Disclaimer: Draft articles are works in progress and not necessarily a reflection of the current billing and coding practices. The draft article information contained in this document does not represent nor does it include all information found in an active LCD-related Policy Article. For example, abridged ICD-10-CM code information relevant to the proposed LCD may be included; unchanged ICD-10-CM code information may not be included. Please refer to the active LCD-related Policy Article in effect on the Medicare Coverage Database, if applicable, for current billing and coding information.

Contractor Information:

Contractor Name	Contract Type	Contract Number	Jurisdiction
CGS Administrators, LLC	DME MAC	17013 - DME MAC	Jurisdiction B
CGS Administrators, LLC	DME MAC	18003 - DME MAC	Jurisdiction C
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	Jurisdiction A
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	Jurisdiction D

DRAFT

Knee Orthoses – Policy Article

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. “reasonable and necessary”).

For a beneficiary’s orthosis to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination (LCD) must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Knee orthoses (KO) 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,

which is 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.

Both "off-the-shelf" (OTS) and custom-fit items are considered prefabricated braces for Medicare coding purposes. 42 CFR §414.402 establishes that correct coding of KO items is dependent upon whether there is a need for "minimal self-adjustment" during the final fitting at the time of delivery. (See definitions below in CODING GUIDELINES.) If a custom fit code is billed when minimal self-adjustment was provided at the final delivery, or if an OTS code is billed when more than minimal self-adjustments were made at the final delivery, the claim will be denied as incorrect coding.

Elastic or other fabric support garments (A4467 (BELT, STRAP, SLEEVE, GARMENT, OR COVERING, ANY TYPE)) with or without stays or panels do not meet the statutory definition of a brace because they are not rigid or semi-rigid devices. Code A4467 is denied as noncovered (no Medicare benefit). Refer to the CODING GUIDELINES section below for additional information.

There is no separate payment for computer-aided design/computer-aided manufacturing (CAD/CAM) technology when it is used to fabricate an orthosis. Reimbursement, of the CAD/CAM technology utilized in the fabrication of an orthosis, is included in the allowance of the orthosis HCPCS code.

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.

Payment for knee orthoses are included in the payment to a hospital or skilled nursing facility (SNF) if:

1. The orthosis is provided to a beneficiary prior to an inpatient hospital admission or Part A covered SNF stay; and

2. The medical necessity for the orthosis begins during the hospital or SNF stay (e.g., after knee surgery).

A claim should not be submitted to the DME MAC in this situation.

Payment for knee orthoses are also included in the payment to a hospital or a Part A covered SNF stay if:

1. The orthosis is provided to a beneficiary during an inpatient hospital or Part A covered SNF stay prior to the day of discharge; and

2. The beneficiary uses the item for medically necessary inpatient treatment or rehabilitation.

A claim must not be submitted to the DME MAC in this situation.

Payment for knee orthoses delivered to a beneficiary in a hospital or a Part A covered SNF stay is eligible for coverage by the DME MAC if:

1. The orthosis is medically necessary for a beneficiary after discharge from a hospital or Part A covered SNF stay; and

2. The orthosis is provided to the beneficiary within two days prior to discharge to home; and

3. The orthosis is not needed for inpatient treatment or rehabilitation but is left in the room for the beneficiary to take home.

REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO FINAL RULE 1713 (84 Fed. Reg Vol 217)

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes. CMS and the DME MACs provide a list of the specified codes, which is periodically updated. The required Face-to-Face Encounter and Written Order Prior to Delivery List is available here .

Claims for the specified items subject to Final Rule 1713 (84 Fed. Reg Vol 217) that do not meet the face-to-face encounter and WOPD requirements specified in the LCD-related Standard Documentation Requirements Article (A55426) will be denied as not reasonable and necessary.

