# PROPOSED/DRAFT Local Coverage Determination (LCD): Lower Limb Prostheses (DL33787)

# [ PROPOSED/DRAFT ]

**Please Note:** This is a Proposed/Draft policy.

Proposed/Draft LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Proposed/Draft LCDs are not necessarily a reflection of the current policies or practices of the contractor.

# **Contractor Information**

Contractor NameContract NumberContract TypeNHIC, Corp.16003DME MAC

# **Proposed/Draft LCD Information**

Document Information

Source LCD ID L33787

Proposed/Draft LCD ID

Original ICD-9 LCD ID

N/A

DL33787

Proposed/Draft LCD Title

Lower Limb Prostheses

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CPT only copyright 2002-2014 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

The Code on Dental Procedures and Nomenclature (Code) is published in Current Dental Terminology (CDT). Copyright (c) American Dental Association. All rights reserved. CDT and CDT-2010 are trademarks of the American Dental Association.

UB-04 Manual. OFFICIAL UB-04 DATA SPECIFICATIONS MANUAL, 2014, is copyrighted by American Hospital Association ("AHA"), Chicago, Illinois. No portion of OFFICIAL UB-04 MANUAL may be

Jurisdiction

Connecticut Delaware

District of Columbia

Maine Maryland Massachusetts New Hampshire

New Jersey

New York - Entire State

Pennsylvania Rhode Island Vermont

DME Region LCD

**Covers**Jurisdiction A

reproduced, sorted in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without prior express, written consent of AHA. Health Forum reserves the right to change the copyright notice from time to time upon written notice to Company.

# **CMS National Coverage Policy**

# **Coverage Guidance**

### Coverage Indications, Limitations, and/or Medical Necessity

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. For the items addressed in this local coverage determination, 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.

Medicare does not automatically assume payment for a durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) item that was covered prior to a beneficiary becoming eligible for the Medicare Fee For Service (FFS) program. When a beneficiary receiving a DMEPOS item from another payer (including Medicare Advantage plans) becomes eligible for the Medicare FFS program, Medicare will pay for continued use of the DMEPOS item only if all Medicare coverage, coding and documentation requirements are met. Additional documentation to support that the item is reasonable and necessary, may be required upon request of the DME MAC.

For an item to be covered by Medicare, a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed DWO, the item will be denied as not reasonable and necessary.

#### **DEFINITIONS**

For purposes of this policy, the following definitions apply.

An initial prosthesis is defined as the first (initial) prosthesis reimbursed by Medicare. This includes (1) a prosthesis provided for the first time after an amputation that occurs during the beneficiary's Medicare eligibility and (2) "replacement" of an existing prosthesis obtained prior to or outside of the Medicare program. Each new, initial prosthesis claim must meet all applicable Medicare payment rules for an initial prosthesis in effect on the date of service of the initial claim.

A replacement prosthesis is defined as the replacement of a complete, existing definitive prosthesis or major component part of an existing definitive prosthesis, such as socket, knee, foot/ankle, etc. (not all-inclusive), previously reimbursed by Medicare. Claims for a replacement must meet the payment rules for replacement of items in effect on the date of service for the replacement claim. Claims for replacement of an existing prosthesis obtained prior to or outside of the Medicare program are considered to be claims for a new, initial item. (See above)

A repair to a prosthesis or a major component means to fix or mend the non-functioning item to restore it to normal working condition. A repair includes the replacement of minor parts but does not include the complete replacement of the prosthesis or major component. A repair includes

reasonable labor charges for the diagnosis of the problem and time necessary to make the repair.

An immediate prosthesis, also referred to as a post-operative prosthesis, is applied in the operating room immediately following amputation. It helps control initial swelling, reduce pain, protect the amputation site by enveloping the residual limb in a rigid dressing, and allows for immediate, although light, ambulatory rehabilitation. Immediate prostheses are for use during the time after amputation when the residual limb is healing prior to the provision of a preparatory prosthesis.

A preparatory prosthesis is an unfinished, functional replacement for an amputated limb, fitted and aligned to accelerate the rehabilitation process, control edema, and prepare the residual limb for the external forces associated with the wearing of a prosthesis on a day-to-day basis. It is provided after the initial surgery after the wound has healed but before the residual limb has matured. Preparatory prostheses are for use during the time after amputation when the residual limb is healing and maturing prior to the provision of the definitive prosthesis.

A definitive prosthesis is a replacement for the missing limb or part of a limb, meeting standards for comfort, fit, alignment, function, appearance, and durability. It is provided after the surgical wound has healed and the residual limb has matured.

A new amputation is defined as the first amputation of a lower extremity, as a revision to the original amputation site, or as a subsequent amputation proximal to the initial amputation site.

A revised amputation is defined as additional surgery to an existing amputation site.

A mature residual limb is defined as one that has healed, reached its optimal volume, and been shaped appropriately to accommodate the chosen socket configuration.

A "Licensed or Certified Medical Professional (LCMP)" is defined as a Physician (MD/DO), Physician Assistant (PA), Nurse Practitioner (NP), or Physical Therapist (PT) with training, experience, and whose scope of practice permits the comprehensive functional assessment of beneficiaries with amputations.

#### I. GENERAL

Lower limb prostheses fall into three general groups: IMMEDIATE (POST OPERATIVE) PROSTHESIS, PREPARATORY PROSTHESES and DEFINITIVE PROSTHESES. Each group has requirements that must be met as specified below.

#### II. IMMEDIATE PROSTHESES (L5400-L5460)

Initial immediate prostheses (L5400-L5460) are covered for a beneficiary with a new or revised amputation when all of the requirements below are met:

- The beneficiary has had an appropriate above or below knee amputation.
- The immediate prosthesis is provided after surgery, while the surgical incision is still healing.
- The beneficiary is motivated to ambulate using the prosthesis.

Immediate prostheses (L5400-L5460) do not require functional (K-level) determinations to be eligible for reimbursement.

If there is no qualifying amputation, claims will be denied as statutorily non-covered, no benefit. Refer to the NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the related Policy Article for additional information about statutory and benefit category requirements.

If the beneficiary is unable or unwilling to use the prosthesis, the claim will be denied as not reasonable and necessary.

If any part of a prosthesis is denied as not reasonable and necessary, all related additions will also be denied as not reasonable and necessary.

Immediate prostheses (L5400-L5460) are complete and all-inclusive as described by the code narratives and in the CODING GUIDELINES section in the related Policy Article. There is no coverage for any additional components, add-ons, upgrades, substitution of components, etc. (not all-inclusive) provided for use with an immediate or post-operative prosthesis. All additional items will be denied as not reasonable and necessary.

A test (diagnostic) socket (L5618-L5628) is not reasonable and necessary for an immediate prosthesis (L5400-L5460). Claims for test sockets will be denied as not reasonable and necessary.

Immediate prostheses (L5400-L5460) provided other than to a new amputee will be denied as not reasonable and necessary.

Immediate prostheses (L5400-L5460) provided after the surgical incision has healed will be denied as not reasonable and necessary.

Medicare payment for prosthetics includes all fitting and adjustments necessary in the 90 days after provision (date of service (DOS)) of the prosthesis, therefore all additions, adjustments, modifications, replacement etc. to any components provided as part of the prosthesis and billed separately during the 90 days after provision of the prosthesis will be denied as unbundling.

Medicare payment rules for prosthetic items include all necessary fitting, adjustments, etc. necessary during the 90 days following the date of service. A replacement immediate prosthesis (L5400-L5460) provided sooner than 90 days after a previous immediate prosthesis will be denied as same/similar item.

Socket or other component replacements provided during the 90 days after provision of the immediate prosthesis will be denied as unbundling.

#### III. PREPARATORY PROSTHESES (L5500-L5600)

A preparatory prosthesis (L5500-L5600) is covered for a beneficiary with a new or revised amputation when all of the requirements below are met:

- The beneficiary has had an appropriate above or below knee amputation.
- The preparatory prosthesis is provided to a beneficiary starting a rehabilitation program.
- The preparatory prosthesis is provided after the surgical incision has healed.
- The beneficiary is motivated to ambulate using the prosthesis.

Preparatory prostheses (L5500-L5600) do not require functional (K-level) determinations to be eligible for reimbursement.

If there is no qualifying amputation, claims will be denied as statutorily non-covered, no benefit. Refer to the NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the related Policy Article for additional information about statutory and benefit category requirements.

If the beneficiary is unable or unwilling to use the prosthesis, the claim will be denied as not reasonable and necessary.

If any part of a prosthesis is denied as not reasonable and necessary, all related additions will also be denied as not reasonable and necessary.

Preparatory prostheses are fitted and used during a rehabilitation program (see below) while the residual limb is reshaping and maturing. Preparatory prostheses fitted to a mature residual limb will be denied as not reasonable and necessary.

Preparatory prostheses use basic prosthetic components, which provide adjustability and alignment changes as limb maturity occurs. Preparatory prostheses (L5500-L5600) are all-inclusive as described by the code narrative and in the CODING GUIDELINES section in the related Policy Article. There is no coverage for any additional components, add-ons, upgrades, additions, adjustments, modifications, replacement etc. substitution of components, etc. provided for concurrent use with a preparatory prosthesis. All additional items will be denied as not reasonable and necessary.

Medicare payment for prosthetics includes all fitting and adjustments necessary in the 90 days after provision of the prosthesis, therefore all additions, adjustments, modifications, replacement etc. to any components provided as part of the prosthesis and billed separately during the 90 days after provision of the prosthesis will be denied as unbundling.

Medicare payment rules for prosthetic items include all necessary fitting, adjustments, etc. necessary during the 90 days following the date of service. A replacement preparatory prosthesis (L5500-L5600) provided sooner than 90 days after a previous preparatory prosthesis will be denied as same/similar item.

Socket or other component replacements provided during the 90 days after provision of the prosthesis will be denied as unbundling.

Preparatory prosthesis (L5500-L5600) provided other than to a new amputee will be denied as not reasonable and necessary.

#### IV. DEFINITIVE PROSTHESIS

#### **Initial Definitive Prosthesis**

An initial definitive prosthesis is covered for a beneficiary who meets all of the criteria below:

- The beneficiary has had an appropriate above or below knee amputation.
- The definitive prosthesis is provided to a beneficiary who has successfully completed a rehabilitation program.
- The definitive prosthesis is provided after the surgical incision is stable (healed).
- The definitive prosthesis is provided after the residual limb has matured.
- The beneficiary is motivated to ambulate using the prosthesis.
- The beneficiary is cognitively capable of using the prosthesis to ambulate effectively at the determined functional level (K0 K4).
- The beneficiary has sufficient neuromuscular control to effectively and appropriately make use of the prosthesis at the determined functional level (K0 K4).

- The beneficiary has sufficient cardio-pulmonary capacity to effectively use the prosthesis at the determined functional level (K0 K4).
- The beneficiary has had an in-person medical evaluation with the ordering physician to establish their overall functional capabilities. (NOTE: The ordering physician my delegate this assessment to a licensed/certified medical professional (LCMP) defined as a physical therapist (PT) or occupational therapist (OT), or physician with training and expertise in the functional evaluation of beneficiaries with amputations. Refer to the DOCUMENTATION REQUIREMENTS section for additional information.) This specialty evaluation must:
  - Evaluate and document the beneficiary's over-all health status taking into consideration factors related to the amputation and prosthesis use as well the effect of co-morbidities on potential function. The evaluation must include a complete physical examination including an objective neuromuscular evaluation, cardiopulmonary capacity evaluation and cognitive evaluation.
  - Determine a global activity level as described by the functional level modifiers. (K-levels).
  - o That the treating physician and/or the LCMP that performed the in-person assessment must have no financial relationship with the supplier.
- The beneficiary has had an in-person evaluation by the prosthetist to evaluate prosthetic needs consistent with the overall functional capabilities identified by the medical examination.
- The beneficiary is able to ambulate using the device at or above the identified functional level.

If there is no qualifying amputation, claims will be denied as statutorily non-covered, no benefit. Refer to the NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the related Policy Article for additional information about statutory and benefit category requirements.

If the beneficiary is unable or unwilling to use the prosthesis, the claim will be denied as not reasonable and necessary.

If any part of a prosthesis is denied as not reasonable and necessary, all related additions will also be denied as not reasonable and necessary.

