

MEDICAL POLICY	Knee Braces (Functional) (All Lines of Business Except Medicare)
Effective Date: 5/1/2021  <div style="text-align: right;">5/1/2021</div>	Medical Policy Number: 91
	Medical Policy Committee Approved Date: 5/07; 11/08; 3/09; 5/09; 12/10; 11/12; 9/13; 10/14; 10/15; 11/16; 12/16; 5/17; 1/19; 2/2020; 4/2021
Medical Officer _____ Date _____	

See Policy HCPCS CODE section below for any prior authorization requirements

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”).

APPLIES TO:

All lines of business except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request. Medical records to include documentation of all of the following:

- All medical records and chart notes pertinent to the request. This includes:
 - Documentation of knee instability by examination of the patient and objective description of joint laxity (e.g., varus/valgus instability, anterior/posterior Drawer test).
- For custom fabricated orthoses (L1834, L1840, L1844, L1846, L1860), there must be detailed documentation in the treating practitioner’s records to support the medical necessity of custom fabricated rather than a prefabricated orthosis.
- When providing knee orthoses, suppliers must:
 - Provide the product that is specified by the prescribing practitioner
 - Be sure that the prescribing practitioner’s medical record justifies the need for the type of product (i.e., Prefabricated versus Custom Fabricated)

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- Only bill for the HCPCS code that accurately reflects both the type of orthosis and the appropriate level of fitting
- Have detailed documentation in supplier's records that justifies the code selected
- The beneficiary's condition (diagnosis code) that necessitates the need for the knee orthosis must be included on the claim.

POLICY CRITERIA

This policy is based on the Centers for Medicare & Medicaid Services Local Coverage Determination (LCD): Knee Orthoses (L33318) and Local Coverage Article (LCA): Knee Orthoses – Policy Article (A52465).^{1,2} This CMS guidance was identified as of the last policy review date on 2/8/2021.

Prefabricated Knee Orthoses

- I. A knee orthosis with joints (L1810, L1812) or knee orthosis with condylar pads and joints with or without patellar control (L1820) may be considered **medically necessary and covered** for ambulatory patients who have weakness or deformity of the knee and require stabilization.
- II. A knee orthosis with a locking knee joint (L1831) or a rigid knee orthosis (L1836) may be **medically necessary and covered** for patients with flexion or extension contractures of the knee with movement on passive range of motion testing of at least 10 degrees (i.e., a nonfixed contracture). (See [Policy Guidelines](#) for definitions of flexion and extension contractures).
- III. A knee immobilizer without joints (L1830), or a knee orthosis with adjustable knee joints (L1832, L1833), or a knee orthosis, with an adjustable flexion and extension joint that provides both medial-lateral and rotation control (L1843, L1845, L1851, L1852), may be considered **medically necessary and covered** if the patient has had recent injury to or a surgical procedure on the knee(s). (Please refer to the LCA A52465 for ICD-10 codes that support medical necessity [Groups 2 or 4 Code Sections]).
- IV. Knee orthoses L1832, L1833, L1843, L1845, L1851 and L1852 may be considered **medically necessary and covered** for a patient who is ambulatory and has knee instability due to a condition specified in Group 4 ICD-10 codes in the LCA A52465.
- V. A knee orthosis, Swedish type, prefabricated (L1850) may be considered **medically necessary and covered** for a patient who is ambulatory and has knee instability due to genu recurvatum - hyperextended knee, congenital or acquired. (Please refer to the LCA A52465 for ICD-10 codes that support medical necessity [Groups 5 Code Sections]).
- VI. If the criteria (I. – V.) above are not met, a knee orthosis is considered **not medically necessary and not covered**.

An inflatable air bladder (also known as an inflatable air support chamber) incorporated into the design of a knee orthoses (L1847 or L1848) is considered **not medically necessary and not covered**.

Additional Components and Features for Prefabricated Knee Orthoses

- VII. Components or features that can be and frequently are physically incorporated in the specified prefabricated base orthosis, designated as “addition codes”, may be considered **medically necessary and covered** when all of the following criteria (A. – C.) are met:
- A. They are provided with the related base code orthosis; **and**
 - B. The base orthosis is reasonable and necessary; **and**
 - C. The addition is reasonable and necessary.
- VIII. Addition components and features are considered **not medically necessary and not covered** if the base orthosis criteria I. – VI. are not met.
- IX. Components or features that can be physically incorporated in the specified prefabricated base orthosis are considered **not medically necessary and not covered** (See [Billing Guidelines](#) for complete code list).