If a supplier delivers an item prior to receipt of a WOPD, it will be denied as not reasonable and necessary. If the WOPD is not obtained prior to delivery, payment will not be made for that item even if a WOPD is subsequently obtained by the supplier. If a similar item is subsequently provided by an unrelated supplier who has obtained a WOPD prior to delivery, it will be eligible for coverage.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

For a knee orthosis with adjustable knee joints or a prefabricated Swedish type knee orthosis (L1832, L1833, L1850), the medical records must include documentation of the beneficiary's physical examination of the affected knee(s), including all of the following:

1. The joint laxity test(s) performed; and,
2. A description of the exam findings that support objective joint laxity.

For a knee orthosis with single or double upright, adjustable flexion and extension joint, medial-lateral and rotation control, with or without varus/valgus adjustment (L1843, L1845, L1851,

L1852) for the management of an ambulatory beneficiary with knee instability, the medical records must include documentation of all of the following:

1. The beneficiary's ambulatory status; and,
2. A physical examination of the affected knee(s), including all of the following:
   a. The joint laxity test(s) performed; and,
   b. A description of the exam findings that support objective joint laxity.

For a knee orthosis with single or double upright, adjustable flexion and extension joint, medial-lateral and rotation control, with varus or valgus adjustment (L1843, L1844, L1845, L1846, L1851, L1852) used for the management of pain affecting mobility and/or function due to medial or lateral tibiofemoral osteoarthritis, the beneficiary's medical records must include documentation of all of the following:

1. The beneficiary's ambulatory status; and,
2. The beneficiary's pain symptoms, or mobility and/or functional reduction due to the medial or lateral tibiofemoral osteoarthritis; and,
3. A physical examination of the beneficiary's affected knee(s); and,
4. An imaging report (e.g., x-ray, CT scan, MRI) that describes arthritic changes (e.g., joint space narrowing, bone spurs, cysts) consistent with medial or lateral compartment tibiofemoral osteoarthritis; and,
5. The beneficiary's willingness to use the knee orthosis.

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

Based on Social Security Act §1834(h)(5), for purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the individual's medical record to support documentation created by the treating practitioner.

General Requirements

The supplier must include on the claim line the diagnosis code(s) for HCPCS codes L1830, L1831, L1832, L1833, L1834, L1836, L1840, L1843, L1844, L1845, L1846, L1850, L1851, L1852 and L1860.

For a custom-fabricated orthosis, there must be documentation in the supplier's records to support the medical necessity of that type of device rather than a prefabricated orthosis. This information must be available upon request.

When providing orthoses suppliers must:

- Provide the product that is specified by the treating practitioner
- Be sure that the treating practitioner's medical record justifies the need for the type of product (i.e., prefabricated versus custom fabricated)
- 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

For prefabricated orthoses (L1810, L1812, L1820, L1821, L1830, L1831, L1832, L1833, L1836, L1843, L1845, L1847, L1848, L1850, L1851, L1852), there is no physical difference between orthoses coded as custom fitted versus those coded as OTS. The differentiating factor for proper coding (see definitions in the CODING GUIDELINES section below) is the need for "minimal self-adjustment" at the time of fitting by the beneficiary, caretaker for the beneficiary, or supplier. This minimal self-adjustment does not require the services of a certified orthotist or an individual who has specialized training (as defined in the CODING GUIDELINES section). Items requiring minimal self-adjustment are coded as OTS orthoses. For example, adjustment of straps and closures, bending or trimming for final fit or comfort (not all-inclusive) fall into this category.

Items requiring more than minimal self-adjustment by a qualified practitioner (as defined in the CODING GUIDELINES below) are coded as custom fitted (L1810, L1832, L1843, L1845, L1847). Documentation must be sufficiently detailed to include, but is not limited to, a detailed description of the modifications necessary at the time of fitting the orthosis to the beneficiary. This information must be available upon request.

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 the custom fabricated orthosis rather than a prefabricated orthosis as described in the "Coverage Indications, Limitations, and/or Medical Necessity" section of the related LCD. This information will be corroborated by the functional evaluation in the orthotist's records and the method of custom fabrication should adhere to the DMEPOS Quality Standards, Appendix C. This information must be available upon request.

MODIFIERS

KX, GA, GZ, LT and RT MODIFIERS:

Suppliers must add a KX modifier to the KO base and addition codes only if all of the coverage criteria in the "Coverage Indications, Limitations, and/or Medical Necessity" section of the related LCD have been met and evidence of such is retained in the supplier's files and available to the DME MAC upon request.