Definitive prosthesis (L5000 through L5341) are all-inclusive for all components necessary for a complete prosthesis. Separate components (sockets, knees, ankles, feet, pylons, etc. (not all-inclusive)) billed with these codes will be denied as unbundling.

Preparatory prostheses are fitted and used during a rehabilitation program while the residual limb is reshaping and maturing. Definitive prostheses and components fitted to a non-mature residual limb will be denied as not reasonable and necessary.

Medicare payment for prosthetics includes all fitting and adjustments necessary in the 90 days after provision of the prosthesis, therefore all additions, adjustments, modifications, replacement etc. to any components provided as part of the prosthesis and billed separately during the 90 days after provision of the prosthesis will be denied as unbundling.

Medicare payment for prosthetics includes all fitting and adjustments necessary in the 90 days after provision of a prosthesis, therefore a definitive prosthesis may not be provided sooner than 90 days after the preparatory prosthesis.

Socket or other component replacements provided during the 90 days after provision of the prosthesis will be denied as unbundling.

#### Replacement of a Definitive Prosthesis

Replacement requirements for beneficiary-owned artificial limbs are statutorily defined. Refer to the NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the related Policy Article for additional information about statutory and benefit category requirements.

#### V. COMPONENTS

#### Sockets

One socket (L5630, L5632-L5636, L5638-L5653) per individual definitive prosthesis is covered.

Socket replacements (L5700-L5703) for a preparatory prosthesis are covered when either 1 or 2 are met:

- There are changes in the residual limb that cannot be accommodated thought the use of socket inserts and/or liners and/or stump stockings, and/or modifications to the existing socket, or
- 2. When the existing socket is irreparable due to damage or wear

Socket replacements (L5630, L5632-L5636, L5638-L5653, L5700-L5703) for a definitive prosthesis are covered when either 1 or 2 are met:

- There are changes in the residual limb that cannot be accommodated thought the use of socket inserts and/or liners and/or stump stockings, and/or modifications to the existing socket, or
- 2. When the existing socket is irreparable due to damage or wear

Sockets replacements (L5630, L5632-L5636, L5638-L5653) are not separately payable when billed with an immediate or preparatory prosthesis (L5400-L5600). Claims for sockets billed with an immediate or preparatory prosthesis will be denied as unbundling.

More than two (2) test (diagnostic) sockets (L5618-L5628) for an individual definitive prosthesis are not reasonable and necessary.

Acrylic resin laminations (L5629, L5631) provide for an intimate fit and a firm, smooth, bearing surface. Acrylic laminations are only covered for sockets that are not molded to a patient or patient model e.g. wood (L5639, L5644). Acrylic laminations are not separately payable when billed with any other socket type (L5630, L5632-L5636, L5638, L5640-L5643, L5645-L5653) as this function is included in the base code. Claims for acrylic resin laminations billed with a socket other than L5639 or L5644 will be denied as unbundling.

A molded distal cushion (L5668) is not covered when used in conjunction with a liner or insert that incorporates materials that provide cushioning (L5646, L5648, L5673, L5679, L5681, L5683, L8417). Claims for L5668 used in this scenario will be denied as not reasonable and necessary, same/similar item.

A total contact addition to lower extremity (L5637 (below knee), L5650 (above knee)) is a socket feature where the intimate fit of the socket around the residual limb creates a negative pressure, therefore, total contact design keeps the prosthesis in position without a pelvic joint and belt. Total contact design is inherent in the production of a molded suction socket and is included in the payment for any molded socket. Claims for L5637 and L5650 will be denied as unbundling when billed with a molded socket design.

#### **Socket Inserts**

A non-custom fabricated socket insert (L5645, L5654-L5665) is a soft form insert that is contoured to fit around the residual limb and fits inside the socket to provide an interface for padding, comfort and to reduce movement of the residual limb within the socket. No more than two (2) non-custom fabricated socket inserts of the same type (same HCPCS code) are allowed per individual prosthesis. It is not necessary to combine different types (different codes) of socket inserts. Combinations of differing types of socket inserts (different HCPCS codes used together on the same limb) will be denied as not reasonable and necessary, same/similar items.

Non-custom socket insert replacement is covered when the existing insert is no longer able to function as an effective interface between the residual limb and socket.

A custom fabricated socket insert (L5673, L5679, L5681, L5683) is covered when non-custom socket inserts (L5645, L5654-L5665,) are unable to provide an adequate interface between the residual limb and socket caused by irregular contours in the shape of the residual limb that can't be compensated for by changing to a different type of non-custom insert.

A custom fabricated socket insert (L5673, L5679, L5681, L5683) is made from a model created from a mold of the beneficiary's residual limb. Codes L5681 and L5683 include the creation of the beneficiary model in addition to the production and fitting of the socket insert. Codes L5673 and L5679 describe inserts created from an existing beneficiary model. Codes L5673 and L5679 includes products that are (1) custom fabricated to an existing beneficiary model, or (2) prefabricated but custom fitted to an existing beneficiary model.

A custom fabricated socket insert coded as L5681 or L5683 is only covered for the first custom fabricated socket insert produced from a newly created beneficiary model. The second and all subsequent inserts created from the same model are coded as L5673 or L5679.

If a beneficiary qualifies for a custom fabricated socket insert (see above), at initial issue only one (1) unit of either L5681 or L5683 is covered. One (1) unit of either L5673 or L5679 is also covered. Claims for more than one (1) unit of L5681 or L5683 (per prosthesis) will be denied as not reasonable and necessary, duplicate item.

Replacement of either L5681 or L5683 is covered only if there has been both; (1) sufficient change in the residual limb such that replacement inserts produced from the existing beneficiary model no longer are functional as an adequate interface between the residual limb and the socket, and (2) non-custom socket inserts are demonstrated to provide an inadequate interface between the residual limb and socket.

Replacement of L5673 or L5679 is covered only if (1) the existing insert is no longer are functional as an adequate interface between the residual limb and the socket, and (2) non-custom socket inserts are demonstrated to provide an inadequate interface between the residual limb and socket.

#### **Suspension Systems**

All prosthesis requires some type of suspension system to keep the prosthesis from falling off the residual limb. Suspension can be achieved by a variety of methods that may be broadly grouped into two categories, (1) mechanical suspension, and (2) suction suspension. A suspension system is covered for immediate, preparatory, and definitive prosthesis.

Claims for more than one method or type of suspension per prosthesis will be denied as not reasonable and necessary (duplicate item).

Some prostheses are complete or all-inclusive systems. Separate billing for a suspension system with these items will be denied as unbundling.

#### **Mechanical Suspension**

Mechanical suspension is accomplished by a variety of techniques including, belts, sleeves, straps, socket design features, and various pin-locking mechanisms (L5666, L5670-L5672).

Claims for a suspension system (L5666, L5670-L5672) are not separately paid when the suspension system is incorporated as part of a socket/liners combination where the liner contains an already integrated suspension mechanism (L5673, L5679, L5681, L5683, L5685). In the Table below Column II items are included in the Column I items. Claims for suspensions billed with these liners will be denied as unbundling.

Column I	Column II
L5673, L5679, L5681, L5683, L5685	L5666, L5670-L5672

An L5671 (ADDITION TO LOWER EXTREMITY, BELOW KNEE / ABOVE KNEE SUSPENSION LOCKING MECHANISM (SHUTTLE, LANYARD OR EQUAL), EXCLUDES SOCKET INSERT) is a 2-part mechanical locking system where one part (locking mechanism) is built into the socket. The second part (locking pin) is added as a part of the socket insert (L5673, L5679, L5681, or L5683). L5671 is only covered when used in combination with a socket insert (L5673, L5681, or L5683) with an integrated pin.

Some L5671 products incorporate a suction valve (L5647, L5652). These valves are used with suction suspension and are not reasonable and necessary for use with a pin-lock mechanical suspension system.

Use of multiple mechanical suspension systems will be denied as not reasonable and necessary (duplicate).

#### **Suction Suspension**

Suction suspension is accomplished through the creation of a negative pressure (suction or vacuum) seal between the socket and the insert or liner.

Passive suction is created as air is expelled from the socket when donning the prosthesis. Some passive suction systems allow air to escape through a valve (L5647, L5652). Other designs allow air to escape around the residual limb while donning.

Active suction is created by using a suction pump as part of the socket design (L5781, L5782). Active suction systems claim to improve residual limb volume management and moisture evacuation. In addition, active systems claim to increase suspension, proprioception and improve gait. There is insufficient published clinical evidence to support these claims. Claims for L5781 and L5782 will be denied as not reasonable and necessary.

A suspension socket system is covered for functional level K2-K4.

Codes L5647, L5652, L5781, and L5782 describe a socket design that incorporates a one-way valve into the socket. The one-way air valve that is a part of the suction sockets described by these codes is not a component of a mechanical suspension locking mechanism (L5671). Claims

for L5671 in combination with a suction suspension system (L5647, L5652, L5781, L5782) will be denied as incorrect coding.

L5685 (ADDITION TO LOWER EXTREMITY PROSTHESIS, BELOW KNEE, SUSPENSION/SEALING SLEEVE, WITH OR WITHOUT VALVE, ANY MATERIAL, EACH) is a sleeve that extends over the socket onto the thigh to form a seal. It is covered for functional level K2-K4.

Use of multiple suction suspension systems will be denied as not reasonable and necessary (duplicate).

#### **Feet and Ankles**

One foot/ankle is covered per definitive prosthesis. The foot/ankle provided must be appropriate for the beneficiary's functional level (K0-K4).

#### Base Foot/Ankle Codes:

A KXXX1 (ALL LOWER LIMB EXTREMITY PROSTHESES, FOOT, DYNAMIC RESPONSE) is only covered for functional levels K3-K4.

An L5970 (ALL LOWER EXTREMITY PROSTHESES, FOOT, EXTERNAL KEEL, SACH FOOT) is only covered for functional levels K1-K4.

An L5972 (ALL LOWER EXTREMITY PROSTHESES, FOOT, FLEXIBLE KEEL) is only covered for functional levels K1-K4.

An L5974 (ALL LOWER EXTREMITY PROSTHESES, FOOT, SINGLE AXIS ANKLE/FOOT) is only covered for functional Levels K1-K4.

An L5978 (ALL LOWER EXTREMITY PROSTHESES, FOOT, MULTIAXIAL ANKLE/FOOT) is only covered for functional levels K2-K4.

#### Foot/Ankle Addition Codes:

KXXX2 ADDITION TO LOWER EXTREMITY PROSTHESIS, AXIAL ROTATION UNIT, WITH OR WITHOUT ADJUSTABILITY is only covered for functional levels K2-K4.

An L5968 (ADDITION TO LOWER LIMB PROSTHESIS, MULTIAXIAL ANKLE WITH SWING PHASE ACTIVE DORSIFLEXION FEATURE) is only covered for functional levels K3-K4.

The microprocessor foot or ankle system addition with power assist which includes any type motor (L5969) will be denied as not reasonable and necessary because they do not meet the medical evidence requirements outlined in the Centers for Medicare & Medicaid Services (CMS) Program Integrity Manual (Internet-only Manual 100-08), Chapter 13, §13.7.1.

An L5973 (ENDOSKELETAL ANKLE FOOT SYSTEM, MICROPROCESSOR CONTROLLED FEATURE, DORSIFLEXION AND/OR PLANTAR FLEXION CONTROL, INCLUDES POWER SOURCE) is only covered for functional levels K3-K4.

An L5985 (ALL ENDOSKELETAL LOWER EXTREMITY PROSTHESES, DYNAMIC PROSTHETIC PYLON) is only covered for functional levels K2-K4.

An L5988 (ADDITION TO LOWER LIMB PROSTHESIS, VERTICAL SHOCK REDUCING PYLON FEATURE) is only covered for functional levels K3-K4 who regularly engage in high impact actives such as sustained fast walking (greater than 1.3 m/s) or running.

Base	K1	K2	К3	K4
L5970	Χ	Χ	Χ	Χ
L5972	Χ	Χ	Χ	Χ
L5973	1	-	Χ	Χ
L5974	Χ	Χ	Χ	Χ
L5978	1	Χ	Χ	Χ
KXXX1	1	-	Χ	Χ
KXXX2	1	Χ	Χ	Χ
Add-on				
L5968	-	-	Χ	Χ
L5985	-	Χ	Χ	Χ
L5988	-	_	Χ	Χ

NOTE: Feet/ankle coding is being revised. Refer to the table included in the related Policy Article CODING GUIDELINES for additional information.

