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KNEE ORTHOSES
Revised April 2023

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Dear Physician,

Knee orthoses have consistently been one of the highest sources of errors in medical reviews performed by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) and the Comprehensive Error Rate Testing (CERT) contractor. We know that ordering treating practitioners are the critical providers to document the medical necessity for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). The following information is intended to provide you with summary guidance on Medicare's coverage and documentation requirements for knee orthoses.

Coverage

Knee orthoses are covered under the Medicare braces benefit (Social Security Act §1861(s)(9)). For coverage under this benefit, the orthosis must:

- be a rigid or semi-rigid device; and,
- be 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.

Items that are not sufficiently rigid to be capable of providing the necessary immobilization or support to the body part for which it is designed do not meet the statutory definition of the braces benefit. Items that do not meet the definition of a brace are statutorily noncovered, no benefit.

Medical Necessity Documentation

CMS requires that the knee orthosis be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Information to support the medical necessity of the orthosis will come from your and other qualified healthcare practitioners' documentation. For knee orthoses to be covered for your patient, the coverage criteria must be met. Criteria are specific to each type of orthosis.

Additionally, some orthoses are included in CMS' required Prior Authorization program and in CMS' list of codes requiring a face-to-face encounter (with a qualified practitioner) and a written order prior to delivery (WOPD). Products coded as L1832, L1833, and L1851 are the affected knee orthoses.

A summary of the coverage criteria for certain types of knee orthoses, and more information pertaining to prior authorization and required face-to-face encounter and WOPD, are provided below.

Required Prior Authorization and Required Face-to-Face Encounter and Written Order Prior to Delivery List

Orthoses coded as L1832, L1833, and L1851 are included in CMS' Required Prior Authorization List and Required Face-to-Face Encounter and Written Order Prior to Delivery List.

Inclusion in the Required Face-to-Face Encounter and Written Order Prior to Delivery List means that **effective for claims with dates of service on or after April 13, 2022**, the supplier must obtain a copy of the face-to-face encounter medical record and a copy of the standard written order before delivering the orthosis to your patient.

Inclusion in the Required Prior Authorization program means that on a state-by-state, phased approach, claims for these orthoses will require that the supplier submit necessary documentation to the DME MAC for review and provisional determination of coverage.

Prior authorization is required as a condition of payment unless provision of the orthosis qualifies for an exception. Exceptions to the requirement of prior authorization include (1) provision of the orthosis by a supplier under a

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competitive bidding program exception, and (2) situations in which the medical records substantiate that submission of a prior authorization request (even if processed by the DME MAC in an expedited fashion) would result in a delay to care that would pose a risk of harm to the health or life of the beneficiary.

Summary of Coverage Criteria

Prefabricated HCPCS Codes L1810, L1812, L1820:

Coverage requires that your documentation show the patient has weakness or deformity of the knee and needs stabilization.

Prefabricated HCPCS Codes L1832, L1833, L1843, L1845, L1851, L1852 and Custom Fabricated HCPCS Codes L1844, L1846:

There are two potential paths to coverage:

1. Recent injury or surgical procedure: Requires that your documentation show the patient has had a recent injury to, or a surgical procedure on, the knee(s). In addition, the medical necessity needs to be supported by one of the ICD-10-CM codes in Group 2 or 4 codes located in the Knee Orthoses Local Coverage Determination (LCD)-related Policy Article (A52465).
2. Ambulatory and Knee Instability: Requires your documentation show that the patient is ambulatory and has knee instability. Your examination of the patient and your objective description of joint laxity (such as varus/valgus instability, anterior/posterior Drawer test) are required. In addition, the medical necessity needs to be supported by one of the Group 4 ICD-10-CM codes listed in the Knee Orthoses LCD-related Policy Article (A52465).

Prefabricated HCPCS Codes L1831 and L1836:

Coverage requires that documentation show the patient has flexion or extension contracture of the knee with movement on passive range of motion testing of at least 10 degrees (i.e., a nonfixed contracture). In addition, the medical necessity needs to be supported by one of the ICD-10-CM codes in Group 1 (located in the Knee Orthoses LCD-related Policy Article (A52465)).

Prefabricated HCPCS Code L1830 and Custom Fabricated HCPCS Codes L1834:

Coverage requires that the beneficiary has either sustained a recent injury to, or had a surgical procedure performed on, the knee(s). In addition, the medical necessity needs to be supported by one of the ICD-10-CM codes in Group 2 or 4 codes located in the Knee Orthoses LCD-related Policy Article (A52465).

