Knee Orthoses

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➲ Terms and Conditions

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Policy Summary

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Overview

For any item to be covered, 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. For the items addressed in this policy guideline, the criteria for "reasonable and necessary", based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

For an item to be covered, a Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed SWO, the item will be denied as not reasonable and necessary.

Guidelines

Prefabricated Knee Orthoses (L1810, L1812, L1820, L1830, L1831, L1832, L1833, L1836, L1843, L1845, L1847, L1848, L1850, L1851, L1852):

A knee flexion contracture is 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). A knee extension contracture is 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. A contracture is distinguished from the temporary loss of range of motion of a joint following injury, surgery, casting, or other immobilization.

A knee orthosis with joints (L1810, L1812) or knee orthosis with condylar pads and joints with or without patellar control (L1820) are covered for ambulatory members who have weakness or deformity of the knee and require stabilization.

If an L1810, L1812 or L1820 is provided but the criteria above are not met, the orthosis will be denied as not reasonable and necessary.

A knee orthosis with a locking knee joint (L1831) or a rigid knee orthosis (L1836) is covered for members 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).

If an L1831 or L1836 orthosis is provided but the criterion above is not met, the orthosis will be denied as not reasonable and necessary.

There is no proven clinical benefit to the inflatable air bladder incorporated into the design of code L1847 or L1848; therefore, claims for code L1847 or L1848 will be denied as not reasonable and necessary.

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), are covered if the member has had recent injury to or a surgical procedure on the knee(s).

Knee orthoses L1832, L1833, L1843, L1845, L1851, and L1852 are also covered for a member who is ambulatory and has knee instability due to a condition specified in the covered diagnosis list.

Knee orthosis, Swedish type, prefabricated (L1850) is covered for a member who is ambulatory and has knee instability due to genu recurvatum – hyperextended knee, congenital or acquired.

For codes L1832, L1833, L1843, L1845, L1850, L1851, and L1852, knee instability must be documented by examination of the member and objective description of joint laxity (e.g., varus/valgus instability, anterior/posterior Drawer test).

Claims for L1832, L1833, L1843, L1845, L1850, L1851, or L1852 will be denied as not reasonable and necessary when the member does not meet the above criteria for coverage. For example, they will be denied if only pain or a subjective description of joint instability is documented.

“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

The following table lists addition codes which describe components or features that can be and frequently are physically incorporated in the specified prefabricated base orthosis. Addition codes may be separately payable if:
- They are provided with the related base code orthosis; and
- The base orthosis is reasonable and necessary; and
- The addition is reasonable and necessary.

Addition codes will be denied as not reasonable and necessary if the base orthosis is not reasonable and necessary or the addition is not reasonable and necessary.

Base Code	Addition Codes – Eligible for Separate Payment
L1810	None
L1812	None
L1820	None
L1830	None
L1831	None
L1832	L2397, L2795, L2810

Base Code	Addition Codes – Eligible for Separate Payment
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

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 not reasonable and necessary. These addition codes, if they are billed with the related base code, will be denied as not reasonable and necessary.

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

The following table lists addition codes which describe components or features that can be physically incorporated in the specified prefabricated bases 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 Code – Not Separately Payable
L1810	L2390, L2750, L2780, L4002
L1812	L2390, L2750, L2780, L4002
L1820	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

Base Code	Addition Code – Not Separately Payable
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

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

A custom fabricated orthosis is 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:

- Deformity of the leg or knee;
- Size of thigh and calf;
- Minimal muscle mass upon which to suspend an orthosis.

Although these are examples of potential situations where a custom fabricated orthosis may be appropriate, suppliers must consider prefabricated alternatives such as pediatric knee orthoses in members with small limbs, straps with additional length for large limbs, etc.

Custom fabricated orthoses (L1834, L1840, L1844, L1846, L1860) are not reasonable and necessary in the treatment of knee contractures in cases where the member is nonambulatory.

A custom fabricated knee immobilizer without joints (L1834) is covered if criteria 1 and 2 are met:

1. The coverage criteria for the prefabricated orthosis code L1830 are met; and
2. The general criterion defined above for a custom fabricated orthosis is met.

If an L1834 orthosis is provided and both criteria 1 and 2 are not met, the orthosis will be denied as not reasonable and necessary.

A custom fabricated derotation knee orthosis (L1840) is covered for instability due to internal ligamentous disruption of the knee.

A custom fabricated knee orthosis with an adjustable flexion and extension joint (L1844, L1846) is covered if criteria 1 and 2 are met:

1. The coverage criteria for the prefabricated orthosis codes L1843, L1845, L1851, and L1852 are met; and
2. The general criterion defined above for a custom fabricated orthosis is met.

If an L1844 or L1846 orthosis is provided and both criteria 1 and 2 are not met the orthosis will be denied as not reasonable and necessary.