If all of the criteria in the "Coverage Indications, Limitations, and/or Medical Necessity" section of the related LCD have not been met, the GA or GZ modifier must be added to the code. When

there is an expectation of a medical necessity denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

Claims lines billed with codes without a KX, GA or GZ modifier will be rejected as missing information.

The right (RT) and/or left (LT) modifiers must be used when billing for orthosis base codes, additions and replacement parts. Effective for claims with dates of service (DOS) on or after 3/1/2019, when the same code for bilateral items (left and right) is billed on the same date of service, bill each item on two separate claim lines using the RT and LT modifiers and 1 unit of service (UOS) on each claim line. Do not use the RTLT modifier on the same claim line and billed with 2 UOS. Claims billed without modifiers RT and/or LT, or with RTLT on the same claim line and 2 UOS, will be rejected as incorrect coding.

MISCELLANEOUS

If the item is custom fabricated and does not have a specific HCPCS code, a complete and clear description of the item, including what makes this item unique, and a breakdown of charges (material and labor used in fabrication) should be entered in the narrative field of an electronic claim or on Item 19 of a paper claim. (Refer to the LCD-related Standard Documentation Requirements article (A55426) for more information regarding billing of items with HCPCS codes that include miscellaneous, NOC, unlisted, or non-specified in their narrative descriptions.)

A claim for code L4205 must include an explanation of what is being repaired. A claim for code L4210 must include a description of each item that is billed. This information should be entered in the narrative field of an electronic claim. (Refer to the REPAIR/REPLACEMENT section for more information regarding billing of L4205 and L4210 HCPCS codes.)

All codes for orthoses or repairs of orthoses billed with the same date of service must be submitted on the same claim.

CODING GUIDELINES:

CUSTOM FABRICATED

A custom fabricated item is one 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-fabricated additions are appropriate only for custom-fabricated base orthotics and should not be billed with prefabricated base orthotics.

Use of an additive manufacturing technique, CAD/CAM, or a similar manufacturing technique is not the sole requirement for a product to be designated as custom fabricated.

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 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 item is being constructed. A positive model can be produced by any of these methods:

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

Additive Manufacturing

Additive manufacturing (such as 3D printing) is an advanced technology that constructs three-dimensional items modeled and designed from CAD software and/or from digital scanning. Additive manufacturing is an acceptable custom fabrication technique as long as it adheres to the CMS DMEPOS Quality Standards, Appendix C.

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.

PREFABRICATED

A prefabricated orthosis is an item that is manufactured in quantity without a specific beneficiary in mind. A prefabricated orthosis may be considered an OTS or a custom fitted device that may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific beneficiary. An orthosis that is assembled from prefabricated components is considered prefabricated. It is inherent in the definition of prefabricated that a particular item is complete.

Off-the-shelf (OTS) orthotics are:

- 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. See “more than minimal self-adjustment” definition below for additional information.

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 more than minimal self-adjustment 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 specialized training in the provision of the orthosis to fit the item to the individual beneficiary.

In contrast to "minimal self-adjustment," "more than minimal self-adjustment" is defined as changes made to achieve an individualized fit during the final fitting at the time of delivery of the item that requires the expertise of a certified orthotist or an individual who has specialized training in the provision of orthotics in compliance with all applicable Federal and State licensure and regulatory requirements. A certified orthotist is defined as an individual who is

certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification.

Correct coding of prefabricated orthoses is dictated by actions that take place at the time of fitting to the beneficiary, either custom fitted (requiring expertise) or OTS (requiring minimal self-adjustment).

Corresponding HCPCS Code Sets

For many prefabricated orthoses, corresponding sets of HCPCS codes are available which describe the identical types of items. The corresponding code sets, when available for identical products, are only differentiated by the nature of the final fitting performed at the time of delivery. The corresponding HCPCS code types are:

- HCPCS codes which describe "PREFABRICATED, OFF-THE-SHELF." These HCPCS codes must be used when minimal self-adjustment is the extent of the fitting performed at delivery.
- HCPCS codes which describe "PREFABRICATED ITEM THAT HAS BEEN TRIMMED, BENT, MOLDED, ASSEMBLED, OR OTHERWISE CUSTOMIZED TO FIT A SPECIFIC PATIENT BY AN INDIVIDUAL WITH EXPERTISE." These HCPCS codes must be used when more than minimal self-adjustment is necessary and performed at delivery.