#### **Knees**

A determination of the type of knee for the prosthesis will be made based upon the functional needs of the patient. Prosthetic knees are considered for coverage based upon functional classification and reasonable and necessary criteria.

Basic lower extremity prostheses include a single axis, constant friction knee. Other prosthetic knees are considered for coverage based upon functional classification.

A fluid, pneumatic, or electronic/microprocessor knee (L5610, L5613, L5614, L5722-L5780, L5814, L5822-L5840, L5848, L5856, L5857, L5858) is covered for beneficiaries whose functional level is 3 or above.

L5859 (ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, POWERED AND PROGRAMMABLE FLEXION/EXTENSION ASSIST CONTROL, INCLUDES ANY TYPE MOTOR(S)) is only covered when the beneficiary meets all of the criteria below:

- 1. Has a microprocessor (swing and stance phase type (L5856)) controlled (electronic) knee
- 2. K3 functional level only
- 3. Weight greater than 110 lbs and less than 275 lbs
- 4. Has a documented comorbidity of the spine and/or sound limb affecting hip extension and/or quadriceps function that impairs K-3 level function with the use of a microprocessor-controlled knee alone
- 5. Is able to make use of a product that requires daily charging
- 6. Is able to understand and respond to error alerts and alarms indicating problems with the function of the unit

If these coverage criteria for the knee component are not met, L5859 will be denied as not reasonable and necessary.

Other knee systems (L5611, L5616, L5710-L5718, L5810-L5812, L5816, L5818) are covered for beneficiaries whose functional level is 1 or above.

	K1	K2	К3	K4
L5610	-	-	Χ	Χ
L5611	Χ	Χ	Χ	Χ
L5613	ı	-	Χ	Χ
L5614	-	-	Χ	Χ
L5616	Χ	Χ	Χ	Χ
L5710-L5718	Χ	Χ	Χ	Χ
L5722-L5780	ı	-	Χ	Χ
L5810-L5812	Χ	Χ	Χ	Χ
L5814	-	-	Χ	Χ
L5816	Χ	Χ	Χ	Χ
L5818	Χ	Χ	Χ	Χ
L5822-L5840	-	-	Χ	Χ
L5856-L5858	-	-	Χ	Χ

A high activity knee control frame (L5930) is covered for patients whose functional level is K4. L5930 is made of high-strength and lightweight materials. It is covered when a prosthetic component is individually made and this component is used in the fabrication process or when specifically included in the Medicare recommended coding for a manufactured item fabricated with these materials.

Quick change self-aligning units (L5617) will be denied as not reasonable and necessary.

#### Hips

A pneumatic or hydraulic polycentric hip joint (L5961) is covered for patients whose functional level is K3 or above.

#### Miscellaneous

An alignable system (L5910, L5920) has movable parts to allow for rotation, height/length adjustment, and linear and angular changes of the prosthesis. This code is a one-time payment with an initial or replacement prosthesis. It is not used with socket replacements. Claims for an alignable system with a socket replacement will be denied as unbundling.

"Ultralight materials" refer to using the lightest and strongest materials available, such as acrylic resin, carbon fiber, fiberglass, and titanium, etc. (Not all-inclusive). Ultralight materials (L5940, L5950, L5960) are covered when a prosthetic component is individually made and these materials are used in the fabrication process or when specifically included in the Medicare recommended coding for a manufactured item fabricated with these materials.

Protective outer surface covering systems (L5962, L5964, and L5966) are specialized covers worn over an existing prosthesis. They are covered when used by a beneficiary who has special needs for protection against unusually harsh environmental situations where it is necessary to protect the lower limb prosthesis beyond the level of that which is afforded by L5704-L5707. They are not covered for cosmetic or convenience reasons, or for everyday usage in a typical environment. This type of product is separate from the covering that is already reimbursed as part of L5704–L5707 and is rarely necessary.

#### VI. REHABILITATION PROGRAM

A prosthetic rehabilitation program is required for a new amputee to ensure successful use of a prosthesis. In a prosthetic rehabilitation program, the beneficiary must:

- Don and doff the prosthesis without assistance
- Transfer without assistance using and without using the prosthesis
- Have sufficient wear tolerance to use the prosthesis for a normal day's activities.
- Attain sufficient balance and stability to ambulate with ease of movement and energy efficiency with the preparatory prosthesis after final residual limb volume stabilization and prior to provision of the definitive prosthesis

Preparatory prosthesis provided to a beneficiary who is not scheduled for, participating in or has not recently (defined as within the previous 90 days) completed a prosthetic rehabilitation program for the affected residual limb will be denied as not reasonable and necessary.

A definitive prosthesis provided to a new amputee who has not successfully completed a prosthetic rehabilitation program will be denied as not reasonable and necessary.

Replacement of a pre-existing definitive prosthesis does not require completion of a rehabilitation program.

#### VII. FUNCTIONAL STATUS (K-LEVEL)

To insure a successful prosthetic outcome, it is necessary to determine the appropriate functional capabilities of each individual amputee. This assessment must include:

- Realistic evaluation of the beneficiary's expectations with documentation using objective measures for the actual level of function able to be achieved with the prosthesis consistent with the beneficiary's overall functional health status
- Comprehensive evaluation of functional health status including any pre-existing or limiting comorbidities

A beneficiary must meet the following minimal requirements to be functionally successful with a lower extremity prosthesis:

- Sufficient trunk control
- Good upper body strength
- Adequate knee stability with good quadriceps strength and control
- Good static and dynamic balance or a Tinetti total score of > 24
- Adequate posture

The prosthesis provided must provide:

- Stability,
- Ease of movement,
- Energy efficiency, and
- The appearance of a natural gait

An in-person, comprehensive medical assessment to determine the functional capabilities of the beneficiary must be performed by a licensed/certified medical professional with expertise in the treatment of amputees prior to the provision of any prosthesis.

The beneficiary's functional level is based on their overall health status, the objective results of the medical assessment and their documented performance using their immediately previous prosthesis (either preparatory or definitive).

Assessment of the beneficiary's functional capabilities must be based on the following classification levels, K0 – K4:

- K0: Does not have the ability to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
- K1: Has demonstrated the ability to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the household ambulator. Who can walk for distances that are considered reasonable for walking inside the home but limited for walking in the community because of endurance, strength, or safety concerns
  - o Use of a walker or crutches while using a prosthesis results in a K1 classification.
- K2: Has demonstrated the ability for ambulation to traverse low-level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator who can ambulate without assistance and is able to function physically and psychologically within the community independently.
  - o Use of a cane while using a prosthesis results in a K2 classification.
- K3: Has demonstrated sufficient and adequate lower extremity function for personal independence during ambulation with variable cadence. Typical of the unlimited community ambulator who has the ability to traverse most environmental barriers without physical or safety concerns and has vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond typical environmental barriers.
  - o Does not require the use of any mobility assistive equipment such as a cane, crutches, walker, or wheelchair.
- K4: has demonstrated sufficient and adequate strength, endurance, range of motion, and coordination for personal independence during ambulation. Exhibiting recreational demands, high impact activities, or elevated energy levels, typical of the prosthetic utilization for the energetic child, active adult, or athlete. An "active community ambulator" who not only can walk distances with no difficulty but also run on even ground with little difficulty.
  - Does not require the use of any mobility assistive equipment such as a cane, crutches, walker, or wheelchair.

If a prosthesis that exceeds the beneficiary's functional capabilities (K-level) is provided, it will be denied as not reasonable and necessary.

If the patient's functional capability is K0, the prosthesis will be denied as not reasonable and necessary.

## VIII. REPAIR AND REPLACEMENT

Repairs and replacement to a beneficiary-owned covered prosthesis are eligible for reimbursement when the criteria described in the NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the related Policy Article are met. Refer to the related Policy article for additional information about these statutory requirements.

# **Proposed/Draft Process Information**

#### **Associated Information**

#### **Documentation Requirements**

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

#### GENERAL (PIM 5.2.1)

All items billed to Medicare require a prescription. An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items dispensed and/or billed that do not meet these prescription requirements and those below must be submitted with an EY modifier added to each affected HCPCS code.

#### DISPENSING ORDERS (PIM 5.2.2)

Equipment and supplies may be delivered upon receipt of a dispensing order except for those items that require a written order prior to delivery. A dispensing order may be verbal or written. The supplier must keep a record of the dispensing order on file. It must contain:

- Description of the item
- Beneficiary's name
- Prescribing physician's name
- Date of the order and the start date, if the start date is different from the date of the order
- Physician signature (if a written order) or supplier signature (if verbal order)

For the "Date of the order" described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The dispensing order must be available upon request.

For items that are provided based on a dispensing order, the supplier must obtain a detailed written order before submitting a claim.

#### DETAILED WRITTEN ORDERS (PIM 5.2.3)

A detailed written order (DWO) is required before billing. Someone other than the ordering physician may produce the DWO. However, the ordering physician must review the content and sign and date the document. It must contain:

- Beneficiary's name
- Physician's name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Physician signature and signature date

For items provided on a periodic basis, including drugs, the written order must include:

- Item(s) to be dispensed
- Dosage or concentration, if applicable
- Route of Administration
- Frequency of use
- Duration of infusion, if applicable
- Quantity to be dispensed
- Number of refills

For the "Date of the order" described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state "PRN" or "as needed" utilization estimates for replacement frequency, use, or consumption are not acceptable. (PIM 5.9)

The detailed description in the written order may be either a narrative description or a brand name/model number.

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

The DWO must be available upon request.

A prescription is not considered as part of the medical record. Medical information intended to demonstrate compliance with coverage criteria may be included on the prescription but must be corroborated by information contained in the medical record. (PIM 5.2.3)

#### MEDICAL RECORD INFORMATION

GENERAL (PIM 5.7 - 5.9)

The Coverage Indications, Limitations and/or Medical Necessity section of this LCD contains numerous reasonable and necessary (R&N) requirements. The Non-Medical Necessity Coverage and Payment Rules section of the related Policy Article contains numerous non-reasonable and necessary, benefit category and statutory requirements that must be met in order for payment to be justified. Suppliers are reminded that:

- Supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes.
- Templates and forms, including CMS Certificates of Medical Necessity, are subject to corroboration with information in the medical record.

Information contained directly in the contemporaneous medical record is the source required to justify payment except as noted elsewhere for prescriptions and CMNs. The medical record is not limited to physician's office records but may include records from hospitals, nursing facilities, home health agencies, other healthcare professionals, etc. (not all-inclusive). Records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that an item is reasonable and necessary.

#### CONTINUED MEDICAL NEED

For all Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items, the initial justification for medical need is established at the time the item(s) is first ordered; therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are created just prior to, or at the time of, the creation of the initial prescription. For purchased items, initial months of a rental item or for initial months of ongoing supplies or drugs, information justifying reimbursement will come from this initial time period. Entries in the beneficiary's medical record must have been created prior to, or at the time of, the initial date of

service (DOS) to establish whether the initial reimbursement was justified based upon the applicable coverage policy.

For ongoing supplies and rental DME items, in addition to information described above that justifies the initial provision of the item(s) and/or supplies, there must be information in the beneficiary's medical record to support that the item continues to be used by the beneficiary and remains reasonable and necessary. Information used to justify continued medical need must be timely for the DOS under review. Any of the following may serve as documentation justifying continued medical need:

- A recent order by the treating physician for refills
- A recent change in prescription
- A properly completed CMN or DIF with an appropriate length of need specified
- Timely documentation in the beneficiary's medical record showing usage of the item

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in the policy.

#### CONTINUED USE

Continued use describes the ongoing utilization of supplies or a rental item by a beneficiary.

Suppliers are responsible for monitoring utilization of DMEPOS rental items and supplies. No monitoring of purchased items or capped rental items that have converted to a purchase is required. Suppliers must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary.

Beneficiary medical records or supplier records may be used to confirm that a DMEPOS item continues to be used by the beneficiary. Any of the following may serve as documentation that an item submitted for reimbursement continues to be used by the beneficiary:

- Timely documentation in the beneficiary's medical record showing usage of the item, related option/accessories and supplies
- Supplier records documenting the request for refill/replacement of supplies in compliance with the Refill Documentation Requirements (This is deemed to be sufficient to document continued use for the base item, as well)
- Supplier records documenting beneficiary confirmation of continued use of a rental item

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in this policy.