Prefabricated HCPCS Code L1850:

Coverage requires that documentation shows the patient is ambulatory and has knee instability due to genu recurvatum - hyperextended knee, congenital or acquired. Examination of the patient and objective description of joint laxity (such as varus/valgus instability, anterior/posterior Drawer test) are required. In addition, the medical necessity needs to be supported by one of the Group 5 ICD-10-CM codes listed in the Knee Orthoses LCD-related Policy Article (A52465).

For any orthosis, documentation of only pain or a subjective description of joint instability does not meet the coverage criteria.

Custom Fabricated Knee Orthoses Documentation (HCPCS Codes L1834, L1840, L1844, L1846, L1860):

A custom fabricated knee orthosis has the same basic coverage criteria as the same type of prefabricated knee orthosis. However, there must also be documentation in your records to medically describe why your patient needs a custom fabricated device instead of a prefabricated knee orthosis.

Examples of situations which meet the criterion for a custom fabricated knee orthosis include, but are not limited to, deformity of the leg or knee, size of thigh or calf, and minimal muscle mass upon which to suspend an orthosis.

This is a brief summary of the Knee Orthoses LCD (https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDid=33318) and related Policy Article (https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52465) requirements, as well as an overview of the impacts for certain products affected by Prior Authorization and the Required Face-to-Face Encounter and Written Order Prior to Delivery List. We encourage you to review the entire LCD, LCD-related Policy Article, and published Prior Authorization and face-to-face encounter and WOPD resources, for a complete description of the coverage, coding, and documentation requirements.

Sincerely,

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ANKLE-FOOT/KNEE-ANKLE-FOOT ORTHOSES
Revised April 2023

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Dear Physician,

Medicare provides reimbursement for ankle-foot orthoses (AFOs) and knee-ankle-foot orthoses (KAFOs) when certain coverage criteria are met. The following information is intended to provide you with summary guidance on Medicare's coverage and documentation requirements for these orthoses.

Coverage

Ankle-foot orthoses and KAFOs are covered under the Medicare braces benefit (Social Security Act §1861(s)(9)). For coverage under this benefit, the orthosis must:

- be a rigid or semi-rigid device; and,
- be 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.

Items that are not sufficiently rigid to be capable of providing the necessary immobilization or support to the body part for which it is designed do not meet the statutory definition of the braces benefit. Items that do not meet the definition of a brace are statutorily noncovered, no benefit.

Medical Necessity Documentation

CMS requires that the orthosis be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Information to support the medical necessity of the orthosis will come from your and other qualified healthcare practitioners' documentation. In order for the orthosis to be covered for your patient, the coverage criteria must be met. A summary of the coverage criteria for certain orthoses is provided below.

AFOs Not Used During Ambulation:

An L4396 or L4397 (static or dynamic positioning AFO) is covered if either all of criteria 1 - 4 or criterion 5 is met:

1. Plantar flexion contracture of the ankle (refer to the Group 1 Codes in the ICD-10 code list in the Local Coverage Determination (LCD) related Policy Article for applicable diagnoses) with dorsiflexion on passive range of motion testing of at least 10 degrees (i.e., a nonfixed contracture); and,
2. Reasonable expectation of the ability to correct the contracture; and,
3. Contracture is interfering or expected to interfere significantly with the beneficiary's functional abilities; and,
4. Used as a component of a therapy program which includes active stretching of the involved muscles and/or tendons.
5. The beneficiary has plantar fasciitis (refer to the Group 1 Codes in the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses).

AFOs and KAFOs Used During Ambulation:

Ankle-foot orthoses described by codes L1900, L1902, L1904, L1906, L1907, L1910, L1920, L1930, L1932, L1940, L1945, L1950, L1951, L1960, L1970, L1971, L1980, L1990, L2106, L2108, L2112, L2114, L2116, L4350, L4360, L4361, L4386, L4387 and L4631 are covered for ambulatory beneficiaries with weakness or deformity of the foot and ankle, who:

1. Require stabilization for medical reasons, and,

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2. Have the potential to benefit functionally.

Knee-ankle-foot orthoses described by codes L2000, L2005, L2010, L2020, L2030, L2034, L2035, L2036, L2037, L2038, L2126, L2128, L2132, L2134, L2136, and L4370 are covered for ambulatory beneficiaries for whom an AFO is covered and for whom additional knee stability is required.

