

Medicare Medical Policy

Knee Braces (Functional)

MEDICARE MEDICAL POLICY NUMBER: 297

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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.

Service	Medicare Guidelines	HCPCS Code(s)
<i>Non-Covered Knee Braces/Orthoses, Components, or Accessories</i>	<ul style="list-style-type: none"> • HCPCS code A9270: Any service reported with this code is non-covered by definition of the code itself. • HCPCS codes L1847 and L1848: Local Coverage Determination (LCD): Knee Orthoses (L33318) • HCPCS codes A4467: Local Coverage Article (LCA): Knee Orthoses - Policy Article (A52465) • HCPCS code L9900: Considered a “bundled” service by Medicare. See A52465, as well as the Noridian webpage for Two New Codes Established for Miscellaneous Supplies. 	A4467, A9270, L1847, L1848, L9900
<i>Knee Orthoses - General</i>	<ul style="list-style-type: none"> • LCD: Knee Orthoses (L33318) • LCA: Knee Orthoses - Policy Article (A52465) <p>NOTES:</p> <ol style="list-style-type: none"> 1. The LCA also addresses the use of Computer-Aided Design-Computer-Aided Manufacturing (CAD-CAM) technology to obtain a digital image of the patient’s body part. 2. See the “Billing Guidelines” section for information regarding prefabricated (off-the-shelf or custom-fitted items) vs. custom-fabricated (custom made) items. 	Multiple – See CPT/HCPCS table below.
<i>Replacement and Repair</i>	<p>LCA: Knee Orthoses - Policy Article (A52465)</p> <ol style="list-style-type: none"> 1. NOTE: This LCA provides the reasonable useful lifetime (RUL) for both prefabricated 	Varies – See CPT/HCPCS table below.

	and custom fabricated orthoses and addresses replacement of knee orthoses during the RUL.	NOTE: Some items can only be billed individually when provided as a replacement and some components have specific replacement HCPCS codes.
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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

DOCUMENTATION REQUIREMENTS

If needed, the Noridian Durable Medical Equipment Medicare Administrative Contractor (DMEMAC) [Documentation Checklist For Knee Orthoses](#) can be used to determine if all applicable documentation to support medical necessity are available, in support of the relevant local coverage determination (LCD) and local coverage article (LCA) found below.

PREFABRICATED VS. CUSTOM FABRICATED

Knee orthoses are rigid or semi-rigid devices used to support a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. These items may be:

- Off the shelf (prefabricated)
 - This includes custom *fitted*
- Custom fabricated (custom *made*)

Items that require measuring, assembling, fitting, or adapting due to a patient’s body size, weight, disability, period of need, or intended use **OR** been assembled using available customized features, modifications or components are considered to be “custom-*fitted*” items. These are **not** considered to be “custom *made*” items under Medicare.

In order to be considered a true “customized” or “custom made” knee orthosis, the item must meet **both** of the following requirements:¹⁻³

1. Must be uniquely constructed or substantially modified for a specific beneficiary according to the description and orders of a physician (aka, one of a kind, no other individual would be able to use the item) **and**
2. Must be so different from another item used for the same purpose that the two items cannot be grouped together for pricing purposes.

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.

BILLING GUIDELINES AND CODING

GENERAL

Certain AFOs and KAFOs may have both covered and non-covered uses. These items must always be coded based on the member's applicable medical condition. See the associated local coverage article (LCA) for additional billing and coding guidance:

- LCA: Knee Orthoses - Policy Article ([A52465](#))

HCPCS code L9900 is never allowed separate reimbursement because Medicare considers this code to be a bundled item or service, no matter what it is used to represent, and even if billed alone. While several LCAs and LCDs specifically call out this code as non-covered when used for specific types of devices, not all possible scenarios where this code may be used are addressed in LCDs or LCAs; however, the Noridian webpage for [Two New Codes Established for Miscellaneous Supplies](#) provides general non-coverage information, for any use not found in an LCD or LCA.