In the following table, the HCPCS codes located in Column I and Column II within the same row are considered a corresponding HCPCS code set. These codes represent identical products which are only differentiated by the nature of the final fitting performed at the time of delivery.

Column I	Column II
L1810	L1812
L1820	L1821
L1832	L1833
L1843	L1851
L1845	L1852
L1847	L1848

For some prefabricated orthoses, corresponding sets of HCPCS codes (which describe the identical types of items) are not available. HCPCS codes with long descriptions of "PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT" describe custom fitted items. For these HCPCS codes there are no corresponding OTS codes. When the unique HCPCS code that most closely describes the product includes "PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT" in the HCPCS long description, the supplier must:

- Code the product using the unique HCPCS code, if the product was custom fitted at the time of delivery to the beneficiary; or,

- Code the product using a miscellaneous HCPCS code, if the product was not custom fitted at delivery to the beneficiary and, instead, was provided as OTS to the beneficiary. The miscellaneous HCPCS code for billing of KOs is HCPCS code L2999.

Kits are:

- A collection of components, materials, and parts that require further assembly before delivery of the final product.
- The elements of a kit may be packaged and complete from a single source or may be an assemblage of separate components from multiple sources by the supplier.

ELASTIC AND SIMILAR STRETCHABLE MATERIALS

For items where the HCPCS code specifies "elastic" or other similar terminology for stretchable material, use the code that is most applicable to the item. A NOC (Not Otherwise Classified) or miscellaneous HCPCS code must not be used instead of the specific code. Refer to the long code narrative and any relevant coding guideline for the criteria applicable for each HCPCS code.

For items where the HCPCS code does not specify elastic or other similar terminology for stretchable material, the following guidelines apply:

- Items that are primarily constructed of elastic or other stretchable materials (e.g. support items made of material such as neoprene or spandex (elastane, Lycra®) (not all-inclusive)) must be coded as A4467 (BELT, STRAP, SLEEVE, GARMENT, OR COVERING, ANY TYPE).

- Items that are primarily constructed of elastic or other stretchable materials (e.g. support items made of material such as neoprene or spandex (elastane, Lycra®) (not all-inclusive)) that contain stays and/or panels must be coded as A4467 (BELT, STRAP, SLEEVE, GARMENT, OR COVERING, ANY TYPE).

- Items that are primarily constructed of inelastic material (e.g., canvas, cotton or nylon (not all-inclusive)) that are incapable of providing the necessary immobilization or support to the body part for which it is designed must be coded using A4467 (BELT, STRAP, SLEEVE, GARMENT, OR COVERING, ANY TYPE).

- Items that are primarily of constructed inelastic material (e.g., canvas, cotton or nylon (not all-inclusive)) that are incapable of providing the necessary immobilization or support to the body part for which it is designed and that have stays and/or panels capable of providing the required immobilization or support to the body part for which it is designed, must be coded using A4467 (BELT, STRAP, SLEEVE, GARMENT, OR COVERING, ANY TYPE).

- Items that are primarily constructed of inelastic material (e.g., canvas, cotton or nylon (not all-inclusive)) capable of providing the necessary immobilization or support to the body part for which it is designed must be coded using the applicable specific HCPCS

code for the type of product. A NOC (Not Otherwise Classified) or miscellaneous HCPCS code must not be used instead of the specific code. Refer to the long code narrative and any relevant coding guideline for the criteria applicable for each HCPCS code.

- Items that are primarily of constructed inelastic material (e.g., canvas, cotton or nylon (not all-inclusive)) capable of providing the necessary immobilization or support to the body part for which it is designed and that have stays and/or panels capable of providing the required immobilization or support to the body part for which it is designed, must be coded using the applicable specific HCPCS code for the type of product. A NOC (Not Otherwise Classified) or miscellaneous HCPCS code must not be used instead of the specific code. Refer to the long code narrative and relevant coding guideline for the criteria applicable for each HCPCS code.

- Items that are not capable of providing the necessary immobilization or support to the body part for which it is designed (regardless of materials) must be coded using A9270 (NON-COVERED ITEM OR SERVICE).