Custom Fabricated AFOs and KAFOs (HCPCS Codes L1900, L1904, L1907, L1920, L1940, L1945, L1950, L1960, L1970, L1980, L1990, L2000, L2005, L2010, L2020, L2030, L2034, L2036, L2037, L2038, L2106, L2108, L2126, L2128, L4631):

Ankle-foot orthoses and KAFOs that are custom-fabricated are covered for ambulatory beneficiaries when the basic coverage criteria and one of the following criteria are met:

1. The beneficiary could not be fit with a prefabricated AFO; or,
2. The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months); or,
3. There is a need to control the knee, ankle or foot in more than one plane; or,
4. The beneficiary has a documented neurological, circulatory, or orthopedic status that requires custom fabricating over a model to prevent tissue injury; or,
5. The beneficiary has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.

This article is only intended to be a general summary. It is not intended to take the place of the written law, regulations, national coverage determinations (NCDs) or LCDs. Coverage, coding and documentation requirements for AFOs and KAFOs may be found in the Ankle-Foot/Knee-Ankle-Foot Orthosis LCD (https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDid=33686) and LCD-related Policy Article (https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52457), located in the Medicare Coverage Database at https://www.cms.gov/medicare-coverage-database.

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DOCUMENTATION OF ARTIFICIAL LIMBS AND BRACES (O&P)
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Dear Physician,

An amendment to the Social Security Act states that documentation created by an orthotist or prosthetist shall be considered part of the individual's medical record to support documentation created by physicians and certain other non-physician practitioners. The Durable Medical Equipment Medical Administrative Contractors (DME MACs) have jurisdiction for processing claims from orthotists and prosthetists for artificial limbs and braces, commonly called orthotics and prosthetics (O&P). In the event of a claim review, the O&P supplier may request your medical records, in addition to providing their notes to the Medicare contractor. The O&P supplier's notes are only part of the whole medical record and are considered in the context of documentation made by you and other healthcare practitioners to provide additional details to demonstrate that the prosthetic arm or leg, or orthotic billed to Medicare was reasonable and necessary. In other words, the O&P supplier's notes are expected to corroborate and provide details consistent with your (physician/practitioner) records. In the event of a conflict between your notes and the O&P supplier's record, the DME MAC would likely deny payment. Similarly, payment may not be provided solely based on O&P documentation. Therefore, in the absence of physician/practitioner documentation, the DME MACs may deny payment for the orthotic or prosthetic.

Your patient's functional capabilities are crucial to establishing the medical necessity for a prosthetic device. Many prosthetic components are restricted to specific functional levels; therefore, it is critical that you thoroughly document the functional capabilities of your patient, both before and after amputation. Clinical assessments of your patient's rehabilitation potential must be based on the following classification levels:

> Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
>
> Level 1: Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
>
> Level 2: Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.
>
> Level 3: Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
>
> Level 4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

Simply stating the functional level in your patient's record is not sufficient. Your records must document your patient's current functional capabilities and their expected functional potential, including an explanation for the difference. Note that it is recognized, within the functional classification hierarchy, that bilateral amputees often cannot be strictly bound by functional level classifications.

Your assessment of your patient's physical and cognitive capabilities should typically include:

- History of the present condition(s) and past medical history that is relevant to functional deficits
    - Symptoms limiting ambulation or dexterity
    - Diagnoses causing these symptoms
    - Other co-morbidities relating to ambulatory problems or impacting the use of a new prosthesis
    - What ambulatory assistance (cane, walker, wheelchair, caregiver) is currently used (either in addition to the prosthesis or prior to amputation)

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- Description of activities of daily living and how impacted by deficit(s)

- Physical examination that is relevant to functional deficits
  - Weight and height, including any recent weight loss/gain
  - Cardiopulmonary examination
  - Musculoskeletal examination
    - Arm and leg strength and range of motion
  - Neurological examination
    - Gait
    - Balance and coordination

The assessment points above are not all-inclusive and you should tailor your patient's history and examination to their individual clinical condition, clearly describing the pre- and post-amputation capabilities of your patient. The history should paint a picture of your patient's functional abilities and limitations on a typical day, taking into account any co-morbidities. It should contain as much objective data as possible. The physical examination should be focused on the body systems that are responsible for your patient's ambulatory or upper extremity difficulties or that impact your patient's functional ability.

With respect to documentation of orthotics, unlike prosthetics, orthotics are not classified by functional levels. A focused history and examination of the impacted body part is critical to establishing medical necessity. Certain types of orthotics have specific coverage requirements with which you should familiarize yourself. These coverage details are available in the Ankle-Foot/Knee-Ankle-Foot Orthosis, Knee Orthoses and Spinal Orthoses: TLSO and LSO Local Coverage Determinations (L33686, L33318, and L33790, respectively) and related Policy Articles found on the Medicare Coverage Database.

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