Custom Fabricated Knee Orthoses (L1834, L1840, L1844, L1846, L1860)

- X. A custom fabricated orthosis may be considered **medically necessary and covered** when there is a documented physical characteristic which requires the use of a custom fabricated orthosis instead of a prefabricated orthosis. Examples of situations which meet the criterion for a custom fabricated orthosis include, but are not limited to:
- A. Deformity of the leg or knee
 - B. Size of thigh and calf
 - C. Minimal muscle mass upon which to suspend an orthosis.

Note: If a custom fabricated orthosis is provided but the medical record does not document why that item is medically necessary instead of a prefabricated orthosis, the custom fabricated orthosis will be denied as **not medically necessary and not covered**.

- XI. Custom fabricated orthoses (L1834, L1840, L1844, L1846, L1860) are considered **not medically necessary and not covered** in the treatment of knee contractures in cases where the patient is nonambulatory.
- XII. A custom fabricated knee immobilizer without joints (L1834) may be considered **medically necessary and covered** when the following criteria (A-B) are met:

- A. The coverage criteria for the prefabricated orthosis code L1830 (Criterion III) are met; **and**
- B. Criterion X is met.

XIII. If an L1834 orthosis is provided and criterion XII. above is not met, the orthosis is considered **not medically necessary and not covered**.

XIV. A custom fabricated derotation knee orthosis (L1840) may be considered **medically necessary and covered** for instability due to internal ligamentous disruption of the knee. (Please refer to the LCA A52465 for ICD-10 codes that support medical necessity [Group 3 Code Section]).

XV. A custom fabricated knee orthosis with an adjustable flexion and extension joint (L1844, L1846) may be considered **medically necessary and covered** if the following criteria (A. - B.) are met:

- A. The coverage criteria for the prefabricated orthosis codes L1843, L1845, L1851 and L1852 are met; **and**
- B. Criterion X is met.

XVI. If an L1844 or L1846 orthosis is provided and criterion XV. above is not met, the orthosis is considered **not medically necessary and not covered**.

XVII. A custom fabricated knee orthosis with a modified supracondylar prosthetic socket (L1860) may be considered **medically necessary and covered** for a patient who is ambulatory and has knee instability due to genu recurvatum - hyperextended knee. . (Please refer to the LCA A52465 for ICD-10 codes that support medical necessity [Group 5 Code Section]).

Additional Components and Features for Custom Knee Orthoses

XVIII. Components or features that can be and frequently are physically incorporated in the specified custom fabricated base orthosis, designated as “addition codes”, may be considered **medically necessary and covered** when all of the following criteria (A. –C.) are met:

- A. They are provided with the related base code orthosis; **and**
- B. The base orthosis is reasonable and necessary; **and**
- C. The addition is reasonable and necessary.

XIX. Addition components and features are considered **not medically necessary and not covered** if the custom fabricated knee orthoses criteria X.-XVII. are not met.

XX. Components or features that can be physically incorporated in the specified custom fabricated base orthosis are considered **not medically necessary and not covered**. These

addition codes, if they are billed with the related base code, will be denied as not reasonable and necessary. (See [Billing Guidelines](#) for complete code list).

Miscellaneous

- XXI. Heavy duty knee joint codes (L2385, L2395) may be considered **medically necessary and covered** for patients who weigh more than 300 pounds.
- XXII. Concentric adjustable torsion style mechanisms used to assist knee joint extension (L2999) may be considered **medically necessary and covered** for patients who require knee extension assist in the absence of any co-existing joint contracture.
- XXIII. Concentric adjustable torsion style mechanisms used for the treatment of contractures (E1810) may be considered **medically necessary and covered**.

Link to [Policy Summary](#)

POLICY GUIDELINES

Definitions

Note: A contracture is distinguished from the temporary loss of range of motion of a joint following injury, surgery, casting, or other immobilization.