CODING PREFABRICATED AND. CUSTOM FABRICATED ORTHOTICS AND ADDITIONS

The Table 1 below includes coding for different types of knee orthotics:

Table 1: HCPCS Codes for Knee Orthoses

Knee Orthosis	HCPCS Code(s)
Prefabricated Knee Orthoses (includes custom <i>fitted</i> orthoses)	L1810, L1812, L1820, L1830, L1831, L1832, L1833, L1836, L1843, L1845, L1847, L1848, L1850, L1851, L1852
Custom <i>Fabricated</i> Knee Orthoses	L1834, L1840, L1844, L1846, L1860
Knee Orthosis Additions	K0672, L2275, L2320, L2330, L2385, L2390, L2395, L2397, L2405, L2415, L2425, L2430, L2492, L2750, L2755, L2780, L2785, L2795, L2800, L2810, L2820, L2830

CODES*		
CPT	None	
HCPCS	A4467	Belt, strap, sleeve, garment, or covering, any type
	A9270	Non-covered item or service
	K0672	Addition to lower extremity orthosis, removable soft interface, all components, replacement only, each
	L1810	Knee orthosis, elastic with joints, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
	L1812	Knee orthosis, elastic with joints, prefabricated, off-the-shelf
	L1820	Knee orthosis, elastic with condylar pads and joints, with or without patellar control, prefabricated, includes fitting and adjustment
	L1830	Knee orthosis, immobilizer, canvas longitudinal, prefabricated, off-the-shelf
	L1831	Knee orthosis, locking knee joint(s), positional orthosis, prefabricated, includes fitting and adjustment
	L1832	Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
	L1833	Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the shelf
	L1834	Knee orthosis, without knee joint, rigid, custom fabricated
	L1836	Knee orthosis, rigid, without joint(s), includes soft interface material, prefabricated, off-the-shelf
	L1840	Knee orthosis, derotation, medial-lateral, anterior cruciate ligament, custom fabricated
	L1843	Knee orthosis, single upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
	L1844	Knee orthosis, single upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, custom fabricated
	L1845	Knee orthosis, double upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
	L1846	Knee orthosis, double upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, custom fabricated
	L1847	Knee orthosis, double upright with adjustable joint, with inflatable air support chamber(s), prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
	L1848	Knee orthosis, double upright with adjustable joint, with inflatable air support chamber(s), prefabricated, off-the-shelf

L1850	Knee orthosis, swedish type, prefabricated, off-the-shelf
L1851	Knee orthosis (ko), single upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated, off-the-shelf
L1852	Knee orthosis (ko), double upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated, off-the-shelf
L1860	Knee orthosis, modification of supracondylar prosthetic socket, custom fabricated (sk)
L2275	Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined
L2320	Addition to lower extremity, non-molded lacer, for custom fabricated orthosis only
L2330	Addition to lower extremity, lacer molded to patient model, for custom fabricated orthosis only
L2385	Addition to lower extremity, straight knee joint, heavy duty, each joint
L2390	Addition to lower extremity, offset knee joint, each joint
L2395	Addition to lower extremity, offset knee joint, heavy duty, each joint
L2397	Addition to lower extremity orthosis, suspension sleeve
L2405	Addition to knee joint, drop lock, each
L2415	Addition to knee lock with integrated release mechanism (bail, cable, or equal), any material, each joint
L2425	Addition to knee joint, disc or dial lock for adjustable knee flexion, each joint
L2430	Addition to knee joint, ratchet lock for active and progressive knee extension, each joint
L2492	Addition to knee joint, lift loop for drop lock ring
L2750	Addition to lower extremity orthosis, plating chrome or nickel, per bar
L2755	Addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthosis only
L2780	Addition to lower extremity orthosis, non-corrosive finish, per bar
L2785	Addition to lower extremity orthosis, drop lock retainer, each
L2795	Addition to lower extremity orthosis, knee control, full kneecap
L2800	Addition to lower extremity orthosis, knee control, knee cap, medial or lateral pull, for use with custom fabricated orthosis only
L2810	Addition to lower extremity orthosis, knee control, condylar pad
L2820	Addition to lower extremity orthosis, soft interface for molded plastic, below knee section
L2830	Addition to lower extremity orthosis, soft interface for molded plastic, above knee section
L2999	Lower extremity orthoses, not otherwise specified
L4002	Replacement strap, any orthosis, includes all components, any length, any type
L4205	Repair of orthotic device, labor component, per 15 minutes
L4210	Repair of orthotic device, repair or replace minor parts
L9900	Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS "L" code <i>(Not separately payable)</i>

***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

1. 42 CFR §414.224 - Customized items; Available at: <https://www.law.cornell.edu/cfr/text/42/414.224>
2. Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §30.3 – Certain Customized Items; Last Updated: 07/19/2013; Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf>
3. Medicare Claims Processing Manual, Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §130.4 - Billing for Certain Customized Items; Last Updated: 10/01/2003; Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf>

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
6/2022	Annual review, no changes (converted to new format 2/2023)
4/2023	Annual review; no change to criteria, added language regarding L9900