVICE W/RANGE OF MOTION ADJUSTMENTS, INCLUDES CUFF

There are no specified diagnoses or ICD-10 codes that indicate medical necessity.

DOCUMENTATION REQUIREMENTS

For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes the physician's office records, hospital records, nursing home records, home health agency records, records from other health care professionals and test reports.

This documentation must be available with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:

- a. Member's name
- b. Date
- c. Description of item. The medical record must contain the information that supports the request for each item and must be submitted with the precertification if the item requires precertification, or with the claim, if no precertification was required
- d. Order must include diagnosis code
- e. Physician signature with date. Date stamps are not appropriate
- f. Quantity of items required and duration. A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used

The supplier is to contact The Health Plan in this instance to update referral

2. There must be documentation in the supplier's records to support the medical necessity of that item. This information must be available upon request usually with precertification per The Health Plan policy.
3. Proof of delivery to be kept on file by the provider of the item.

Note: If templates or forms are submitted, (i.e., a Medicare Certificate of Medical Necessity, and/or a provider created form), and all of the required information is not included, The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing facility records, and home health records.

Note: Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

Items listed in this policy that are provided without first obtaining authorization required per The Health Plan DME POS Authorization and Compensation Guide may be denied for no precertification.

PROVIDED WHILE MEMBER IN PART A FACILITY

Reimbursement for dynamic splinting devices provided to a member while covered in a Part A facility is based on specific contract information with the individual facility, and whether or not the device is intended for use while the member is in the facility.

Payment for the device is included in the payment to a hospital if:

1. The device is provided to a patient during an inpatient hospital stay prior to the day of discharge; and
2. The patient uses the device for medically necessary inpatient treatment or rehabilitation.

A claim must not be submitted in this situation.

Reimbursement for a dynamic splinting device provided while a member is in a SNF receiving Part A services, will be reimbursed according to individual facility contracts.

EQUIPMENT RETAINED FROM A PRIOR PAYOR:

The Health Plan will not pay in excess of the contracted purchase price for any item in this policy. If the provider is seeking payment from The Health Plan, the item must be precerted and The Health Plan will pay the remaining rental months up to purchase price- if member meets guidelines above.

BILLING GUIDELINES

Providers should precertify E-codes for concentric torsion mechanisms being used for any condition other than as an assistive function to joint extension of the knee, or to joint plantar or dorsiflexion motion of the ankle.

Codes E1810 and E1815 are to be used when requesting concentric adjustable torsion style mechanism for treatment of a contracture, regardless of any coexisting condition, providers are directed to the dynamic splinting policy as indicated above.

Concentric adjustable torsion style mechanisms used to assist **ankle** joint plantarflexion or dorsiflexion for member's who require ankle plantar or dorsiflexion assist in the absence of any coexisting joint contracture are coded L2999. Precertification is required. The provider is to submit the following: make, model, description of item, and manufacturer's invoice, and specific documentation from the member's physician's medical record of member's need for the device.

Concentric adjustable torsion style mechanisms precerted with L2999 and the primary or secondary diagnosis is contracture the request will be denied as incorrect coding.

If concentric adjustable torsion style mechanism is being used solely to provide an assistive function for joint extension of the knee, or plantar or dorsiflexion motion of the ankle, it must be coded L2999. Coverage guidelines for these devices are found in the ankle foot/ankle foot knee orthoses policy and the knee orthotic policy.

Code E1825 is not separately payable during rental period of the base code.

KX, GA, and GZ MODIFIERS

Suppliers may submit a claim with a KX modifier only if all the criteria for that item are met.

If coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier, if they have not obtained a valid ABN.

ADVANCED BENEFICIARY NOTICE

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

NOTE: Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

PRICING, DATA ANALYSIS, AND CODING (PDAC)

The Health Plan has implemented use of Medicare's PDAC contractor for review of authorizations. Suppliers should contact the PDAC contractor for guidance on the correct coding of these items. dmepdac.com/

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INTERNET LINKS AND SOURCES

The Pricing, Data Analysis, and Coding Contractor. Noridian. Internet website. Last accessed 10/25/18. Retrieved from: <https://www.dmepdac.com/dmecsapp/>

West Virginia Medicaid Internet Provider Manual. Chapter 506. Covered Services, Limitations, and Exclusions for DME Medical Supplies. Last accessed: 10/25/18. Retrieved from dhhr.wv.gov/bms/Pages/default.aspx

National Government Services Local Coverage Determination Policy: Ankle Foot/Knee Ankle Foot Orthotics Policy. LCD L27229. Last accessed: 10/25/18. Retrieved from apps.ngsmedicare.com/applications/lcd.aspx?CatID=3&RegID=51

National Government Services Local Coverage Determination Policy: Ankle Foot/Knee Ankle Foot Orthotics Policy. Article A47227. Last accessed: 10/25/18. Retrieved from <http://www.ngsmedicare.com>

Medicare Learning Network MLN. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards. ICN 905709 2/2013. Last accessed: 10/25/18. Retrieved from <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html>

CGS: A Celerian Group Company. Local Coverage Determination Policy Ankle Foot Orthosis and Article. L11517 and A19885. Last accessed 10/25/18. Retrieved from cgsmedicare.com/jc/coverage/lcdinfo.html

Aetna Clinical Policy Bulletin, (7/26/13). Mechanical Stretching Devices for Contracture and Joint Stiffness, Number: 0405. Last Accessed 10/25/18. Retrieved from: http://www.aetna.com/cpb/medical/data/400_499/0405.html

United Healthcare Medical Policy: Mechanical Stretching and Continuous Passive Motion Devices; Policy Number 2013T04811. Last Accessed: 10/25/18. Retrieved from unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20policies/Medical%20Policies/Mech_Stretch_Contin_Motion_Devices.pdf

Health Net National Medical Policy: Mechanical Stretching Devices for Joint Stiffness and Contracture;
Policy number: CP.MP.144 ; Last Accessed 10/25/18. Retrieved

from: <https://www.healthnet.com/static/general/unprotected/pdfs/national/policies/MechanicalStretchingDevices.pdf>

Hayes Technology Inc: Mechanical Stretching Devices for the Treatment of Joint Contractures of the
Extremities. Pub 2/20/13. Updated 1/2016. Last Accessed: 06/01/2018. Retrieved

from <https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=12718&§ionSelector=HayesRating>

The Health Plan Provider Procedural Manual. Payment Voucher, Section 14, Page 11