#### PROOF OF DELIVERY (PIM 4.26, 5.8)

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. For medical review purposes, POD serves to assist in determining correct coding and billing information for claims submitted for Medicare reimbursement. Regardless of the method of delivery, the contractor must be able to determine from delivery documentation that the supplier properly coded the item(s), that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) are intended for, and received by, a specific Medicare beneficiary.

Suppliers, their employees, or anyone else having a financial interest in the delivery of the item are prohibited from signing and accepting an item on behalf of a beneficiary (i.e., acting as a designee on behalf of the beneficiary). The signature and date the beneficiary or designee accepted delivery must be legible.

For the purpose of the delivery methods noted below, designee is defined as any person who can sign and accept the delivery of DMEPOS on behalf of the beneficiary.

Proof of delivery documentation must be available to the Medicare contractor on request. All services that do not have appropriate proof of delivery from the supplier will be denied and overpayments will be requested. Suppliers who consistently fail to provide documentation to support their services may be referred to the OIG for imposition of Civil Monetary Penalties or other administrative sanctions.

Suppliers are required to maintain POD documentation in their files. For items addressed in this policy there are three methods of delivery:

- 1. Delivery directly to the beneficiary or authorized representative
- 2. Delivery via shipping or delivery service
- 3. Delivery of items to a nursing facility on behalf of the beneficiary

#### Method 1—Direct Delivery to the Beneficiary by the Supplier

Suppliers may deliver directly to the beneficiary or the designee. In this case, POD to a beneficiary must be a signed and dated delivery document. The POD document must include:

- Beneficiary's name
- Delivery address
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description (Note: repetition of HCPCS code narrative verbiage alone is not sufficient.))
- Quantity delivered
- Date delivered
- Beneficiary (or designee) signature

The date delivered on the POD must be the date that the DMEPOS item was received by the beneficiary or designee. The date of delivery may be entered by the beneficiary, designee or the supplier. When the supplier's delivery documents have both a supplier-entered date and a beneficiary or beneficiary's designee signature date on the POD document, the beneficiary or beneficiary's designee-entered date is the date of service.

In instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS supply must be the date of service on the claim.

#### Method 2—Delivery via Shipping or Delivery Service Directly to a Beneficiary

If the supplier utilizes a shipping service or mail order, the POD documentation must be a complete record tracking the item(s) from the DMEPOS supplier to the beneficiary. An example of acceptable proof of delivery would include both the supplier's own detailed shipping invoice and the delivery service's tracking information. The supplier's record must be linked to the delivery service record by some clear method like the delivery service's package identification number or supplier's invoice number for the package sent to the beneficiary. The POD record must include:

- Beneficiary's name
- Delivery address
- Delivery service's package identification number, supplier invoice number or alternative method that links the supplier's delivery documents with the delivery service's records
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description (Note: repetition of HCPCS code narrative verbiage alone is not sufficient.))
- Quantity delivered

- Date delivered
- Evidence of delivery

If a supplier utilizes a shipping service or mail order, suppliers must use the shipping date as the date of service on the claim.

Suppliers may also utilize a return postage-paid delivery invoice from the beneficiary or designee as a POD. This type of POD record must contain the information specified above.

#### Method 3—Delivery to Nursing Facility on Behalf of a Beneficiary

When a supplier delivers items directly to a nursing facility, the documentation described for Method 1 (see above) is required.

When a delivery service or mail order is used to deliver the item to a nursing facility, the documentation described for Method 2 (see above) is required.

Regardless the method of delivery, for those beneficiaries that are residents of a nursing facility, information from the nursing facility showing that the item(s) delivered for the beneficiary's use were actually provided to and used by the beneficiary must be available upon request.

#### EQUIPMENT RETAINED FROM A PRIOR PAYER

When a beneficiary receiving a DMEPOS item from another payer (including a Medicare Advantage plan) becomes eligible for the Medicare FFS program, the first Medicare claim for that item or service is considered a new initial Medicare claim for the item. Even if there is no change in the beneficiary's medical condition, the beneficiary must meet all coverage, coding and documentation requirements for the DMEPOS item in effect on the date of service of the initial Medicare claim.

A POD is required for all items, even those in the beneficiary's possession provided by another insurer prior to Medicare eligibility. To meet the POD requirements for a beneficiary transitioning to Medicare, the suppler:

- 1. Must obtain a new POD as described above under "Methods of Delivery" (whichever method is applicable); or,
- 2. Must obtain a statement, signed and dated by the beneficiary (or beneficiary's designee), attesting that the supplier has examined the DMEPOS item, it is in good working order and that it meets Medicare requirements.

For the purposes of reasonable useful lifetime and calculation of continuous use, the first day of the first rental month in which Medicare payments are made for the item (i.e., date of service) serves as the start date of the reasonable useful lifetime and period of continuous use. In these cases, the proof of delivery documentation serves as evidence that the beneficiary is already in possession of the item.

#### REPAIR /REPLACEMENT (BPM Ch 15, §120)

Adjustments and repairs of prostheses and prosthetic components are covered under the original order for the prosthetic device.

Medicare payment may be made for the replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the replacement device, or replacement part of such a device, is reasonable and necessary.

Claims involving the replacement of a prosthesis or major component (foot, ankle, knee, socket) must be supported by a new physician's order and documentation supporting the reason for the replacement. The reason for replacement must be documented by the treating physician, either on the order or in the medical record, and must fall under one of the following:

- 1. A change in the physiological condition of the patient resulting in the need for a replacement. Examples include but are not limited to, changes in beneficiary weight, changes in the residual limb, beneficiary functional need changes; or,
- 2. An irreparable change in the condition of the device, or in a part of the device resulting in the need for a replacement; or,
- 3. The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

The prosthetist must retain documentation as described above of the prosthesis or prosthetic component replaced, the reason for replacement, and a description of the labor involved irrespective of the time since the prosthesis was provided to the beneficiary. This information must be available upon request.

#### POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

When submitting a prosthetic claim, the billed code for knee, foot, ankle and hip (HCPCS codes L5610-L5616, L5710-L5780, L5810-L5840, L5848, L5856, L5857, L5858, L5930,L5961,L5970-L5987) components must be submitted with modifiers K0 - K4, indicating the beneficiary's functional level. This functional ability information must be clearly documented in the medical record and retained in the prosthetist's files. The simple entry of a K modifier in those records is not sufficient. There must be information about the patient's history and current condition which supports the designation of the functional level. (See Independent Medical Exam requirements below)

For L5859, the medical records should describe the nature and extent of the comorbidity of the spine or the sound limb that is limiting the beneficiary to a household ambulator status. The medical record must clearly document how this feature (L5859) will enable the beneficiary to improve function to that of a community ambulator.

Custom fabricated socket inserts (L5673, L5679, L5681, L5683) require that there be information in the prosthetic record demonstrating that various coverage requirement are met. Suppliers are reminded that this information must be specific to the individual beneficiary and sufficiently detailed to demonstrate clearly that the relevant requirement(s) has been met and that payment is justified. This information must be available upon request.

The prosthetic record must contain information (1) describing the beneficiary's participation in a rehabilitation program, (2) demonstrating that the beneficiary is sufficiently able ambulate and manage the use of their preparatory prosthesis, and (3) documenting that the residual limb is sufficiently mature and stable to justify the provision of a definitive prosthesis

There must be information in the prosthetic file demonstrating that protective outer surface covering systems (L5962, L5964, and L5966 are necessary. This information must be available upon request.

INDEPENDENT MEDICAL EXAMINATION

For a definitive lower limb prosthesis to be covered the treating physician must conduct an inperson examination documenting the overall functional abilities and limitations of the beneficiary before writing the order and the supplier must receive a written report of this examination within 45 days after completion of the examination and prior to delivery of the prosthesis.

If this examination is performed during a hospital or nursing home stay, the supplier must receive the report of the examination within 45 days after discharge and prior to delivery of the prosthesis.

The physician may refer the beneficiary to a licensed/certified medical professional, who has experience and training in the functional assessment of beneficiaries with amputations to perform all or part of the in-person functional assessment examination. This person may have no financial relationship with the supplier. (Exception: If the supplier is owned by a hospital, an LCMP working in the inpatient or outpatient hospital setting may perform part of this examination.)

If the beneficiary was referred to the LCMP by the treating physician before being seen by the treating physician, then once the physician has received and reviewed the written report of this examination, the physician must see the beneficiary and perform any additional examination that is needed. The report of the physician's visit must specifically state concurrence or any disagreement with the LCMP examination.

- If the treating physician agrees with the LCMP assessment, the physician must provide the supplier with a copy of all examination record within 45 days after the in-person with the treating physician.
- If the treating physician disagrees with all or any part of the LCMP assessment, the treating physician must clearly explain the nature and basis for their disagreement. In addition, the treating physician must specifically document all changes in the functional level-determination that occur as a result of their personal assessment.

If the physician saw the beneficiary to begin the examination before referring the beneficiary to an LCMP, then if the physician sees the beneficiary again in person after receiving the report of the LCMP examination, the 45-day period begins on the date of that second physician visit. However, it is also acceptable for the physician to review the written report of the LCMP examination, to sign and date that report, and to state concurrence or any disagreement with that examination. In this situation, the physician must send a copy of the note from his/her initial visit to evaluate the beneficiary plus the annotated, signed, and dated copy of the LCMP examination to the supplier. The 45-day period begins when the physician signs and dates the LCMP examination.

The examination must be a comprehensive functional assessment that describes the beneficiary's overall health status at the time of the examination. The treating physician or LCMP performing the examination must clearly and specifically document:

- The beneficiary has had an appropriate above or below knee amputation.
- The beneficiary has successfully participated a rehabilitation program.
- The surgical incision is stable (healed).
- The residual limb has matured.
- The beneficiary is motivated to ambulate using the prosthesis.
- The beneficiary is cognitively capable of using the prosthesis to ambulate effectively at the determined functional level (K0 K4).
- The beneficiary has sufficient neuromuscular control to effectively and appropriately make use of the prosthesis at the determined functional level (K0 K4).
- The beneficiary has sufficient cardio-pulmonary capacity to effectively use the prosthesis at the determined functional level (K0 K4).

The treating physician or LCMP must explicitly identify what overall functional status to which the beneficiary is assigned based upon the criteria set out in the COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY section of this policy. The applicable K-level must be determined. The selected K-level along with the rationale justifying the selection must be included as part of the examination report.

A date stamp or equivalent must be used to document the date that the supplier receives the report of the in-person examination. The written report of this examination must be available upon request.

The treating physician and the LCMP (if applicable) must document the examination in a detailed record in the beneficiary's medical record in the same format that they use for other entries. The note must clearly indicate that the reason for the visit was a lower limb prosthesis functional assessment.

Physicians shall also provide reports of pertinent laboratory tests, x-rays, and/or other diagnostic tests (e.g., pulmonary function tests, cardiac stress test, electromyogram, etc.) performed in the course of management of the beneficiary. Upon request, suppliers shall provide notes from prior visits to give a historical perspective of the progression of disease over time and to corroborate the information in the face-to-face examination.

Healthcare providers and supplies may choose to use standardized forms or template for record keeping. CMS provides guidance regarding the use of these types of documents. CMS Program Integrity Manual (Internet-Only Manual 100-08) Chapter 3, Section 3.3.2.1.1.B states, in relevant part:

CMS does not prohibit the use of templates to facilitate record keeping. CMS also does not endorse or approve any particular templates. A physician/LCMP may choose any template to assist in documenting medical information.

Some templates provide limited options and/or space for the collection of information such as by using "check boxes," predefined answers, limited space to enter information, etc. CMS discourages the use of such templates. Claim review experience shows that that limited space templates often fail to capture sufficient detailed clinical information to demonstrate that all coverage and coding requirements are met.

Physician/LCMPs should be aware that templates designed to gather selected information focused primarily for reimbursement purposes are often insufficient to demonstrate that all coverage and coding requirements are met. This is often because these documents generally do not provide sufficient information to adequately show that the medical necessity criteria for the item/service are met.