KNEE ORTHOSES

Codes 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) and L1812 (KNEE ORTHOSIS, ELASTIC WITH JOINTS, PREFABRICATED, OFF-THE-SHELF) describe prefabricated knee orthoses constructed of latex, neoprene, spandex or other elastic material. There are no condylar pads. There are hinges or joints.
Codes L1820 (KNEE ORTHOSIS, ELASTIC WITH CONDYLAR PADS AND JOINTS, WITH OR WITHOUT PATELLAR CONTROL, PREFABRICATED ITEM THAT HAS BEEN TRIMMED, BENT, MOLDED, ASSEMBLED, OR OTHERWISE CUSTOMIZED TO FIT A SPECIFIC PATIENT BY AN INDIVIDUAL WITH EXPERTISE) and L1821 (KNEE ORTHOSIS, ELASTIC WITH CONDYLAR PADS AND JOINTS, WITH OR WITHOUT PATELLAR CONTROL, PREFABRICATED, OFF THE SHELF) describe prefabricated knee orthoses with hinges or joints, constructed of latex, neoprene, spandex or other elastic material. There are medial and lateral condylar pads.

Code L1830 (KNEE ORTHOSIS, IMMOBILIZER, CANVAS LONGITUDINAL, PREFABRICATED, OFF-THE-SHELF) describes a prefabricated knee orthosis immobilizer, with rigid metal or plastic stays placed laterally and posteriorly. The interface material is constructed of canvas, closed cell foam or equal. The thigh and calf cuffs are one-piece construction held in place by Velcro® straps or equal. The orthosis immobilizes the knee joint and prevents flexion or extension. There are no hinges or joints.

Codes L1831 (KNEE ORTHOSIS, LOCKING KNEE JOINT(S), POSITIONAL ORTHOSIS, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT), L1847 (KNEE ORTHOSIS, DOUBLE UPRIGHT WITH ADJUSTABLE JOINT, WITH INFLATABLE AIR SUPPLY CHAMBER(S), PREFABRICATED ITEM THAT HAS BEEN TRIMMED, BENT, MOLDED,

ASSEMBLED, OR OTHERWISE CUSTOMIZED TO FIT A SPECIFIC PATIENT BY AN INDIVIDUAL WITH EXPERTISE) and L1848 (KNEE ORTHOSIS, DOUBLE UPRIGHT WITH ADJUSTABLE JOINT, WITH INFLATABLE AIR SUPPLY CHAMBER(S), PREFABRICATED, OFF-THE-SHELF) describe prefabricated knee orthoses with joint(s) which lock the knee into a particular position. Codes L1847 and L1848 are distinguished from L1831 by the addition of an air bladder in the space behind the knee. These orthoses are designed for beneficiaries who are nonambulatory. They are typically used to treat flexion/extension contractures of the knee.

An adjustable flexion and extension joint is one that enables the practitioner to set limits on flexion and extension but allows the beneficiary free motion of the knee within those limits. The increments of adjustability must be, at a minimum, 15 degrees. The joint may be either unicentric or polycentric.

Codes 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) and L1833 (KNEE ORTHOSIS, ADJUSTABLE KNEE JOINTS (UNICENTRIC OR POLYCENTRIC), POSITIONAL ORTHOSIS, RIGID SUPPORT, PREFABRICATED, OFF-THE-SHELF) describe prefabricated knee orthoses that have double uprights and adjustable flexion and extension joints. Medial-lateral control of the knee is accomplished by the solid metal (or similar material) structure of the double uprights. They may have condylar pads. These orthoses are designed for a beneficiary who can bear weight on the knee and is capable of ambulation. They are typically used for early rehabilitation following knee surgery.
Codes L1834 (KNEE ORTHOSIS, WITHOUT KNEE JOINT, RIGID, MOLDED TO PATIENT MODEL, CUSTOM-FABRICATED) and L1836 (KNEE ORTHOSIS, RIGID, WITHOUT JOINT(S), INCLUDES SOFT INTERFACE MATERIAL, PREFABRICATED, OFF-THE-SHELF) describe rigid knee orthoses without a knee joint. Both are designed to prevent knee motion. These orthoses are designed for beneficiaries who can bear weight on the knee, are capable of ambulating, and need additional support provided through immobilization of the knee joint. Code L1834 refers to a custom fabricated knee orthotic while L1836 refers to one that is pre-fabricated.