Knee flexion contracture: a condition in which there is shortening of the muscles and/or tendons with the resulting inability to bring the knee to 0 degrees extension or greater (i.e., hyperextension) by passive range of motion. (0 degrees knee extension is when the femur and tibia are in alignment in a horizontal plane).

Knee extension contracture: a condition in which there is shortening of the muscles and/or tendons with the resulting inability to bring the knee to 80 degrees flexion or greater by passive range of motion.

Knee Orthoses: are rigid or semi-rigid devices, which are used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body.

Custom Fabricated item: is an item that is individually made for a specific patient. No other patient would be able to use this item. A custom fabricated item is a device which is fabricated based on clinically derived and rectified castings, tracings, measurements, and/or other images (such as X-rays) of the body part. The fabrication may involve using calculations, templates, and components. This process requires the use of basic materials including, but not limited to, plastic, metal, leather, or cloth in the form of uncut or unshaped sheets, bars, or other basic forms and involves substantial work such as vacuum forming, cutting, bending, molding, sewing, drilling, and finishing prior to fitting on the patient.

Custom fitted orthotics are:

- Devices that are prefabricated.
- They may or may not be supplied as a kit that requires some assembly. Assembly of the item and/or installation of add-on components and/or the use of some basic materials in preparation of the item does not change classification from OTS to custom fitted.
- Classification as custom fitted requires substantial modification for fitting at the time of delivery in order to provide an individualized fit, i.e., the item must be trimmed, bent, molded (with or without heat), or otherwise modified resulting in alterations beyond minimal self-adjustment.
- This fitting at delivery does require expertise of a certified orthotist or an individual who has equivalent specialized training in the provision of orthosis to fit the item to the individual.

Molded-to-Patient-Model

A particular type of custom fabricated device in which either:

- An impression (usually by means of a plaster or fiberglass cast) of the specific body part is made directly on the patient, and this impression is then used to make a positive model of the body part from which the final product is crafted; or
- A digital image of the patient's body part is made using Computer-Aided Design-Computer-Aided Manufacturing (CAD-CAM) systems software. This technology includes specialized probes/digitizers and scanners that create a computerized positive model, and then direct milling equipment to carve a positive model. The device is then individually fabricated and molded over the positive model of the patient.

Positive Model of the Patient

A positive model is an exact replica of the actual body part for which the custom fabricated is being constructed. A positive model can be produced by any of these methods:

- Molded-to-patient-model is a negative impression taken of the patient's body member and a positive model rectification is constructed;
- CAD-CAM system, by use of digitizers, transmits surface contour data to software that the practitioner uses to rectify or modify the model on the computer screen. The data depicting the modified shape is electronically transmitted to a commercial milling machine that carves the rectified model; or
- Direct formed model is one in which the patient serves as the positive model. The device is constructed over the model of the patient and is then fabricated to the patient. The completed custom fabrication is checked and all necessary adjustments are made.

Fabrication of an orthosis using molding, CAD/CAM, or similar technology without the creation of a positive model is considered to be a prefabricated orthosis.

Specialized Training

Specialized training is defined as training that provides the knowledge, skills, and experience in the provision of orthotics in compliance with all applicable Federal and State licensure and regulatory requirements.

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- Items that are prefabricated.
- They may or may not be supplied as a kit that requires some assembly. Assembly of the item and/or installation of add-on components and/or the use of some basic materials in preparation of the item does not change classification from OTS to custom fitted.
- OTS items require minimal self-adjustment for fitting at the time of delivery for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit an individual.
- This fitting does not require expertise of a certified orthotist or an individual who has specialized training in the provision of orthoses to fit the item to the individual beneficiary.
The term “minimal self-adjustment” is defined at 42 CFR §414.402 as an adjustment the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and that does not require the services of a certified orthotist (that is, an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training. For example, adjustment of straps and closures, bending or trimming for final fit or comfort (not all-inclusive) fall into this category.

Use of CAD/CAM or similar technology to create an orthosis without a positive model of the patient may be considered as OTS if the final fitting upon delivery to the patient requires minimal self-adjustment as described in this section.