If a physician/LCMP chooses to use a template during the patient visit, CMS encourages them to select one that allows for a full and complete collection of information to demonstrate that the applicable coverage and coding criteria are met.

Certificates of Medical Necessity (CMN), DME Information Forms (DIF), supplier-prepared statements and physician attestations by themselves do NOT provide sufficient documentation of medical necessity, even if signed by the signed by the ordering physician. See CMS Program Integrity Manual (Internet-Only Manual 100-08) Chapter 5, Section 5.7, for additional information on documentation.

Refer to the Supplier Manual for more information on documentation requirements.

#### **Appendices**

PIM citations above denote references to CMS Program Integrity Manual, Internet Only Manual 100-08.

#### **Utilization Guidelines**

Refer to Coverage Indications, Limitations and/or Medical Necessity.

Sources of Information and Basis for Decision Reserved for future use.

# **Meeting Date Meeting Type**

08/26/2015 Open Meeting

Meeting State(s)

# **Meeting Information**

If you are providing comments on more than one LCD, please provide a separate communication for each policy with the policy indicated in the subject line of the submission. All comments will be collected at a single point of contact. Please submit your comments electronically to the DME MAC medical director at the e-mail address below no later than Close of Business (COB) August 31, 2015. Stacey V. Brennan, M.D., FAAFP Medical Director, DME MAC, Jurisdiction B National Government Services 8115 Knue Rd. Indianapolis, IN 46250-1936

DMAC\_Draft\_LCD\_Comments@anthem.com The comment process requires a public meeting. A joint DME MAC public meeting will be held on August 26, 2015, from 08:00 AM EDT until 12:00 PM EDT at: Airport Square Business Park 1304 Concourse Drive Linthicum, MD 21090

Comment Period Start Date

Comment Period End Date 08/31/2015

07/16/2015

Released to Final LCD Date Not yet released.

Reason for Proposed LCD Provider Education/Guidance

Proposed Contact Stacey Brennan, M.D. National Government Services 8115 Knue Rd Indianapolis, Indiana 46250-

DMAC\_Draft\_LCD\_Comments@anthem.com

# **Coding Information**

# [ PROPOSED/DRAFT ]

## **Bill Type Codes:**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

#### **Revenue Codes:**

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the article services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

#### **CPT/HCPCS Codes**

# **Group 1 Paragraph:**

The appearance of a code in this section does not necessarily indicate coverage.

#### **HCPCS MODIFIERS:**

- EY No physician or other licensed health care provider order for this item or service
- KO Lower limb extremity prosthesis functional Level 0 Does not have the ability to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility
- K1 Lower extremity prosthesis functional Level 1 Has the ability to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
- K2 Lower extremity prosthesis functional Level 2 Has the ability for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Typical of the limited community ambulator.
- K3 Lower extremity prosthesis functional Level 3 Has the ability for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
- K4 Lower extremity prosthesis functional Level 4 Has the ability for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.

LT - Left side

RT - Right side

#### **HCPCS CODES:**

Group 1 Co	
L5000	PARTIAL FOOT, SHOE INSERT WITH LONGITUDINAL ARCH, TOE FILLER
L5010	PARTIAL FOOT, MOLDED SOCKET, ANKLE HEIGHT, WITH TOE FILLER
L5020	PARTIAL FOOT, MOLDED SOCKET, TIBIAL TUBERCLE HEIGHT, WITH TOE FILLER
L5050	ANKLE, SYMES, MOLDED SOCKET, SACH FOOT
L5060	ANKLE, SYMES, METAL FRAME, MOLDED LEATHER SOCKET, ARTICULATED ANKLE/FOOT
L5100	BELOW KNEE, MOLDED SOCKET, SHIN, SACH FOOT
L5105	BELOW KNEE, PLASTIC SOCKET, JOINTS AND THIGH LACER, SACH FOOT
L5150	KNEE DISARTICULATION (OR THROUGH KNEE), MOLDED SOCKET, EXTERNAL KNEE JOINTS, SHIN, SACH FOOT
L5160	KNEE DISARTICULATION (OR THROUGH KNEE), MOLDED SOCKET, BENT KNEE CONFIGURATION, EXTERNAL KNEE JOINTS, SHIN, SACH FOOT
L5200	ABOVE KNEE, MOLDED SOCKET, SINGLE AXIS CONSTANT FRICTION KNEE, SHIN, SACH FOOT
L5210	ABOVE KNEE, SHORT PROSTHESIS, NO KNEE JOINT ('STUBBIES'), WITH FOOT BLOCKS, NO ANKLE JOINTS, EACH
L5220	ABOVE KNEE, SHORT PROSTHESIS, NO KNEE JOINT ('STUBBIES'), WITH ARTICULATED ANKLE/FOOT, DYNAMICALLY ALIGNED, EACH
L5230	ABOVE KNEE, FOR PROXIMAL FEMORAL FOCAL DEFICIENCY, CONSTANT FRICTION KNEE, SHIN, SACH FOOT
L5250	HIP DISARTICULATION, CANADIAN TYPE; MOLDED SOCKET, HIP JOINT, SINGLE AXIS CONSTANT FRICTION KNEE, SHIN, SACH FOOT
L5270	HIP DISARTICULATION, TILT TABLE TYPE; MOLDED SOCKET, LOCKING HIP JOINT, SINGLE AXIS CONSTANT FRICTION KNEE, SHIN, SACH FOOT
L5280	HEMIPELVECTOMY, CANADIAN TYPE; MOLDED SOCKET, HIP JOINT, SINGLE AXIS CONSTANT FRICTION KNEE, SHIN, SACH FOOT
L5301	BELOW KNEE, MOLDED SOCKET, SHIN, SACH FOOT, ENDOSKELETAL SYSTEM
L5312	KNEE DISARTICULATION (OR THROUGH KNEE), MOLDED SOCKET, SINGLE AXIS KNEE, PYLON, SACH FOOT, ENDOSKELETAL SYSTEM
L5321	ABOVE KNEE, MOLDED SOCKET, OPEN END, SACH FOOT, ENDOSKELETAL SYSTEM, SINGLE AXIS KNEE
L5331	HIP DISARTICULATION, CANADIAN TYPE, MOLDED SOCKET, ENDOSKELETAL SYSTEM, HIP JOINT, SINGLE AXIS KNEE, SACH FOOT
L5341	HEMIPELVECTOMY, CANADIAN TYPE, MOLDED SOCKET, ENDOSKELETAL SYSTEM, HIP JOINT, SINGLE AXIS KNEE, SACH FOOT
L5400	IMMEDIATE POST SURGICAL OR EARLY FITTING, APPLICATION OF INITIAL RIGID DRESSING, INCLUDING FITTING, ALIGNMENT, SUSPENSION, AND ONE CAST CHANGE, BELOW KNEE
L5410	IMMEDIATE POST SURGICAL OR EARLY FITTING, APPLICATION OF INITIAL RIGID DRESSING, INCLUDING FITTING, ALIGNMENT AND SUSPENSION, BELOW KNEE, EACH ADDITIONAL CAST CHANGE AND REALIGNMENT

L5420 IMMEDIATE POST SURGICAL OR EARLY FITTING, APPLICATION OF INITIAL RIGID DRESSING, INCLUDING FITTING, ALIGNMENT AND SUSPENSION AND ONE CAST CHANGE 'AK' OR KNEE DISARTICULATION IMMEDIATE POST SURGICAL OR EARLY FITTING, APPLICATION OF INITIAL RIGID L5430 DRESSING, INCL. FITTING, ALIGNMENT AND SUPENSION, 'AK' OR KNEE DISARTICULATION, EACH ADDITIONAL CAST CHANGE AND REALIGNMENT L5450 IMMEDIATE POST SURGICAL OR EARLY FITTING, APPLICATION OF NON-WEIGHT BEARING RIGID DRESSING, BELOW KNEE IMMEDIATE POST SURGICAL OR EARLY FITTING, APPLICATION OF NON-WEIGHT L5460 BEARING RIGID DRESSING, ABOVE KNEE INITIAL, BELOW KNEE 'PTB' TYPE SOCKET, NON-ALIGNABLE SYSTEM, PYLON, NO L5500 COVER, SACH FOOT, PLASTER SOCKET, DIRECT FORMED INITIAL, ABOVE KNEE - KNEE DISARTICULATION, ISCHIAL LEVEL SOCKET, NON-L5505 ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, PLASTER SOCKET, DIRECT **FORMED** L5510 PREPARATORY, BELOW KNEE 'PTB' TYPE SOCKET, NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, PLASTER SOCKET, MOLDED TO MODEL L5520 PREPARATORY, BELOW KNEE 'PTB' TYPE SOCKET, NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, THERMOPLASTIC OR EQUAL, DIRECT FORMED L5530 PREPARATORY, BELOW KNEE 'PTB' TYPE SOCKET, NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, THERMOPLASTIC OR EQUAL, MOLDED TO MODEL PREPARATORY, BELOW KNEE 'PTB' TYPE SOCKET, NON-ALIGNABLE SYSTEM, NO L5535 COVER, SACH FOOT, PREFABRICATED, ADJUSTABLE OPEN END SOCKET PREPARATORY, BELOW KNEE 'PTB' TYPE SOCKET, NON-ALIGNABLE SYSTEM, L5540 PYLON, NO COVER, SACH FOOT, LAMINATED SOCKET, MOLDED TO MODEL PREPARATORY, ABOVE KNEE- KNEE DISARTICULATION, ISCHIAL LEVEL SOCKET, L5560 NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, PLASTER SOCKET, MOLDED TO MODEL L5570 PREPARATORY, ABOVE KNEE - KNEE DISARTICULATION, ISCHIAL LEVEL SOCKET, NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, THERMOPLASTIC OR EQUAL, DIRECT FORMED PREPARATORY, ABOVE KNEE - KNEE DISARTICULATION ISCHIAL LEVEL SOCKET. L5580 NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, THERMOPLASTIC OR EQUAL, MOLDED TO MODEL L5585 PREPARATORY, ABOVE KNEE - KNEE DISARTICULATION, ISCHIAL LEVEL SOCKET, NON-ALIGNABLE SYSTEM, PYLON, NO COVER, SACH FOOT, PREFABRICATED ADJUSTABLE OPEN END SOCKET PREPARATORY, ABOVE KNEE - KNEE DISARTICULATION ISCHIAL LEVEL SOCKET, L5590 NON-ALIGNABLE SYSTEM, PYLON NO COVER, SACH FOOT, LAMINATED SOCKET, MOLDED TO MODEL L5595 PREPARATORY, HIP DISARTICULATION-HEMIPELVECTOMY, PYLON, NO COVER, SACH FOOT, THERMOPLASTIC OR EQUAL, MOLDED TO PATIENT MODEL PREPARATORY, HIP DISARTICULATION-HEMIPELVECTOMY, PYLON, NO COVER, L5600 SACH FOOT, LAMINATED SOCKET, MOLDED TO PATIENT MODEL

