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.

A summary of the coverage criteria for certain types of knee orthoses, and 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 Lists

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, L1843, L1845, and L1851 are the affected knee orthoses included in CMS' Required Prior Authorization List. Products coded as L1832, L1843, L1845, L1851, and L1852 are the affected knee orthoses included in CMS' 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 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 the supplier is to 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 competitive bidding program exception, and (2) situations in which the medical records substantiate that submission

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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 (L33318) and LCD-related Policy Article (A52465) 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. Please refer to the complete Knee Orthoses LCD (L33318) and LCD-related Policy Articles (A52465 and A55426) in the Medicare Coverage Database at http://www.cms.gov/medicare-coverage-database. For detailed information on prior authorization requirements, see the DME MAC webpage dedicated to prior authorization (https://www.cgsmedicare.com/jb/pa/index.html). For detailed information on face-to-face and written order prior to delivery requirements, see CMS' Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Order and Face-to-Face Encounter Requirements webpage (https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/FacetoFaceEncounterRequirementforCertainDurableMedicalEquipment). We encourage you to review the entirety of these resources, for a full description of the coverage, coding, and documentation requirements.

Sincerely,

Smitha M. Ballyamanda MD, CAQSM
Medical Director, DME MAC, Jurisdiction A
Noridian Healthcare Solutions, LLC

Robert D. Hoover, Jr., MD, MPH, FACP
Medical Director, DME MAC, Jurisdiction C
CGS Administrators, LLC

Sunil V. Lalla, MD, FACS, CPC
Medical Director, DME MAC, Jurisdiction B
CGS Administrators, LLC

Angela S. Jenny, DO, DABFM
Medical Director, DME MAC, Jurisdiction D
Noridian Healthcare Solutions, LLC