A custom fabricated knee orthosis with a modified supracondylar prosthetic socket (L1860) is covered for a member who is ambulatory and has knee instability due to genu recurvatum – hyperextended knee.

The following table lists addition codes which describe components or features that can be and frequently are physically incorporated in the specified custom fabricated base orthosis. Addition codes may be separately payable if:

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

Addition codes will be denied as not reasonable and necessary if the base orthosis is not reasonable and necessary or the addition is not reasonable and necessary.

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

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 not reasonable and necessary. These addition codes, if they are billed with the related base code, will be denied as not reasonable and necessary.

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

The following table lists addition codes which describe components or features that can be physically incorporated in the specified custom fabricated bases orthosis but that 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

Miscellaneous

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 and 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))
- 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
- 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
- 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

Items that are primarily constructed of inelastic material (e.g., canvas, cotton or nylon (not all-inclusive)), with or without stays and/or panels 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 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 (Noncovered Item or Service).

Code L2999 (lower extremity orthosis, not otherwise specified) should be used only when billing for item(s) that do not meet the definition of an existing code(s).

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).

Policy Specific Documentation Requirements

For prefabricated orthoses, there is no physical difference between orthoses coded as custom fitted versus those coded as off-the-shelf. The differentiating factor for proper coding is the need for "minimal self-adjustment" at the time of fitting by the member, caretaker for the member, or supplier. This minimal self-adjustment does not require the services of a certified orthotist or an individual who has specialized training. Items requiring minimal self-adjustment are coded as off-the-shelf orthoses. For example, adjustment of straps and closures, bending or trimming for final fit or comfort (not all-inclusive) fall into this category.

Fabrication of an orthosis using CAD/CAM or similar technology without the creation of a positive model with minimal self-adjustment at delivery is considered as OTS.

Items requiring substantial modification by a qualified practitioner 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 member. 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 custom fabricated rather than a prefabricated orthosis. This information will be corroborated by the functional evaluation in the orthotist or prosthetist' s records. This information must be available upon request. There is no separate billing if CAD-CAM technology is used to fabricate an orthosis. Reimbursement is included in the allowance of the codes for custom fabricated orthoses.

When providing these items suppliers must:

- Provide the product that is specified by the prescribing practitioner
- Be sure that the ordering physician/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

Suppliers must add a KX modifier to knee orthoses base and addition codes only if all of the coverage criteria have been met and evidence of such is retained in the supplier's files and available upon request.

Repair/Replacement

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.

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.

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. A treating practitioner's order, when required, is needed to reaffirm the medical necessity of the item for replacement of an item.

Documentation Requirements – General

There are numerous CMS manual requirements, reasonable and necessary requirements, benefit category, and other statutory and regulatory requirements that must be met in order for payment to be justified. In the event of a claim review, a DMEPOS supplier must provide sufficient information to demonstrate that the applicable criteria have been met thus justifying payment. Refer to the LCD, NCD or other CMS Manuals for more information on what documents may be required.

See Article A55426 Standard Documentation Requirements for All Claims Submitted to DME MACs.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
A4467	Belt, strap, sleeve, garment, or covering, any type (Status Indicator of "N" on Medicare Physician Fee Schedule) (Not Covered by Medicare)
A9270	Non-covered item or service (Status Indicator of "N" on Medicare Physician Fee Schedule) (Not covered by Medicare)
K0672	Addition to lower extremity orthotic, 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 orthotic, 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 orthotic, locking knee joint(s), positional orthotic, prefabricated, includes fitting and adjustment
L1832	Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1833	Knee orthosis, adjustable knee joints (unicentric or polycentric), positional orthosis, rigid support, prefabricated, off-the shelf
L1834	Knee orthotic (KO), without knee joint, rigid, custom fabricated
L1836	Knee orthosis, rigid, without joint(s), includes soft interface material, prefabricated, off-the-shelf
L1840	Knee orthotic (KO), 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

HCPCS Code	Description
L1844	Knee orthotic (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, 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 orthotic, double upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, custom fabricated
L1847	Knee orthosis, double upright with adjustable joint, with inflatable air support chamber(s), prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1848	Knee orthosis, double upright with adjustable joint, with inflatable air support chamber(s), prefabricated, off-the-shelf
L1850	Knee orthosis, Swedish type, prefabricated, off-the-shelf
L1851	Knee orthosis (KO), single upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated, off-the-shelf
L1852	Knee orthosis (KO), double upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated, off-the-shelf
L1860	Knee orthotic (KO), 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 orthotic only
L2330	Addition to lower extremity, lacer molded to patient model, for custom fabricated orthotic 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 orthotic, 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 orthotic, plating chrome or nickel, per bar
L2755	Addition to lower extremity orthotic, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthotic only
L2780	Addition to lower extremity orthotic, noncorrosive finish, per bar
L2785	Addition to lower extremity orthotic, drop lock retainer, each
L2795	Addition to lower extremity orthotic, knee control, full kneecap
L2800	Addition to lower extremity orthotic, knee control, knee cap, medial or lateral pull, for use with custom fabricated orthotic only
L2810	Addition to lower extremity orthotic, knee control, condylar pad
L2820	Addition to lower extremity orthotic, soft interface for molded plastic, below knee section