L5610	ADDITION TO LOWER EXTREMITY, ENDOSKELETAL SYSTEM, ABOVE KNEE, HYDRACADENCE SYSTEM
L5611	ADDITION TO LOWER EXTREMITY, ENDOSKELETAL SYSTEM, ABOVE KNEE - KNEE DISARTICULATION, 4 BAR LINKAGE, WITH FRICTION SWING PHASE CONTROL
L5613	ADDITION TO LOWER EXTREMITY, ENDOSKELETAL SYSTEM, ABOVE KNEE-KNEE DISARTICULATION, 4 BAR LINKAGE, WITH HYDRAULIC SWING PHASE CONTROL
L5614	ADDITION TO LOWER EXTREMITY, EXOSKELETAL SYSTEM, ABOVE KNEE-KNEE DISARTICULATION, 4 BAR LINKAGE, WITH PNEUMATIC SWING PHASE CONTROL
L5616	ADDITION TO LOWER EXTREMITY, ENDOSKELETAL SYSTEM, ABOVE KNEE, UNIVERSAL MULTIPLEX SYSTEM, FRICTION SWING PHASE CONTROL
L5617	ADDITION TO LOWER EXTREMITY, QUICK CHANGE SELF-ALIGNING UNIT, ABOVE KNEE OR BELOW KNEE, EACH
L5618	ADDITION TO LOWER EXTREMITY, TEST SOCKET, SYMES
L5620	ADDITION TO LOWER EXTREMITY, TEST SOCKET, BELOW KNEE
L5622	ADDITION TO LOWER EXTREMITY, TEST SOCKET, KNEE DISARTICULATION
L5624	ADDITION TO LOWER EXTREMITY, TEST SOCKET, ABOVE KNEE
L5626	ADDITION TO LOWER EXTREMITY, TEST SOCKET, HIP DISARTICULATION
L5628	ADDITION TO LOWER EXTREMITY, TEST SOCKET, HEMIPELVECTOMY
L5629	ADDITION TO LOWER EXTREMITY, BELOW KNEE, ACRYLIC SOCKET
L5630	ADDITION TO LOWER EXTREMITY, SYMES TYPE, EXPANDABLE WALL SOCKET
L5631	ADDITION TO LOWER EXTREMITY, ABOVE KNEE OR KNEE DISARTICULATION, ACRYLIC SOCKET
L5632	ADDITION TO LOWER EXTREMITY, SYMES TYPE, 'PTB' BRIM DESIGN SOCKET
L5634	ADDITION TO LOWER EXTREMITY, SYMES TYPE, POSTERIOR OPENING (CANADIAN) SOCKET
L5636	ADDITION TO LOWER EXTREMITY, SYMES TYPE, MEDIAL OPENING SOCKET
L5637	ADDITION TO LOWER EXTREMITY, BELOW KNEE, TOTAL CONTACT
L5638	ADDITION TO LOWER EXTREMITY, BELOW KNEE, LEATHER SOCKET
L5639	ADDITION TO LOWER EXTREMITY, BELOW KNEE, WOOD SOCKET
L5640	ADDITION TO LOWER EXTREMITY, KNEE DISARTICULATION, LEATHER SOCKET
L5642	ADDITION TO LOWER EXTREMITY, ABOVE KNEE, LEATHER SOCKET
L5643	ADDITION TO LOWER EXTREMITY, HIP DISARTICULATION, FLEXIBLE INNER SOCKET, EXTERNAL FRAME
L5644	ADDITION TO LOWER EXTREMITY, ABOVE KNEE, WOOD SOCKET
L5645	ADDITION TO LOWER EXTREMITY, BELOW KNEE, FLEXIBLE INNER SOCKET, EXTERNAL FRAME
L5646	ADDITION TO LOWER EXTREMITY, BELOW KNEE, AIR, FLUID, GEL OR EQUAL, CUSHION SOCKET
L5647	ADDITION TO LOWER EXTREMITY, BELOW KNEE SUCTION SOCKET
L5648	ADDITION TO LOWER EXTREMITY, ABOVE KNEE, AIR, FLUID, GEL OR EQUAL, CUSHION SOCKET

L5649	ADDITION TO LOWER EXTREMITY, ISCHIAL CONTAINMENT/NARROW M-L SOCKET
L5650	ADDITIONS TO LOWER EXTREMITY, TOTAL CONTACT, ABOVE KNEE OR KNEE DISARTICULATION SOCKET
L5651	ADDITION TO LOWER EXTREMITY, ABOVE KNEE, FLEXIBLE INNER SOCKET, EXTERNAL FRAME
L5652	ADDITION TO LOWER EXTREMITY, SUCTION SUSPENSION, ABOVE KNEE OR KNEE DISARTICULATION SOCKET
L5653	ADDITION TO LOWER EXTREMITY, KNEE DISARTICULATION, EXPANDABLE WALL SOCKET
L5654	ADDITION TO LOWER EXTREMITY, SOCKET INSERT, SYMES, (KEMBLO, PELITE, ALIPLAST, PLASTAZOTE OR EQUAL)
L5655	ADDITION TO LOWER EXTREMITY, SOCKET INSERT, BELOW KNEE (KEMBLO, PELITE, ALIPLAST, PLASTAZOTE OR EQUAL)
L5656	ADDITION TO LOWER EXTREMITY, SOCKET INSERT, KNEE DISARTICULATION (KEMBLO, PELITE, ALIPLAST, PLASTAZOTE OR EQUAL)
L5658	ADDITION TO LOWER EXTREMITY, SOCKET INSERT, ABOVE KNEE (KEMBLO, PELITE, ALIPLAST, PLASTAZOTE OR EQUAL)
L5661	ADDITION TO LOWER EXTREMITY, SOCKET INSERT, MULTI-DUROMETER SYMES
L5665	ADDITION TO LOWER EXTREMITY, SOCKET INSERT, MULTI-DUROMETER, BELOW KNEE
L5666	ADDITION TO LOWER EXTREMITY, BELOW KNEE, CUFF SUSPENSION
L5668	ADDITION TO LOWER EXTREMITY, BELOW KNEE, MOLDED DISTAL CUSHION
L5670	ADDITION TO LOWER EXTREMITY, BELOW KNEE, MOLDED SUPRACONDYLAR SUSPENSION ('PTS' OR SIMILAR)
L5671	ADDITION TO LOWER EXTREMITY, BELOW KNEE / ABOVE KNEE SUSPENSION LOCKING MECHANISM (SHUTTLE, LANYARD OR EQUAL), EXCLUDES SOCKET INSERT
L5672	ADDITION TO LOWER EXTREMITY, BELOW KNEE, REMOVABLE MEDIAL BRIM SUSPENSION
L5673	ADDITION TO LOWER EXTREMITY, BELOW KNEE/ABOVE KNEE, CUSTOM FABRICATED FROM EXISTING MOLD OR PREFABRICATED, SOCKET INSERT, SILICONE GEL, ELASTOMERIC OR EQUAL, FOR USE WITH LOCKING MECHANISM
L5676	ADDITIONS TO LOWER EXTREMITY, BELOW KNEE, KNEE JOINTS, SINGLE AXIS, PAIR
L5677	ADDITIONS TO LOWER EXTREMITY, BELOW KNEE, KNEE JOINTS, POLYCENTRIC, PAIR
L5678	ADDITIONS TO LOWER EXTREMITY, BELOW KNEE, JOINT COVERS, PAIR
L5679	ADDITION TO LOWER EXTREMITY, BELOW KNEE/ABOVE KNEE, CUSTOM FABRICATED FROM EXISTING MOLD OR PREFABRICATED, SOCKET INSERT, SILICONE GEL, ELASTOMERIC OR EQUAL, NOT FOR USE WITH LOCKING MECHANISM
15680	ADDITION TO LOWER EXTREMITY BELOW KNEE THIGH LACER NONMOLDED

L5681	ADDITION TO LOWER EXTREMITY, BELOW KNEE/ABOVE KNEE, CUSTOM FABRICATED SOCKET INSERT FOR CONGENITAL OR ATYPICAL TRAUMATIC AMPUTEE, SILICONE GEL, ELASTOMERIC OR EQUAL, FOR USE WITH OR WITHOUT LOCKING MECHANISM, INITIAL ONLY (FOR OTHER THAN INITIAL, USE CODE L5673 OR L5679)
L5682	ADDITION TO LOWER EXTREMITY, BELOW KNEE, THIGH LACER, GLUTEAL/ISCHIAL, MOLDED
L5683	ADDITION TO LOWER EXTREMITY, BELOW KNEE/ABOVE KNEE, CUSTOM FABRICATED SOCKET INSERT FOR OTHER THAN CONGENITAL OR ATYPICAL TRAUMATIC AMPUTEE, SILICONE GEL, ELASTOMERIC OR EQUAL, FOR USE WITH OR WITHOUT LOCKING MECHANISM, INITIAL ONLY (FOR OTHER THAN INITIAL, USE CODE L5673 OR L5679)
L5684	ADDITION TO LOWER EXTREMITY, BELOW KNEE, FORK STRAP
L5685	ADDITION TO LOWER EXTREMITY PROSTHESIS, BELOW KNEE, SUSPENSION/SEALING SLEEVE, WITH OR WITHOUT VALVE, ANY MATERIAL, EACH
L5686	ADDITION TO LOWER EXTREMITY, BELOW KNEE, BACK CHECK (EXTENSION CONTROL)
L5688	ADDITION TO LOWER EXTREMITY, BELOW KNEE, WAIST BELT, WEBBING
L5690	ADDITION TO LOWER EXTREMITY, BELOW KNEE, WAIST BELT, PADDED AND LINED
L5692	ADDITION TO LOWER EXTREMITY, ABOVE KNEE, PELVIC CONTROL BELT, LIGHT
L5694	ADDITION TO LOWER EXTREMITY, ABOVE KNEE, PELVIC CONTROL BELT, PADDED AND LINED
L5695	ADDITION TO LOWER EXTREMITY, ABOVE KNEE, PELVIC CONTROL, SLEEVE SUSPENSION, NEOPRENE OR EQUAL, EACH
L5696	ADDITION TO LOWER EXTREMITY, ABOVE KNEE OR KNEE DISARTICULATION, PELVIC JOINT
L5697	ADDITION TO LOWER EXTREMITY, ABOVE KNEE OR KNEE DISARTICULATION, PELVIC BAND
L5698	ADDITION TO LOWER EXTREMITY, ABOVE KNEE OR KNEE DISARTICULATION, SILESIAN BANDAGE
L5699	ALL LOWER EXTREMITY PROSTHESES, SHOULDER HARNESS
L5700	REPLACEMENT, SOCKET, BELOW KNEE, MOLDED TO PATIENT MODEL
L5701	REPLACEMENT, SOCKET, ABOVE KNEE/KNEE DISARTICULATION, INCLUDING ATTACHMENT PLATE, MOLDED TO PATIENT MODEL
L5702	REPLACEMENT, SOCKET, HIP DISARTICULATION, INCLUDING HIP JOINT, MOLDED TO PATIENT MODEL
L5703	ANKLE, SYMES, MOLDED TO PATIENT MODEL, SOCKET WITHOUT SOLID ANKLE CUSHION HEEL (SACH) FOOT, REPLACEMENT ONLY
L5704	CUSTOM SHAPED PROTECTIVE COVER, BELOW KNEE
L5705	CUSTOM SHAPED PROTECTIVE COVER, ABOVE KNEE
L5706	CUSTOM SHAPED PROTECTIVE COVER, KNEE DISARTICULATION
L5707	CUSTOM SHAPED PROTECTIVE COVER, HIP DISARTICULATION
L5710	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, MANUAL LOCK

L5711	ADDITIONS EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, MANUAL LOCK, ULTRA-LIGHT MATERIAL
L5712	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FRICTION SWING AND STANCE PHASE CONTROL (SAFETY KNEE)
L5714	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, VARIABLE FRICTION SWING PHASE CONTROL
L5716	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, POLYCENTRIC, MECHANICAL STANCE PHASE LOCK
L5718	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, POLYCENTRIC, FRICTION SWING AND STANCE PHASE CONTROL
L5722	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, PNEUMATIC SWING, FRICTION STANCE PHASE CONTROL
L5724	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FLUID SWING PHASE CONTROL
L5726	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, EXTERNAL JOINTS FLUID SWING PHASE CONTROL
L5728	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FLUID SWING AND STANCE PHASE CONTROL
L5780	ADDITION, EXOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, PNEUMATIC/HYDRA PNEUMATIC SWING PHASE CONTROL
L5781	ADDITION TO LOWER LIMB PROSTHESIS, VACUUM PUMP, RESIDUAL LIMB VOLUME MANAGEMENT AND MOISTURE EVACUATION SYSTEM
L5782	ADDITION TO LOWER LIMB PROSTHESIS, VACUUM PUMP, RESIDUAL LIMB VOLUME MANAGEMENT AND MOISTURE EVACUATION SYSTEM, HEAVY DUTY
L5785	ADDITION, EXOSKELETAL SYSTEM, BELOW KNEE, ULTRA-LIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL)
L5790	ADDITION, EXOSKELETAL SYSTEM, ABOVE KNEE, ULTRA-LIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL)
L5795	ADDITION, EXOSKELETAL SYSTEM, HIP DISARTICULATION, ULTRA-LIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL)
L5810	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, MANUAL LOCK
L5811	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, MANUAL LOCK, ULTRA-LIGHT MATERIAL
L5812	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FRICTION SWING AND STANCE PHASE CONTROL (SAFETY KNEE)
L5814	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, POLYCENTRIC, HYDRAULIC SWING PHASE CONTROL, MECHANICAL STANCE PHASE LOCK
L5816	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, POLYCENTRIC, MECHANICAL STANCE PHASE LOCK
L5818	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, POLYCENTRIC, FRICTION SWING, AND STANCE PHASE CONTROL
L5822	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, PNEUMATIC SWING, FRICTION STANCE PHASE CONTROL

