

Reference: L33369, A52501

All Therapeutic Shoes, Accessories, and Supplies

- Dispensing Order**, if applicable
- Detailed Written Order (DWO)**
The DWO must be dated on or after in-person visit with the prescribing physician. If the prescribing physician is also the supplier, a separate order is not required, but the item provided must be clearly noted in the beneficiary's record.
- Beneficiary Authorization**
- Proof of Delivery (POD)**
Direct delivery is the only acceptable method of delivery for Therapeutic Shoes and inserts.
- 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

- 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:
 - a. Amputation of the other foot, or part of either foot, **or**
 - b. History of foot ulceration of either foot, **or**
 - c. History of pre-ulcerative calluses of either foot, **or**
 - d. Peripheral neuropathy with evidence of callus formation of either foot, **or**
 - e. Foot deformity of either foot, **or**
 - f. 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 medical records of an in-person visit with a podiatrist, other M.D or D.O., PA, NP, or CNS that is within 6 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 6 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 3 months prior to delivery of the shoes/inserts.
- Supplier documentation
 - Criterion 4 – An in-person evaluation by the supplier prior to selection of the items including the following:
 - 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), taking impressions, making casts, **or** obtaining CAD-CAM images of the beneficiary's feet.
 - Criterion 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.

Billing Reminders

- RT and/or LT modifiers must be submitted with all HCPCS codes in the therapeutic shoes policy. If bilateral items are provided on the same date of service, bill for both items on the same claim line using the RTL modifiers and 2 units of service.
- A new order is required for replacement of any shoe.
- A new order is not required for the replacement of an insert or modification within one year of the order.
- A new order is required for replacement of an insert or modification more than one year from the most recent order.
- A new certification statement is required for a shoe, insert or modification provided more than one year from the most recent Certification Statement.
- The KX modifier must be added to codes for shoes and inserts only if criteria 1-5 noted in the medical records section have been met.

- The GY modifier must be added to each code if criteria 1-5 noted in the medical records section have not been met.
- The only products that may be billed using code A5512 are those that are specified in the Product Classification List on the Pricing, Data Analysis, and Coding (PDAC) contractor web site.
- For beneficiaries meeting the coverage criteria, coverage is limited to one of the following within one calendar year (January – December):
 - One pair of custom molded shoes (A5501) (which includes inserts provided with these shoes) and 2 additional pairs of inserts (A5512 or A5513); **or**
 - One pair of depth shoes (A5500) and 3 pairs of inserts (A5512 or A5513) (not including the non-customized removable inserts provided with such shoes).

The content of this document was prepared as an education tool and is not intended to grant rights or impose obligations. Use of this document is not intended to take the place of either written law or regulations. Suppliers are reminded to review the Local Coverage Determination and Policy Article for specific documentation guidelines.

[Print Form](#)

[Go Back to Front Page](#)