

## **Lower Limb Prosthesis Electronic Clinical Template Background**

CMS is working in collaboration with the DHHS Office of the National Coordinator for Health IT (ONC) to develop an electronic template that will assist providers with data collection and medical documentation to support selected items and services such as Lower Limb Prostheses. This template may also facilitate the electronic submission of medical documentation. The attached document describes the clinical elements that CMS believes would be useful in supporting the documentation requirements for coverage of Lower Limb Prostheses. Once finalized, these proposed clinical elements will be delivered to ONC for consideration and/or inclusion in ONC's development process. This list of clinical elements is NOT intended to be a final data entry form.

Medical documentation submitted to CMS in support of a claim for a lower limb prosthesis should accurately reflect the beneficiary's medical condition(s) that necessitate the use of the specifically ordered device(s) as well as beneficiary's medical condition(s) that would impact the beneficiary's ability to effectively utilize the specifically ordered device(s). 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). Not all clinical elements noted in this document will be applicable to all beneficiaries and answers to all clinical elements in any given record would not generally be expected. Only those clinical elements that pertain to the individual's medical condition would be relevant.

Lower limb prostheses are covered under the Medicare Artificial Legs, Arms and Eyes benefit (Social Security Act §1861(s)(9)). In order for a beneficiary to be eligible for reimbursement, reasonable and necessary (R&N) requirements must be established as set out in the related Local Coverage Determinations (LCD: L11442, L27013, L11464, and L11453).

A lower limb prosthesis is covered when the beneficiary:

1. Will reach or maintain a defined functional state within a reasonable period of time; and
2. Is motivated to ambulate.

For Medicare payment purposes, the medical necessity for certain components/additions to a lower limb prosthesis is based on the beneficiary's functional abilities. A beneficiary is placed at one of the five functional levels listed below based on the reasonable expectations of the supplier and the referring physician. It is important to note that the ordering physician's medical documentation must support the medical necessity, within the context of his or her overall medical condition, for the device(s) selected and delivered to the beneficiary.

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

**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. Specifically in this case, since the prosthetist is billing Medicare as the Supplier of the Durable Medical Equipment (DME) item the prosthetist's records cannot be relied on in isolation to establish medical necessity.**

- \* **Supplier-produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are insufficient, by themselves, to support medical necessity for Medicare payment purposes.**
- \* **Templates and forms, including CMS Certificates of Medical Necessity, are subject to corroboration with information in the medical record.**

**Suggested Electronic Clinical Template Elements for  
Medical Documentation Submitted to CMS in Support of Claims for Lower Limb Prostheses**

**DRAFT v5 (11/06/13)**

The clinical elements listed below are designed to prompt the practitioner to include key aspects of documentation for lower limb prostheses in the medical record.

**A. Chief Complaint**

A1. State the beneficiary's current lower limb prosthetic needs.

**B. History of Present Illness**

- B1. Describe the beneficiary's current medical conditions that affect ambulation and overall functional capabilities, such as congestive heart failure, chronic lung disease, arthritis, etc.
- B2. Describe the beneficiary's lower limb amputation leading to the need for a lower limb prosthesis and its etiology.
  - B2a. Describe any current and/or past problems or complications with the amputated limb that affect functional capability.
- B3. Describe the beneficiary's activity level such as transfers, ambulation, balance, endurance, and strength and any functional limitations relating to ambulation and the anticipated functional capability with a properly fitted prosthesis. (For example, do you anticipate that the beneficiary will be capable of traversing low level environmental barriers such as curbs, stairs or uneven surfaces or perform activity that demands prosthesis utilization beyond simple locomotion?)
- B4. Describe any impairments of the non-amputated limb(s).
- B5. Describe the beneficiary's motivation to ambulate and use a lower limb prosthesis.

**C. Past Medical and Surgical History**

- C1. List the beneficiary's medical conditions and previous surgeries.
- C2. List the beneficiary's current medications.

**D. Social History**

- D1. Describe any current or anticipated activities that demand prosthetic utilization beyond short distances, not already noted.
  - D1a. Describe any environmental barriers (e.g. number of steps to enter the home, number of steps within the home, type of home (tri-level, 2-story, etc.), navigation of multiple flights of steps, farm fields, construction sites, etc.) not already noted.
  - D1b. Describe any assistance the beneficiary requires or will require to don/doff his/her prosthesis or to transfer/ambulate (with or without mobility aids).

**E. Review of Systems (ROS)**

Describe any symptoms affecting level of function/ambulation.

**E1. Constitutional**

- E1a. Describe any recent change in the beneficiary's overall general health condition or functional capability such as weight change of greater than 10 pounds, etc.
- E1b. Describe any medical or surgical procedures planned that will affect the beneficiary's level of function/ambulation (including revision of the residual limb).
- E1c. Describe any significant change in the beneficiary's level of function/ambulation during the last 6 months.
- E1d. Describe any current use of a Power Mobility Device, cane, walker, or wheelchair.

**E2. Eyes**

- E.2a. Describe any visual impairment affecting the beneficiary's level of function/ambulation?

