

Medicare Medical Policy

Mechanical Stretching Devices for Joints of the Extremities

MEDICARE MEDICAL POLICY NUMBER: 382

Effective Date: 3/1/2023

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Next Annual Review: 2/2024

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Note: This policy does not address low-load prolonged-duration stretch (LLPS) devices/dynamic stretch devices (e.g., Dynasplint® System, Ultraflex® System, Pro-Glide™ Dynamic Splints; HCPCS E1800, E1802, E1805, E1810, E1812, E1825), which may be considered medically necessary.

Service	Medicare Guidelines
<i>Mechanical Stretching Devices – Static Progressive (SP) Stretch Devices and Patient-Actuated Serial Stretch (PASS) devices</i>	Company medical policy for Mechanical Stretching Devices for Joints of the Extremities I. These devices are considered not medically necessary for Medicare based on the Company medical policy. <i>See Policy Guidelines below.</i>

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. (*Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021*)

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

BACKGROUND

Joint Contracture

A joint contracture is characterized by a chronically reduced range of motion (ROM) secondary to structural changes in non-bony tissues, including muscle, tendons, ligaments, and skin. This joint dysfunction is due to elastic connective tissue being replaced with inelastic fibrous material, which is most commonly due to prolonged immobilization following surgery or trauma. Treatment and prevention of joint contractures include manual joint mobilization by a physical therapist, serial plastering, static splinting, mechanical stretching devices, continuous device-assisted passive motion (CPM), massage, exercise, electrical stimulation, botulinum toxin, and surgery.

Static Progressive (SP) Stretch Devices

SP stretch devices hold the joint in a set position while allowing for modification of the joint angle and may also allow for active motion without resistance. The SP device does not exert stress on the tissue unless the joint angle is set to maximum range of motion. (See “Regulatory Status” section below.)

Patient-Actuated Serial Stretch (PASS) Devices

PASS devices allow for resisted active and passive motion within a limited range. PASS devices are adjusted by the patient and provide a low-to-high level load to the joint using pneumatic (e.g., Extensionator®) or hydraulic (e.g., Flexionator®) systems. (See “Regulatory Status” section below.)

MEDICARE AND MEDICAL NECESSITY

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*.

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare’s definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan’s use of evidence-based processes for policy development. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.) which addresses the medical necessity of a given medical service, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. (*Medicare Managed Care Manual, Ch. 4, §90.5*)

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment

policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

TYPES OF MECHANICAL STRETCHING DEVICES

Static Progressive (SP) Stretch Devices

Static progressive (SP) stretch devices include:

- Joint Active Systems® (JAS) Static Progressive Stretch devices (finger, wrist, elbow, shoulder, knee, ankle)

Patient-Actuated Serial Stretch (PASS) Devices

Patient-actuated serial stretch (PASS) devices include:

- ERMI, Inc. Knee Extensionator®
- ERMI, Inc. Knee/Ankle Flexionator®
- ERMI, Inc. Shoulder Flexionator®
- ERMI, Inc. MPJ Extensionator®
- ERMI, Inc. Elbow Extensionator®

BILLING GUIDELINES AND CODING

CODES*		
CPT	None	
HCPCS	E1399	Durable medical equipment, miscellaneous
	E1801	Static progressive stretch elbow device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
	E1806	Static progressive stretch wrist device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories
	E1811	Static progressive stretch knee device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
	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 forearm pronation / supination device, with or without range of motion adjustment, includes all components and accessories
	E1821	Replacement soft interface material/cuffs for bi-directional static progressive stretch device
	E1831	Static progressive stretch toe device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
	E1841	Static progressive stretch shoulder device, with or without range of motion adjustment, includes all components and accessories

*Coding Notes:

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical

necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, “presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare.” The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. (*Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician’s Fee Schedule, A. Physician’s Services*)

- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
3/2023	New Medicare Advantage medical policy