Code L1840 (KNEE ORTHOSIS, DEROTATION, MEDIAL-LATERAL, ANTERIOR CRUCIATE LIGAMENT, CUSTOM-FABRICATED) describes a custom fabricated knee orthosis with knee joints designed to protect the ligaments of the knee through medial-lateral torsion, providing stability and preventing rotation.

Codes 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), and L1851 (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, OFF-THE-SHELF) describe prefabricated and custom fabricated knee orthoses which are constructed of rigid thigh and calf cuffs and a single upright with an adjustable flexion and extension knee joint. These orthoses must have condylar pads. Through a series of straps/supports that cross over and around the knee joint, rotational control and varus or valgus force is exerted on the knee joint. These orthoses are designed to open the medial or lateral compartment of the knee to provide pain relief due to osteoarthritis. These orthoses are designed for beneficiaries who are fully ambulatory.

Codes 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), and L1852 (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, OFF-THE-SHELF) describe prefabricated and custom fabricated knee orthoses that have double uprights, condylar pads, and an adjustable flexion and extension joint and provide both medial-lateral and rotation control. Medial-lateral control of the knee is accomplished by the solid metal (or similar material) structure of the double uprights. Rotation control is accomplished by the combination of (1) solid metal (or similar material) in the anterior or posterior portion of the thigh and calf cuffs and (2) the condylar pads. These orthoses are designed for beneficiaries who are fully ambulatory.

Code L1850 (KNEE ORTHOSIS, SWEDISH TYPE, PREFABRICATED, OFF-THE-SHELF) describes a prefabricated knee orthosis with double uprights and thigh and calf pads. It may or may not have joints. These orthoses are used to prevent hyperextension of the knee joint in ambulatory beneficiaries.

Code L1860 (KNEE ORTHOSIS, MODIFICATION OF SUPRACONDYLAR PROSTHETIC SOCKET, CUSTOM-FABRICATED (SK)) describes a custom fabricated knee orthosis without joints, constructed of plastic or other similar material. These orthoses are used to prevent hyperextension of the knee joint in ambulatory beneficiaries.

LOWER EXTREMITY ADDITIONS

Custom-fabricated additions are appropriate only for custom-fabricated base orthotics and should not be billed with prefabricated base orthotics unless a product has been previously assigned an addition code per PDAC/CMS prior to 1/1/2023. Correct coding with use of addition codes should not include, or partially include, features or functions described by other codes billed for a specific device.

Code L2755 (ADDITION TO LOWER EXTREMITY ORTHOSIS, HIGH STRENGTH, LIGHTWEIGHT MATERIAL, ALL HYBRID LAMINATION/PREPREG COMPOSITE, PER SEGMENT, FOR CUSTOM FABRICATED ORTHOSIS ONLY) describes an addition to a lower extremity orthosis composed of high strength and/or lightweight material such as Kevlar®, carbon fiber or other laminated or impregnated composite material.

"Addition" codes are grouped into four (4) categories in relation to knee orthosis base codes.

- Eligible for separate payment
- Not reasonable and necessary
- Not separately payable
- Incompatible

Addition codes in the first two categories are addressed in the related LCD. Addition codes that are not separately payable are addressed in the tables below.

The following table lists addition codes which describe components or features that can be physically incorporated in the **specified prefabricated base orthosis** but are considered to be included in the allowance for the orthosis.