HCPCS Code	Description
L2830	Addition to lower extremity orthotic, soft interface for molded plastic, above knee section
L2999	Lower extremity orthotic, not otherwise specified
L4002	Replacement strap, any orthotic, 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

Modifier	Description
EY	No physician or other licensed health care provider order for this item or service
GZ	Item or service expected to be denied as not reasonable and necessary
KX	Requirements specified in the medical policy have been met
LT	Left side
RT	Right side

Diagnosis Code
Knee Orthoses: Diagnosis Code List

Definitions

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 Fitted Orthotics: Prefabricated item that requires substantial modification e.g., has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by certified orthotist or an individual with equivalent expertise.

Minimal Self-Adjustment: An adjustment the member, caretaker for the member, 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.

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.

Off-the-Shelf (OTS) Orthotics: Prefabricated item that requires minimal self-adjustment such as being trimmed, bent, molded, assembled, or otherwise adjusted to fit the member. Minimal self-adjustment does not require the expertise of a certified orthotist or an individual with equivalent expertise.

Orthosis (Brace): 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. An orthosis can be classified as either prefabricated (off-the-shelf or custom fitted) or custom-fabricated.

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.

Specialized Training: Training that provides the knowledge, skills, and experience in the fitting of orthoses comparable to that of a certified orthotist. Individuals with specialized training necessary to provide custom fitting services for patients with a medical need for orthotics include: a physician, a treating practitioner (a physician assistant, nurse practitioner, or clinical nurse specialist), an occupational therapist, or physical therapist. All providers must be in compliance with all applicable Federal and State licensure and regulatory requirements.

Substantial Modification: 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 equivalent specialized training in the provision of orthotics such as a physician, treating practitioner, an occupational therapist, or physical therapist 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.

Questions and Answers

1	Q:	Is the prefabricated orthotic furnished with custom fitting that is and can only be provided by an individual with expertise or furnished off-the-shelf (OTS)?
	A:	Classification depends on (1) what must be done at final fitting and (2) who must do it. Expertise of a qualified practitioner and substantial modification at the time of delivery qualify the items for classification as custom fitted. Fail either one of these criteria and the item is classified as off-the-shelf.

References

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	DME MAC
L33318 Knee Orthoses	A52465 Knee Orthoses – Policy Article	CGS	AL, AR, CO, FL, GA, ID, IL, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV
		Noridian	AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MP, MT, NH, NJ, ND, NE, NV, NY, OR, PA, RI, SD, UT, VT, WA, WY
	A55426 Standard Documentation Requirements for All Claims Submitted to DME MACs	CGS	AL, AR, CO, FL, GA, ID, IL, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV
		Noridian	AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MP, MT, NH, NJ, ND, NE, NV, NY, OR, PA, RI, SD, UT, VT, WA, WY

CMS Benefit Policy Manual

Chapter 15; §110 Durable Medical Equipment – General

CMS Transmittal(s)

Transmittal 3052, Change Request 8839, Dated 08/26/2014 (Two New "K" Codes for Prefabricated Single and Double Upright Knee Orthosis That Are Furnished Off-The-Shelf (OTS))

MLN Matters

Article MM8839, Two New "K" Codes for Prefabricated Single and Double Upright Knee Orthoses that are Furnished Off-The-Shelf (OTS)

UnitedHealthcare Commercial Policy

Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies, and Repairs/Replacements

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	**Template Update** • Reformatted policy; transferred content to new template

06/10/2020	**Policy Summary**
	Overview
	• Replaced language indicating "for an item to be covered, a *detailed written order (DWO)* must be *received by the supplier* before a claim is submitted" with "for an item to be covered, a *standard written order (SWO)* must be *communicated* to the supplier before a claim is submitted"
	Repair/Replacement
	• Removed language pertaining to documentation requirements for repairs to a member owned item
	Documentation Requirements
	• Removed detailed documentation requirements
	• Added language to indicate:
	  ○ There are numerous CMS manual requirements, reasonable and necessary requirements, benefit category, and other statutory and regulatory requirements that must be met in order for payment to be justified
	  ○ In the event of a claim review, a DMEPOS supplier must provide sufficient information to demonstrate that the applicable criteria have been met thus justifying payment
	  ○ Refer to the Local Coverage Determination (LCD), National Coverage Determination (NCD) or other Centers for Medicare & Medicare Services (CMS) manuals for more information on what documents may be required
	  ○ See the Local Coverage Article (LCA) titled *Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)*
	Supporting Information
	• Updated *References* section to reflect the most current information
	• Archived previous policy version MPG184.04

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.