Reasonable Useful Lifetime Chart

The following chart reflects the reasonable useful lifetime of prefabricated Knee Orthoses:

L1810	1 year
L1812	1 year
L1820	1 year
L1830	1 year
L1831	2 years
L1832	2 years
L1833	2 years
L1836	3 years
L1843	3 years
L1845	3 years
L1850	2 years
L1851	3 years
L1852	3 years

The reasonable useful lifetime of custom fabricated orthosis is 3 years.

- Replacement during the “reasonable useful lifetime,” is covered if the item is lost or irreparably damaged. Replacement for other reasons, including but not limited to irreparable wear, during the period of reasonable useful lifetime is denied as noncovered. L-coded additions to knee orthoses (L2275, L2320, L2330, L2385, L2390, L2395, L2397, L2405, L2415, L2425, L2430, L2492, L2750, L2755, L2780, L2785, L2795, L2800, L2810, L2820, L2830, K0672) will be denied as noncovered when the base orthosis is noncovered.

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Repairs to a covered orthosis are covered when they are necessary to make the orthosis functional. The reason for the repair must be documented in the supplier’s record. If the expense for repairs exceeds the estimated expense of providing another entire orthosis, no payment will be made for the amount in excess.

BILLING GUIDELINES

Additional Components and Features for Prefabricated Knee Orthoses

Base Code	Addition Codes - Eligible for Separate Payment
L1810	None
L1812	None
L1820	None
L1830	None
L1831	None
L1832	L2397, L2795, L2810
L1833	L2397, L2795, L2810
L1836	None
L1843	L2385, L2395, L2397
L1845	L2385, L2395, L2397, L2795
L1847	None
L1848	None
L1850	L2397
L1851	L2385, L2395, L2397
L1852	L2385, L2395, L2397, L2795

Components or features that can be physically incorporated in the specified prefabricated base orthosis but are considered not medically necessary and not covered:

Base Code	Addition Codes - Not Reasonable and Necessary
L1810	L2397
L1812	L2397
L1820	L2397
L1830	L2397

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L1831	L2397, L2795
L1832	L2405, L2415, L2492, L2785
L1833	L2405, L2415, L2492, L2785
L1836	L2397
L1843	L2405, L2492, L2785
L1845	L2405, L2415, L2492, L2785
L1847	L2397, L2795
L1848	L2397, L2795
L1850	L2275
L1851	L2405, L2492, L2785
L1852	L2405, L2415, L2492, L2785

Additional Components and Features for Prefabricated Knee Orthoses

Base Code	Addition Codes – Eligible for Separate Payment
L1834	L2795
L1840	L2385, L2390, L2395, L2397, L2405, L2415, L2425, L2430, L2492, L2755, L2785, L2795
L1844	L2385, L2390, L2395, L2397, L2405, L2492, L2755, L2785
L1846	L2385, L2390, L2395, L2397, L2405, L2415, L2492, L2755, L2785, L2795, L2800
L1860	None

Components or features that can be physically incorporated in the specified custom fabricated base orthosis but are considered not medically necessary and not covered:

Base Code	Addition Codes – Not Reasonable and Necessary
L1834	L2397, L2800
L1840	L2275, L2800
L1844	None
L1846	None
L1860	L2397

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- Brace sleeves (A9270) used in conjunction with orthoses are noncovered because they are not used to support a weak or deformed body member or to restrict or eliminate motion in a diseased or injured part of the body (i.e., it does not meet the definition of a brace).
- There is no separate payment if CAD-CAM technology is used to fabricate an Orthosis. Reimbursement is included in the allowance of the codes for custom fabricated orthoses.
- Evaluation of the beneficiary, measurement and/or casting, and fitting/adjustments of the orthosis are included in the allowance for the orthosis. There is no separate payment for these services.

Please see Local Coverage Article: Knee Orthoses - Policy Article (A52465) for additional coding guidelines.²

HCPCS CODES

All Lines of Business	
Not Covered	
A4467	Belt, strap, sleeve, garment, or covering, any type
A9270	Non-covered item or service
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
All Lines of Business	
No Prior Authorization Required	
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

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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
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

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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

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

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.

REFERENCES

1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Knee Orthoses (L33318). Effective 1/1/2020. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33318>. Accessed 2/10/2021.
2. Centers for Medicare & Medicaid Services. Local Coverage Article: Knee Orthoses - Policy Article (A52465). Effective date 2/1/2021. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52465>. Accessed 2/10/2021.