**E3. Respiratory**

- E3a. Describe the beneficiary's respiratory symptoms that affect level of function/ambulation.
- E3b. Does the beneficiary require the use of supplemental oxygen? If yes, list the frequency, duration, delivery system, and flow rate.
- E3c. Does beneficiary get Shortness of Breath (SOB) while performing Mobility Related Activities of Daily Living (MRADLs)? If yes:
  - E3ci. Describe Activities of Daily Living (ADLs) that make the beneficiary SOB in or outside the home (with supplemental oxygen if required);

E3cii. Describe interventions (other than the use of oxygen) that palliate SOB while performing MRADLs.

#### **E4. Cardiovascular**

- E4a. Describe the beneficiary's cardiovascular symptoms that affect level of function/ambulation.
- E4b. Describe the beneficiary's complaints of increased heart rate, palpitation, ischemic pain, etc., that occur or worsen when the beneficiary attempts or performs ADLs or ambulate (with supplemental oxygen if required)?
- E4c. Describe measures that have been taken in the past that have worked or failed to alleviate these symptoms.

#### **E5. Musculoskeletal**

- E5a. Describe the beneficiary's musculoskeletal symptoms that affect level of function/ambulation.
- E5b. If the beneficiary has a history of falls, detail where they occur; the reason the beneficiary believes that she/he falls; the frequency and timing of the falls. Note whether the beneficiary is able to rise to a seated/standing position without the help of another person after a fall.
- E5c. If the beneficiary experiences joint/bone pain, describe the signs/symptoms (decreased range of motion, crepitus, laxity, etc.) that occur or worsen with MRADLs. Specifically, describe any arthritic impairments or disabilities with the non-amputated limb.
- E5d. Describe management of the beneficiary's chronic pain symptoms, including use of analgesics, particularly Schedule II drugs.
- E5e. Describe complaints of abnormalities in strength or coordination with MRADLs.

#### **E6. Neurological**

- E.6.a Describe any neurological symptoms that affect level of function/ambulation such as balance disturbance, peripheral neuropathy, base line Parkinsonian gait abnormality, etc.

#### **E7. Skin**

- E.7.a Describe any skin ulcer(s) or other loss of skin integrity that affect level of function/ambulation.

#### **E8. Cognitive/Behavioral/Psychiatric**

- E.8.a Describe any complaints of cognitive impairment that affect level of function/ambulation.

### **F. Physical Exam**

Provide quantifiable, objective measures/tests of the beneficiary's physical condition;

#### **F1. Constitutional**

- F1a. List Height, Weight, Blood Pressure (BP), Pulse Rate (P), and Respiratory Rate (RR) at rest.

#### **F2. Eyes**

- F2a. Document visual acuity.

#### **F3. Respiratory**

- F3a. Document the respiratory exam at rest and with ambulation with current best mobility assistive device and supplemental oxygen if required (auscultation, pulse, respiratory rate, and O2Sat).

#### **F4. Cardiovascular**

- F4a. Document the cardiovascular exam including any jugular venous distention, lower and upper extremity edema, and orthostatic pressures if applicable.

#### **F5. Musculoskeletal**

- F5a. Document the upper extremity and lower extremity individual muscle groups tone and strength (from 0 – 5) and then discuss how as they pertain to mobility related activities of daily living (MRADLs).
- F5b. Document any abnormalities of joint range of motion and architecture (e.g., swelling, erythema, subluxation contractures, heterotopic ossificans).

0: no muscular contraction detected
1: a trace muscular contraction detected
2: active movement of the muscle accomplished with gravity eliminated

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| 3: active movement of the muscle accomplished against gravity with no resistance applied<br>4: active movement of the muscle accomplished against gravity with less than full resistance applied<br>5: active movement of the muscle accomplished against gravity and against full resistance |
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F5c. Document the condition (length, shape, etc.) of the beneficiary's residual limb, if any.

F5d. Document the beneficiary's ability/inability to transfer (include the use of current mobility aides, mechanical lift, one or two person assistance, and transfer board) and/or change from sit to stand position.

F5e. Describe the beneficiary's gait with the use of any current mobility aides.

#### **F6. Neurological**

F6a. Record any neurologic abnormalities that limit level of function/ambulation.

#### **F7. Skin**

F7a. Describe current areas of open wounds, edema, scarring or venous stasis that would affect level of function/ambulation.

#### **F8. Psychiatric**

F8a. Document the beneficiary's mental status, judgment, insight, and memory that would affect level of function/ambulation.

### **G. Beneficiary Assessment**

Medical documentation submitted to CMS in support of a claim must document the beneficiary's functional capabilities. Based on this examination indicate the beneficiary's anticipated functional activity achievable with a properly fitted lower limb prosthesis, within the context of his or her overall medical problems. Please keep in mind that the activity level supported by this exam must be consistent with the level of device delivered to the beneficiary.

### **H. Plan**

H1. Based on this assessment, indicate your plan for satisfying the beneficiary's prosthetic requirements.