L5824	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FLUID SWING PHASE CONTROL
L5826	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, HYDRAULIC SWING PHASE CONTROL, WITH MINIATURE HIGH ACTIVITY FRAME
L5828	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, FLUID SWING AND STANCE PHASE CONTROL
L5830	ADDITION, ENDOSKELETAL KNEE-SHIN SYSTEM, SINGLE AXIS, PNEUMATIC/ SWING PHASE CONTROL
L5840	ADDITION, ENDOSKELETAL KNEE/SHIN SYSTEM, 4-BAR LINKAGE OR MULTIAXIAL, PNEUMATIC SWING PHASE CONTROL
L5845	ADDITION, ENDOSKELETAL, KNEE-SHIN SYSTEM, STANCE FLEXION FEATURE, ADJUSTABLE
L5848	ADDITION TO ENDOSKELETAL KNEE-SHIN SYSTEM, FLUID STANCE EXTENSION, DAMPENING FEATURE, WITH OR WITHOUT ADJUSTABILITY
L5850	ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE OR HIP DISARTICULATION, KNEE EXTENSION ASSIST
L5855	ADDITION, ENDOSKELETAL SYSTEM, HIP DISARTICULATION, MECHANICAL HIP EXTENSION ASSIST
L5856	ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, MICROPROCESSOR CONTROL FEATURE, SWING AND STANCE PHASE, INCLUDES ELECTRONIC SENSOR(S), ANY TYPE
L5857	ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, MICROPROCESSOR CONTROL FEATURE, SWING PHASE ONLY, INCLUDES ELECTRONIC SENSOR(S), ANY TYPE
L5858	ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE SHIN SYSTEM, MICROPROCESSOR CONTROL FEATURE, STANCE PHASE ONLY, INCLUDES ELECTRONIC SENSOR(S), ANY TYPE
L5859	ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, POWERED AND PROGRAMMABLE FLEXION/EXTENSION ASSIST CONTROL, INCLUDES ANY TYPE MOTOR(S)
L5910	ADDITION, ENDOSKELETAL SYSTEM, BELOW KNEE, ALIGNABLE SYSTEM
L5920	ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE OR HIP DISARTICULATION, ALIGNABLE SYSTEM
L5925	ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE, KNEE DISARTICULATION OR HIP DISARTICULATION, MANUAL LOCK
L5930	ADDITION, ENDOSKELETAL SYSTEM, HIGH ACTIVITY KNEE CONTROL FRAME
L5940	ADDITION, ENDOSKELETAL SYSTEM, BELOW KNEE, ULTRA-LIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL)
L5950	ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE, ULTRA-LIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL)
L5960	ADDITION, ENDOSKELETAL SYSTEM, HIP DISARTICULATION, ULTRA-LIGHT MATERIAL (TITANIUM, CARBON FIBER OR EQUAL)

L5961	ADDITION, ENDOSKELETAL SYSTEM, POLYCENTRIC HIP JOINT, PNEUMATIC OR HYDRAULIC CONTROL, ROTATION CONTROL, WITH OR WITHOUT FLEXION AND/OR EXTENSION CONTROL
L5962	ADDITION, ENDOSKELETAL SYSTEM, BELOW KNEE, FLEXIBLE PROTECTIVE OUTER SURFACE COVERING SYSTEM
L5964	ADDITION, ENDOSKELETAL SYSTEM, ABOVE KNEE, FLEXIBLE PROTECTIVE OUTER SURFACE COVERING SYSTEM
L5966	ADDITION, ENDOSKELETAL SYSTEM, HIP DISARTICULATION, FLEXIBLE PROTECTIVE OUTER SURFACE COVERING SYSTEM
L5968	ADDITION TO LOWER LIMB PROSTHESIS, MULTIAXIAL ANKLE WITH SWING PHASE ACTIVE DORSIFLEXION FEATURE
L5969	ADDITION, ENDOSKELETAL ANKLE-FOOT OR ANKLE SYSTEM, POWER ASSIST, INCLUDES ANY TYPE MOTOR(S)
L5970	ALL LOWER EXTREMITY PROSTHESES, FOOT, EXTERNAL KEEL, SACH FOOT
L5971	ALL LOWER EXTREMITY PROSTHESIS, SOLID ANKLE CUSHION HEEL (SACH) FOOT, REPLACEMENT ONLY
L5972	ALL LOWER EXTREMITY PROSTHESES, FOOT, FLEXIBLE KEEL
L5973	ENDOSKELETAL ANKLE FOOT SYSTEM, MICROPROCESSOR CONTROLLED FEATURE, DORSIFLEXION AND/OR PLANTAR FLEXION CONTROL, INCLUDES POWER SOURCE
L5974	ALL LOWER EXTREMITY PROSTHESES, FOOT, SINGLE AXIS ANKLE/FOOT
L5975	ALL LOWER EXTREMITY PROSTHESIS, COMBINATION SINGLE AXIS ANKLE AND FLEXIBLE KEEL FOOT
L5976	ALL LOWER EXTREMITY PROSTHESES, ENERGY STORING FOOT (SEATTLE CARBON COPY II OR EQUAL)
L5978	ALL LOWER EXTREMITY PROSTHESES, FOOT, MULTIAXIAL ANKLE/FOOT
L5979	ALL LOWER EXTREMITY PROSTHESIS, MULTI-AXIAL ANKLE, DYNAMIC RESPONSE FOOT, ONE PIECE SYSTEM
L5980	ALL LOWER EXTREMITY PROSTHESES, FLEX FOOT SYSTEM
L5981	ALL LOWER EXTREMITY PROSTHESES, FLEX-WALK SYSTEM OR EQUAL
L5982	ALL EXOSKELETAL LOWER EXTREMITY PROSTHESES, AXIAL ROTATION UNIT
L5984	ALL ENDOSKELETAL LOWER EXTREMITY PROSTHESIS, AXIAL ROTATION UNIT, WITH OR WITHOUT ADJUSTABILITY
L5985	ALL ENDOSKELETAL LOWER EXTREMITY PROSTHESES, DYNAMIC PROSTHETIC PYLON
L5986	ALL LOWER EXTREMITY PROSTHESES, MULTI-AXIAL ROTATION UNIT ('MCP' OR EQUAL)
L5987	ALL LOWER EXTREMITY PROSTHESIS, SHANK FOOT SYSTEM WITH VERTICAL LOADING PYLON
L5988	ADDITION TO LOWER LIMB PROSTHESIS, VERTICAL SHOCK REDUCING PYLON FEATURE
L5990	ADDITION TO LOWER EXTREMITY PROSTHESIS, USER ADJUSTABLE HEEL HEIGHT
L5999	LOWER EXTREMITY PROSTHESIS, NOT OTHERWISE SPECIFIED

L7367	LITHIUM ION BATTERY, RECHARGEABLE, REPLACEMENT
L7368	LITHIUM ION BATTERY CHARGER, REPLACEMENT ONLY
L7510	REPAIR OF PROSTHETIC DEVICE, REPAIR OR REPLACE MINOR PARTS
L7520	REPAIR PROSTHETIC DEVICE, LABOR COMPONENT, PER 15 MINUTES
L7600	PROSTHETIC DONNING SLEEVE, ANY MATERIAL, EACH
L8400	PROSTHETIC SHEATH, BELOW KNEE, EACH
L8410	PROSTHETIC SHEATH, ABOVE KNEE, EACH
L8417	PROSTHETIC SHEATH/SOCK, INCLUDING A GEL CUSHION LAYER, BELOW KNEE OR ABOVE KNEE, EACH
L8420	PROSTHETIC SOCK, MULTIPLE PLY, BELOW KNEE, EACH
L8430	PROSTHETIC SOCK, MULTIPLE PLY, ABOVE KNEE, EACH
L8440	PROSTHETIC SHRINKER, BELOW KNEE, EACH
L8460	PROSTHETIC SHRINKER, ABOVE KNEE, EACH
L8470	PROSTHETIC SOCK, SINGLE PLY, FITTING, BELOW KNEE, EACH
L8480	PROSTHETIC SOCK, SINGLE PLY, FITTING, ABOVE KNEE, EACH

## **ICD-10 Codes that Support Medical Necessity**

# **Group 1 Paragraph:**

Not specified.

## **Group 1 Codes:**

# **ICD-10 Codes that DO NOT Support Medical Necessity**

## **Group 1 Paragraph:**

Not specified.

## **Group 1 Codes:**

# **Associated Documents**

#### **Attachments**

There are no attachments for this LCD.

# Related Local Coverage Documents Article(s)

A54517 - DRAFT Lower Limb Prostheses - Policy Article - Effective XXXX XXXX

## **Related National Coverage Documents**

This LCD version has no Related National Coverage Documents.

# Local Coverage Article: DRAFT Lower Limb Prostheses - Policy Article - Effective XXXX XXXX (A54517)



Please note: Future Effective Date.

# **Contractor Information**

Contractor Name NHIC, Corp.

Contract Number 16003

**Contract Type** DME MAC

# **Article Information**

Article ID Number A54517

Original ICD-9 Article ID

A47081 - Lower Limb Prostheses - Policy Article - Effective January 2014

#### **Article Title**

DRAFT Lower Limb Prostheses - Policy Article - Effective XXXX XXXX

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CPT only copyright 2002-2014 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

The Code on Dental Procedures and Nomenclature (Code) is published in Current Dental Terminology (CDT). Copyright (c) American Dental Association. All rights reserved. CDT and CDT-2010 are trademarks of the American Dental Association.

UB-04 Manual. OFFICIAL UB-04 DATA SPECIFICATIONS MANUAL, 2014, is copyrighted by American Hospital Association ("AHA"), Chicago, Illinois. No portion of OFFICIAL UB-04 MANUAL may be reproduced, sorted in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without prior express, written consent of AHA. Health Forum reserves the right to change the copyright notice from time to time upon written notice to Company.

Jurisdiction

Connecticut Delaware

District of Columbia

Maine Maryland

Massachusetts New Hampshire

New Jersey

New York - Entire State

Pennsylvania Rhode Island Vermont

DME Region Article Covers

Jurisdiction A

Original Effective Date 10/01/2015

**Revision Effective Date** 

**Revision Ending Date** 

Retirement Date

# **Article Guidance**

#### 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").

Lower limb prostheses are covered under the Medicare Artificial Legs, Arms and Eyes (i.e., Prosthetic Limbs) Benefit (Social Security Act §1861(s)(9)). In order for a beneficiary to be eligible for reimbursement, the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition to meeting the benefit category requirements, there are specific statutory payment policy requirements, discussed below, that also must be met.

#### **GENERAL:**

The following items are included in the reimbursement for a prosthesis and, therefore, are not separately billable to Medicare under the prosthetic benefit:

- Evaluation of the residual limb and gait
- Fitting of the prosthesis
- Cost of base component parts and labor contained in HCPCS base codes
- Repairs due to normal wear or tear within 90 days of delivery
- Adjustments of the prosthesis or the prosthetic component made when fitting the
  prosthesis or component and for 90 days from the date of delivery when the adjustments
  are not necessitated by changes in the residual limb or the beneficiary's functional
  abilities.

#### FACILITY REQUIREMENTS

Payment for a prosthesis is included in the payment to a hospital if:

- The prosthesis is provided to a beneficiary during an inpatient hospital stay prior to the day of discharge; and
- The beneficiary uses the prosthesis for medically necessary inpatient treatment or rehabilitation.

A claim must not be submitted in this situation.

Payment for a prosthesis described by codes L5000-L5020, L5400-L5460, L5987, and L8400-L8480 is included in the payment to a Skilled Nursing Facility (SNF) if:

- The prosthesis is provided to a beneficiary during Medicare Part A covered SNF stay prior to the day of discharge; and
- The beneficiary uses the prosthesis for medically necessary inpatient treatment or rehabilitation.

A claim must not be submitted in this situation.

