

Policy References: [Local Coverage Determination Therapeutic Shoes for Persons with Diabetes \(L33369\)](#) and [Policy Article \(A52501\)](#)

Documentation References: [Standard Documentation Requirements Policy Article \(PA\) A55426](#)

The supplier must be able to provide all of these items on request:

- [Standard Written Order \(SWO\)](#)
- [Beneficiary Authorization](#)
- [Proof of Delivery \(POD\)](#)
- [Continued Need](#)
- [Continued Use](#)
- Signed and dated statement from the certifying physician who is treating the beneficiary's diabetes specifying the following:
 - Beneficiary has diabetes mellitus; **and**
 - Beneficiary has one or more of the conditions noted below; **and**
 - Beneficiary is being treated under a comprehensive plan of care for his/her diabetes; **and**
 - Beneficiary needs diabetic shoes.

The certifying physician must be an M.D. or D.O, not a DPM, PA, NP or CNS, The certification statement must be completed, signed and dated by the certifying physician on or after the date of the in-person visit and within three months prior to delivery of the shoes/inserts. This statement should not be signed prior to documented medical records supporting conditions noted below.

- Medical records from treating practitioner as noted below

Medical Records should contain:

Documentation of an in-person visit within six months prior to delivery of the shoes/inserts documenting the following:

- Criterion 1: - The beneficiary has diabetes mellitus
- Criterion 2: - The beneficiary has one or more of the following conditions:
 - Amputation of the other foot, or part of either foot; **or**
 - History of foot ulceration of either foot; **or**
 - History of pre-ulcerative calluses of either foot; **or**
 - Peripheral neuropathy with evidence of callus formation of either foot; **or**
 - Foot deformity of either foot; **or**

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- Poor circulation in either foot.

Diagnoses such as hypertension, coronary artery disease, or congestive heart failure or the presence of edema are not by themselves sufficient. Documentation must include objective and quantifying information such as pedal pulses or clearly indicate the condition is of the foot/feet.

- In order to meet criterion 2, the certifying physician must either:
 - Personally document one or more of criteria a – f in the medical record of an in-person visit within six months prior to delivery of the shoes/inserts and prior to or on the same day as signing the certification statement; **or**
 - Obtain, initial, date (prior to signing the certification statement), and indicate agreement with the information from the medical records of an in-person visit with a podiatrist, other M.D or D.O, PA, NP, or CNS that is within six months prior to delivery of the shoes/inserts, and that documents one or more of criteria a-f.
- Criterion 3: - The certifying physician has certified that criteria (1) and (2) are met, that he/she is treating the beneficiary under a comprehensive plan of care for his/her diabetes and that the beneficiary needs diabetic shoes.
 - Have an in-person visit with the beneficiary during which diabetes management is addressed within six months prior to delivery of the shoes/inserts; **and**
 - Sign the certification statement on or after the date of the in-person visit and within three months prior to the delivery of the shoes/inserts.

Supplier documentation

- Criteria 4 – An in-person evaluation by the supplier prior to selection of the items including the following criteria:
 - An examination of the beneficiary's feet with a description of the abnormalities that will need to be accommodated by the shoes/inserts; **and**
 - Measurements of the beneficiary's feet.
 - For custom molded shoes (A5501) and inserts (A5513 and A5514), taking impressions, making casts, or obtaining CAD-CAM images of the beneficiary's feet.
- Criteria 5 – An objective in-person evaluation at the time of delivery including the following:
 - Assessment with the beneficiary wearing the shoes and inserts: **and**
 - Documentation that the shoes/inserts fit properly.