Base Code	Addition Codes - Not Separately Payable
L1810	L2390, L2750, L2780, L4002
L1812	L2390, L2750, L2780, L4002
L1820	L2390, L2750, L2780, L2810, L4002
L1821	L2390, L2750, L2780, L2810, L4002
L1830	K0672, L4002
L1831	K0672, L2390, L2425, L2430, L2750, L2780, L2810, L2820, L2830, L4002
L1832	K0672, L2390, L2425, L2430, L2750, L2780, L2820, L2830, L4002
L1833	K0672, L2390, L2425, L2430, L2750, L2780, L2820, L2830, L4002
L1836	K0672, L2750, L2780, L2810, L2820, L2830, L4002
L1843	K0672, L2275, L2390, L2425, L2430, L2750, L2780, L2810, L2820, L2830, L4002
L1845	K0672, L2275, L2390, L2425, L2430, L2750, L2780, L2810, L2820, L2830, L4002
L1847	K0672, L2390, L2425, L2430, L2750, L2780, L2810, L2820, L2830, L4002
L1848	K0672, L2390, L2425, L2430, L2750, L2780, L2810, L2820, L2830, L4002
L1850	K0672, L2750, L2780, L2810, L2820, L2830, L4002
L1851	K0672, L2275, L2390, L2425, L2430, L2750, L2780, L2810, L2820, L2830, L4002
L1852	K0672, L2275, L2390, L2425, L2430, L2750, L2780, L2810, L2820, L2830, L4002

The following table lists addition codes which describe components or features that can be physically incorporated in the **specified custom fabricated base orthosis** but are considered to

be included in the allowance for the orthosis. The addition codes will be denied as not separately payable if they are billed with the related base code.

Base Code	Addition Codes - Not Separately Payable
L1834	K0672, L2820, L2830, L4002
L1840	K0672, L2320, L2330, L2750, L2780, L2810, L2820, L2830, L4002
L1844	K0672, L2275, L2320, L2330, L2425, L2430, L2750, L2780, L2810, L2820, L2830, L4002
L1846	K0672, L2275, L2320, L2330, L2425, L2430, L2750, L2780, L2810, L2820, L2830, L4002
L1860	K0672, L2820, L2830, L4002

All addition codes that are not listed as either separately payable or not reasonable and necessary in the tables in the LCD or as not separately payable in the tables above, describe components or features that either cannot be physically incorporated in the specified base orthosis or whose narrative description is incompatible with base orthosis code (e.g., billing a prefabricated base code with an addition code which specifies that it is only used with custom fabricated orthoses). These incompatible addition codes will be rejected as incorrect coding.

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.

A replacement removable soft interface for a knee orthosis is billed with code K0672 (ADDITION TO LOWER EXTREMITY ORTHOSIS, REMOVABLE SOFT INTERFACE, ALL COMPONENTS, REPLACEMENT ONLY, EACH). One unit of service includes all the components that are used at the same time on a single orthosis.
Either a nonremovable soft interface, 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), or two (2) removable soft interfaces (K0672) are included in the allowance for a knee orthosis. Soft interfaces billed separately at the time of initial issue will be denied as not separately payable.

Codes L2320 (ADDITION TO LOWER EXTREMITY, NON-MOLDED LACER, FOR CUSTOM FABRICATED ORTHOSIS ONLY) and L2330 (ADDITION TO LOWER EXTREMITY, LACER MOLDED TO PATIENT MODEL, FOR CUSTOM FABRICATED ORTHOSIS ONLY), non-molded and molded lacers, respectively, may only be billed as replacement items.

CONCENTRIC TORSION JOINTS

All claims for devices that contain a concentric adjustable torsion style mechanism in the knee joint for any condition other than an assistive function to joint extension motion must be coded as durable medical equipment using code E1810 (DYNAMIC ADJUSTABLE KNEE EXTENSION AND FLEXION DEVICE, INCLUDES SOFT INTERFACE MATERIAL), E1813 (DYNAMIC ADJUSTABLE KNEE EXTENSION ONLY DEVICE, INCLUDES SOFT

INTERFACE MATERIAL), or E1814 (DYNAMIC ADJUSTABLE KNEE FLEXION ONLY DEVICE, INCLUDES SOFT INTERFACE MATERIAL). If a concentric adjustable torsion style mechanism in the knee joint is used solely to provide an assistive function for joint extension, it must be coded as L2999 (See the Coverage Indications, Limitations and/or Medical Necessity section of the related LCD).

Claims for devices that contain a concentric adjustable torsion style mechanism in the knee joint and that are being used to treat any condition other than an assistive function to joint extension motion are not covered under the braces benefit and will be denied as incorrect coding when billed using code L2999 (See the Coverage Indications, Limitations and/or Medical Necessity section of the related LCD).