Claims for other lower limb prostheses provided to a beneficiary in a Part A covered SNF stay and claims for any lower limb prosthesis provided in a SNF when the stay is not covered by Part A are submitted to the DME MAC.

Payment for a prosthesis delivered to a beneficiary in a hospital or SNF is eligible for coverage if:

- The prosthesis is medically necessary for a beneficiary after discharge from a hospital or Part A covered SNF stay; and
- The prosthesis is provided to the beneficiary within two days prior to discharge to home;
   and
- The prosthesis is not needed for inpatient treatment or rehabilitation, but is left in the room for the beneficiary to take home.

#### ADJUSTMENTS, REPAIRS, AND COMPONENT REPLACEMENT:

A repair is a restoration of the prosthesis to correct problems due to wear or damage. Repairs to a prosthesis are covered when necessary to make the prosthesis functional.

An adjustment is any modification to the prosthesis due to a change in the beneficiary's condition or to improve the function of the prosthesis.

Adjustments to an artificial limb or other appliance required by wear or by a change in the patient's condition (aside from those that are necessary during the first 90 days after delivery) are covered when ordered by a physician.

Adjustments, repairs and replacements are covered even when the item had been in use before the user enrolled in Part B of the program so long as the device continues to be medically required.

Routine periodic servicing, such as testing, (re)programming, cleaning, and checking of the prosthesis is noncovered. Adjustments to a prosthesis required by wear or by a change in the beneficiary's condition are covered under the initial physician's order for the prosthesis for the life of the prosthesis.

Maintenance which may be necessitated by manufacturer's recommendations or the construction of the prosthesis and must be performed by the prosthetist is covered as a repair.

Replacement of a prosthesis or prosthetic component is covered if the treating physician orders a replacement device or part because of any of the following:

- A change in the physiological condition of the beneficiary; or
- Irreparable wear of the device or a part of the device; or
- The condition of the device, or part of the device, requires repairs and the cost of such repairs would be more than 60% of the cost of a replacement device, or of the part being replaced.

#### **MISCELLANEOUS**

An L5990 (ADDITION TO LOWER EXTREMITY PROSTHESIS, USER ADJUSTABLE HEEL HEIGHT) is a user adjustable convenience feature. Claims for L5990 will be denied as noncovered, convenience item.

A prosthetic donning sleeve (L7600) will be denied as noncovered, convenience item.

#### **CODING GUIDELINES**

Code L7510 is used to bill for any "minor" materials (i.e., those without specific HCPCS codes) used to achieve the adjustment and/or repair.

Code L7520 is used to bill for labor associated with adjustments and repairs that either do not involve replacement parts or that involve replacement parts billed with code L7510. Code L7520 must not be billed for labor time involved in the replacement of parts that are billed with a specific HCPCS code. Labor is included in the allowance for those codes.

One unit of service of code L7520 represents 15 minutes of labor time. Documentation must exist in the supplier's records indicating the specific adjustment and/or repair performed and the time involved. The time reported for L7520 must only be for actual repair time. Time performing the following services (not all-inclusive) must not be billed using code L7520:

- Evaluation to determine the need for a repair or adjustment or follow-up assessment
- Evaluation of problems regarding the fit or function of the prosthesis
- General beneficiary education or gait instruction
- Programming of electronic componentry

An L5671 (ADDITION TO LOWER EXTREMITY, BELOW KNEE / ABOVE KNEE SUSPENSION LOCKING MECHANISM (SHUTTLE, LANYARD OR EQUAL), EXCLUDES SOCKET INSERT) is a 2-part mechanical locking system where one part (locking mechanism) is built into the socket. The second part (locking pin) is a component of the socket insert (L5673, L5679, L5681, or L5683). L5671 is only used in combination with a socket insert (L5673, L5681, or L5683) with an integrated pin.

Some L5671 products incorporate a suction valve (L5647, L5652). Separate billing for a suction valve included as an integral part of a product assigned to L5671 is unbundling.

Codes L5673, L5679, L5681, or L5683 also include socket inserts without a distal umbrella adapter used for attaching the pin or lanyard of the locking mechanism (L5671).

A custom fabricated socket insert (L5673, L5679, L5681, L5683) is made from a model created from a mold of the beneficiary's residual limb. Codes L5681 and L5683 include the creation of the beneficiary model in addition to the production and fitting of the socket insert. Codes L5673 and L5679 describe inserts created from an existing beneficiary model. Codes L5673 and L5679 includes (1) products that are custom fabricated to an existing beneficiary model, or (2) prefabricated but custom fitted to an existing beneficiary model.

Codes L5647 and L5652 describe a prosthetic socket that incorporates a one-way valve into the socket. The one-way air valve that is included as a part of the sockets described by these codes is not a component of a suspension locking mechanism (L5671)(see above).

With the exception of items described by specific HCPCS codes, there should be no separate billing and there is no separate payment for a component or feature of a microprocessor controlled knee, including but not limited to real time gait analysis, continuous gait assessment, or electronically controlled static stance regulator.

Codes L5940-L5960 for ultra-light materials may only be used when materials such as carbon fiber, fiberglass, Kevlar®, or other advanced composite lamination materials are used in the fabrication of a socket for an endoskeletal prosthesis. They are not used for ultralight materials used in other components of a prosthesis – e.g., knee/shin system, pylon, ankle, foot, etc. For codes L5940-L5960, the unit of service is per limb.

A microprocessor ankle-foot system with power assist (BiOM® Ankle-Foot System by iWalk, Inc) is coded as the combination of L5969 (ADDITION, ENDOSKELETAL ANKLE-FOOT OR ANKLE SYSTEM, POWER ASSIST, INCLUDES ANY TYPE MOTOR(S)) and L5973 (ENDOSKELETAL ANKLE

FOOT SYSTEM, MICROPROCESSOR CONTROLLED FEATURE, DORSIFLEXION AND/OR PLANTAR FLEXION CONTROL, INCLUDES POWER SOURCE).

The only products which may be billed using code L5969 are those for which a written coding verification review has been made by the Pricing, Data Analysis, and Coding (PDAC) contractor and subsequently published on the appropriate Product Classification List. Information concerning the documentation that must be submitted to the PDAC for a Coding Verification Request can be found on the PDAC web site or by contacting the PDAC. A Product Classification List with products which have received a coding verification can be found on the PADC web site

Foot covers are included in the codes for a prosthetic foot component and are not separately payable upon initial issue.

The right (RT) and left (LT) modifiers must be used with prosthesis codes. When the same code for prostheses, sockets, or components for bilateral amputees are billed on the same date of service, the items (RT and LT) will be entered on the same line of the claim using the LTRT modifiers and billed with 2 units of service. Claim lines billed without the RT and/or LT modifiers will be rejected as incorrect coding.

Suppliers should contact the DME Pricing, Data Analysis, and Coding Contractor (PDAC) for guidance on the correct coding of these items.

#### FOOT/ANKLE CODING CHANGES

HCPCS	NARRATIVE	CHANGE
KXXX1	ALL LOWER LIMB EXTREMITY PROSTHESES, FOOT, DYNAMIC RESPONSE	New code
KXXX2	ADDITION TO LOWER EXTREMITY PROSTHESIS, AXIAL ROTATION UNIT, WITH OR WITHOUT ADJUSTABILITY	New code
L5859	ADDITION TO LOWER EXTREMITY PROSTHESIS, ENDOSKELETAL KNEE-SHIN SYSTEM, POWERED AND PROGRAMMABLE FLEXION/EXTENSION ASSIST CONTROL, INCLUDES ANY TYPE MOTOR(S)	Unchanged
L5968	ADDITION TO LOWER LIMB PROSTHESIS, MULTIAXIAL ANKLE WITH SWING PHASE ACTIVE DORSIFLEXION FEATURE	Unchanged
L5970	ALL LOWER EXTREMITY PROSTHESES, FOOT, EXTERNAL KEEL, SACH FOOT	Narrative revised to: ALL LOWER EXTREMITY PROSTHESES, SACH FOOT, REPLACEMENT ONLY
L5971	ALL LOWER EXTREMITY PROSTHESIS, SOLID ANKLE CUSHION HEEL (SACH) FOOT, REPLACEMENT ONLY	Discontinued CROSSWALK TO L5070
L5972	ALL LOWER EXTREMITY PROSTHESES, FLEXIBLE KEEL FOOT (SAFE, STEN, BOCK DYNAMIC OR EQUAL)	Unchanged
L5973	ENDOSKELETAL ANKLE FOOT SYSTEM, MICROPROCESSOR CONTROLLED FEATURE, DORSIFLEXION AND/OR PLANTAR FLEXION CONTROL, INCLUDES POWER SOURCE	Unchanged
L5974	ALL LOWER EXTREMITY PROSTHESES, FOOT, SINGLE AXIS ANKLE/FOOT	Unchanged
L5975	ALL LOWER EXTREMITY PROSTHESIS, COMBINATION SINGLE AXIS ANKLE AND FLEXIBLE KEEL FOOT	Discontinued CROSSWALK TO L5974

HCPCS	NARRATIVE	CHANGE
L5976	ALL LOWER EXTREMITY PROSTHESES, ENERGY	Discontinued CROSSWALK
	STORING FOOT (SEATTLE CARBON COPY II OR	TO KXXX1
	EQUAL)	
L5978	ALL LOWER EXTREMITY PROSTHESES, FOOT,	Unchanged
	MULTIAXIAL ANKLE/FOOT	
L5979	ALL LOWER EXTREMITY PROSTHESIS, MULTI-AXIAL	Discontinued CROSSWALK
	ANKLE, DYNAMIC RESPONSE FOOT, ONE PIECE	TO L5978
	SYSTEM	
L5980	ALL LOWER EXTREMITY PROSTHESES, FLEX FOOT	Discontinued CROSSWALK
	SYSTEM	TO KXXX1
L5981	ALL LOWER EXTREMITY PROSTHESES, FLEX-WALK	Discontinued CROSSWALK
	SYSTEM OR EQUAL	TO KXXX1
L5982	ALL EXOSKELETAL LOWER EXTREMITY PROSTHESES,	Discontinued CROSSWALK
	AXIAL ROTATION UNIT	TO KXXX2
L5984	ALL ENDOSKELETAL LOWER EXTREMITY	Discontinued CROSSWALK
	PROSTHESIS, AXIAL ROTATION UNIT, WITH OR	TO KXXX2
	WITHOUT ADJUSTABILITY	
L5985	ALL ENDOSKELETAL LOWER EXTREMITY	Unchanged
	PROSTHESES, DYNAMIC PROSTHETIC PYLON	
L5986	ALL LOWER EXTREMITY PROSTHESES, MULTI-AXIAL	Discontinued CROSSWALK
	ROTATION UNIT ('MCP' OR EQUAL)	TO KXXX2
L5987	ALL LOWER EXTREMITY PROSTHESIS, SHANK FOOT	Discontinued CROSSWALK
	SYSTEM WITH VERTICAL LOADING PYLON	TO KXXX1
L5988	ADDITION TO LOWER LIMB PROSTHESIS, VERTICAL	Unchanged
	SHOCK REDUCING PYLON FEATURE	

# **Coding Information**

# **Bill Type Codes:**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

#### **Revenue Codes:**

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless

specified in the article services reported under other Revenue Codes are equally subject to this
coverage determination. Complete absence of all Revenue Codes indicates that coverage is not
influenced by Revenue Code and the article should be assumed to apply equally to all Revenue
Codes.

**CPT/HCPCS Codes** 

**Group 1 Paragraph:** 

**Group 1 Codes:** 

**Covered ICD-10 Codes** 

Group 1 Paragraph:

**Group 1 Codes:** 

Non-Covered ICD-10 Codes

**Group 1 Paragraph:** 

**Group 1 Codes:** 

# **Revision History Information**

**Please note:** The Revision History information included in this Article prior to 06/20/2013 will now display with a Revision History Number of "R1" at the bottom of this table. All new Revision History information entries completed on or after 06/20/2013 will display as a row in the Revision History section of the Article and numbering will begin with "R2".

# **Associated Documents**

Related Local Coverage Document(s) LCD(s)

DL33787 - Lower Limb Prostheses

# Related National Coverage Document(s)

This Article version has no Related National Coverage Documents.

Statutory Requirements URL(s)

Rules and Regulations URL(s)

CMS Manual Explanations URL(s)

Other URL(s)