

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 data elements that CMS believes would be useful in supporting the documentation requirements for coverage of Lower Limb Prostheses. Once finalized these proposed data elements will be delivered to ONC for consideration and/or inclusion in ONC's development process. This list of data 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 Prosthetic should accurately reflect the beneficiary's medical condition(s) that necessitate the use of the specifically ordered Lower Limb Prosthetic as well as beneficiary's medical condition(s) that would impact the beneficiary's ability to effectively utilize the specifically ordered Lower Limb Prosthetic in achieving a defined functional state. 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). As such not all data elements will be applicable to all beneficiaries and answers to all data elements in any given record would not generally be expected. Only those data 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, ~~the~~ 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, lower limb prosthetic devices are categorized based on the following five K-Levels. A beneficiary is placed at one of the five potential functional levels 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 ~~problems~~condition, for the corresponding level of device that is selected and delivered to the beneficiary.

<p>Level 0: 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>Level 1: 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>Level 2: 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>Level 3: 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>Level 4: 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>

****IMPORTANT NOTE TO PHYSICIANS AND SUPPLIERS****

Records from suppliers or healthcare professionals ~~(specifically in this case, prosthetists)~~ 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 DME item the prosthetist's records can not 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 ~~v3 (05/07/13)~~ v4 (07/04/13)

The data 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 need for an initial or replacement prosthesis.

B. History of Present Illness

- B1. Describe the beneficiary's current medical conditions that effect 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 prosthetic and its etiology.
- B2a. Describe any current and/or past problems or complications with the amputated limb that effect potential functional capability.
- ~~B2b. Describe any past complications with the residual limb.~~
- ~~B4. Describe the beneficiary's activity level 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 to traversing low level environmental barriers such as curbs, stairs or uneven surfaces or do you expect the beneficiary will performing vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion?)~~
- B3. If this is an evaluation for a replacement of an existing prosthesis
- B3a. Describe how often and how long the beneficiary uses the current prosthesis (if applicable) each day along with the activities that the beneficiary currently is able to perform with the existing prosthesis and anticipated activities with the replacement prosthesis.
- ~~B3b. Explain the reason for replacement and any change in prosthetic requirements.~~
- ~~B4. Describe the beneficiary's activity level transfers, ambulation, balance, endurance, and strength and any functional limitations relating to ambulation.~~
- B4. Describe any impairments of the non-amputated limb(s).
- B5. Describe the beneficiary's motivation to ambulate and general desired ambulation goals including vocational requirements and athletic goals beyond simple locomotion.

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 vocational, therapeutic, exercise or athletic 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. If the beneficiary requires assistance to don/doff his/her prosthesis independently or transfer/ ambulate independently (with or without mobility aids), describe the availability of caregiver assistance and if applicable, any reliance on caregivers for ADLs.

E. Review of Systems (ROS)

Describe any symptoms effecting 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 rehabilitation potential (including revision of the residual limb). ~~If applicable, describe: type of procedure, expected recovery time.~~
- E1c. Describe any significant change in the beneficiary's rehabilitation potential during the last 6 months.
- E1d. Describe any current use of a Power Mobility Device, cane, walker, or wheelchair.

E2. Eyes

E.2.a Is the beneficiary's vision sufficient to ambulate safely with the proposed prosthetic device?

E3. Respiratory

E3a. Describe the beneficiary's respiratory symptoms that effect restrict his/her ambulation or rehabilitation potential.

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 SOB while performing MRADLs? If yes:

E3ci. Describe 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 effect that limit his/her ambulation or rehabilitation potential.

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 effect ambulation or rehabilitation potential.

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 arise 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 effect that restrict ambulation or rehabilitation potential MRADLs 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 effect ambulation or rehabilitation potential, and the etiology.

E8. Cognitive/Behavioral/Psychiatric

E.8.a Describe any complaints of cognitive impairment that effect ambulation or rehabilitation potential that could limit rehabilitation.

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, resp rate, and ~~Sa~~O₂Sat).
- ~~F3b. After walking the maximum distance possible on level ground (up to 50 ft) with current best mobility device and supplemental oxygen if required, document the distance ambulated, pulse, respiratory rate, and O₂Sat.~~
- ~~F3bi. Describe beneficiary's respiratory effort (e.g., use of accessory muscles, intercostal retractions).~~
- ~~F3bii. Was mobility aid used? If yes, describe. If supplemental O₂ is used, list the frequency, duration delivery system and flow rate.~~
- ~~F3biii. Conduct a 6 minute walk test and document the results.~~

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 ossifications).

0: no muscular contraction detected 1: a trace muscular contraction detected 2: active movement of the muscle accomplished with gravity eliminated 3: active movement of the muscle accomplished against gravity with no resistance applied 4: active movement of the muscle accomplished against gravity with less than full resistance applied 5: active movement of the muscle accomplished against gravity and against full resistance

- 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 ambulation or rehabilitation potential.

F7. Skin

- F7a. Describe current areas of open wounds, edema, scarring or venous stasis that would affect ambulation or rehabilitation potential.

F8. Psychiatric

- F8a. Document the beneficiary's mental status, judgment, insight, and memory that would affect ambulation or rehabilitation potential.

G. Beneficiary Assessment

Medical documentation submitted to CMS in support of a claim must document the beneficiary's current functional capabilities and his/her expected rehabilitation potential. 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.