REPAIR/REPLACEMENT

Code L4205 (REPAIR OF ORTHOTIC DEVICE, LABOR COMPONENT, PER 15 MINUTES) may only be billed for time involved with the actual repair of an orthosis or for medically necessary adjustments made more than 90 days after delivery. Code L4205 must not be used to bill for time involved with other professional services including, but not limited to:

- Evaluating the beneficiary
- Taking measurements, making a cast, making a model, use of CAD/CAM
- Making modifications to a prefabricated item to fit it to the individual beneficiary
- Follow-up visits
- Making adjustments at the time of or within 90 days after delivery

Suppliers must distinguish between repair and replacement of an orthosis. When an orthotic is replaced, there is no separate billing for the above services because reimbursement for these services is included in the allowance for the replacement item.

Repairs to a covered orthosis due to wear or to accidental damage 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.

The allowance for the labor involved in replacing/repairing an orthotic component that is coded with a specific L-code is included in the allowance for that component. The allowance for the labor (L4205) involved in replacing/repairing an orthotic component that is coded with the miscellaneous code L4210 (REPAIR OF ORTHOTIC DEVICE, REPAIR OR REPLACE MINOR PARTS) is separately payable in addition to the allowance for that component. (Code L4210 must not be used for casting supplies or other materials used in the fitting or fabrication of an orthosis.)

The following chart reflects the reasonable useful lifetime of prefabricated knee orthoses:

Code	Reasonable Useful Lifetime
L1810	1 year
L1812	1 year
L1820	1 year
L1821	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 a 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.

Addition codes K0672, L2390, L2750, L2780, L4002 are for billing of replacement component(s) and are not payable at initial issue of a base orthosis. When code L4002 is billed at the time of initial issue of a base orthosis, it will be denied as not separately payable.
Should a supplier wish to submit a claim for services/items that are included in the allowance for the orthosis, code L9900 (ORTHOTIC AND PROSTHETIC SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS "L" CODE) must be used. Code L9900 is denied as not separately payable.

Some replacement items have unique Healthcare Common Procedure Coding System (HCPCS) codes. Replacement components that do not have a unique HCPCS code must be billed with a "not otherwise specified" code - L2999. Items that have unique codes must not be billed using a NOC code.

Suppliers should contact the PDAC contractor for guidance on the correct coding of these items.

CODING VERIFICATION REVIEW

The only products which may be billed using the following list of HCPCS codes are those for which a written coding verification review (CVR) has been made by the PDAC contractor and subsequently published on the Product Classification List (PCL). Information concerning the documentation that must be submitted to the PDAC for a CVR can be found on the PDAC web

site or by contacting the PDAC. A PCL with products which have received a coding verification can be found on the PDAC web site. The effective date of the CVR is included for each code.

Effective for claims with dates of service on or after July 1, 2008:
L1845

Effective for claims with dates of service on or after January 1, 2017:
L1852

Effective for claims with dates of service on or after October 10, 2022:
L1832, L1833 and L1851

Effective for claims with dates of service on or after December 1, 2024:
L1843

If a product is billed to Medicare using a HCPCS code that requires written CVR, but the product is not on the PCL for that particular HCPCS code, then the claim line will be denied as incorrect coding.

Coding Information

ICD-10-CM Codes that Support Medical Necessity

[addition] **Group 6 Paragraph**
For HCPCS Codes L1843, L1844, L1845, L1846, L1851 and L1852:

Group 6 Codes
[addition] M17.0 Bilateral primary osteoarthritis of knee
[addition] M17.11 Unilateral primary osteoarthritis, right knee
[addition] M17.12 Unilateral primary osteoarthritis, left knee
[addition] M17.2 Bilateral post-traumatic osteoarthritis of knee
[addition] M17.31 Unilateral post-traumatic osteoarthritis, right knee
[addition] M17.32 Unilateral post-traumatic osteoarthritis, left knee
[addition] M17.4 Other bilateral secondary osteoarthritis of knee
[addition] M17.5 Other unilateral secondary osteoarthritis of knee
[addition] M17.9 Osteoarthritis of knee, unspecified

ICD-10-CM Codes that DO NOT Support Medical Necessity
[no change]

Associated Documents:

This draft document is an attachment to the proposed Knee Orthoses LCD (DL33318) that has a Proposed LCD Posting Date of 07/24/2025.