Dear Physician,

Medicare covers therapeutic shoes and inserts for persons with diabetes. This statutory benefit is limited to one pair of shoes and up to 3 pairs of inserts or shoe modifications per calendar year. However, in order for these items to be covered for your patient, the following criteria must be met:

1. A certifying physician must be managing the patient’s diabetes under a comprehensive plan of care and must certify that the patient needs therapeutic shoes.
2. That certifying physician must document that the patient has one or more of the following qualifying conditions:
   a. Foot deformity
   b. Current or previous foot ulceration
   c. Current or previous pre-ulcerative calluses
   d. Previous partial amputation of one or both feet, or complete amputation of one foot
   e. Peripheral neuropathy with evidence of callus formation
   f. Poor circulation in one or both feet

The Social Security Act §1861(s)(12) requires that a Doctor of Medicine (MD) or doctor of osteopathy (DO) certify that the beneficiary receiving therapeutic shoes and inserts is under a comprehensive plan of care for their diabetes. As a result of the statutory MD or DO restriction, nurse practitioners (NPs) and physician assistants (PAs) may not serve in the role of the certifying physician except in limited circumstances such as NPs and PAs meeting the “incident to” requirements or states where the NP can practice independently (see the Therapeutic Shoes for Persons with Diabetes Local Coverage Determination (LCD) related Policy Article at https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=52501).

The following documentation is required in order for Medicare to pay for therapeutic shoes and inserts and must be provided by the physician to the supplier, if requested:

1. A standard written order (SWO). This may be prepared by the supplier but must be reviewed and signed by the prescribing practitioner to indicate agreement. The SWO must be signed on or after the date of the visit with the Prescribing Practitioner.
2. A copy of an office visit note, from the patient's medical record, that shows management of the patient's diabetes. This office visit must occur within 6 months prior to delivery of the shoes and inserts.
3. A copy of an office visit note, from the patient's medical record, that describes one of the qualifying conditions (a-f) listed above. This office visit note may document an interaction between (a) the patient and the certifying physician or (b) the patient and another qualified practitioner (such as a podiatrist, NP, PA, or certified nurse specialist [CNS]). If option (b) is used, then the certifying physician must sign, date, and make a note on that document indicating agreement and send that to the supplier.

The note documenting the qualifying condition(s) must be more detailed than the general descriptions that are listed above (a-f). It must describe (examples not all-inclusive):

- The specific foot deformity (such as bunion, hammer toe, etc.); or
- The location of a foot ulcer or callus or a history of one these conditions; or
- The type of foot amputation; or
- Symptoms, signs, or tests supporting a diagnosis of peripheral neuropathy plus the presence of a callus; or
The specifics about poor circulation in the feet (such as, a diagnosis of venous or arterial insufficiency or symptoms, signs, or test documenting one of these diagnoses). A diagnosis of hypertension, coronary artery disease, or congestive heart failure or the presence of edema is not by itself sufficient.

4. **A certification form stating that the coverage criteria described above have been met.** This form will be provided by the supplier but must be completed, signed, and dated by the certifying physician after the visits described in #2 and #3 and within 3 months prior to delivery of the shoes/inserts. A new Certification Statement is required for a shoe, insert or modification provided more than one year from the most recent Certification Statement on file. If option 3(b) is used, that visit note must be signed prior to or at the same time as the completion of the certification form. **This form is not sufficient by itself to show that the coverage criteria have been met and therefore must be supported by other documents in the patient’s medical record, as noted in #2 and #3.**

New documentation is required yearly in order for Medicare to pay for replacement shoes and inserts. As well, a new order is required for the replacement of any shoe. A new order is also required for the replacement of an insert or modification more than one year from the most recent order on file.


Suppliers may ask you to provide the medical documentation described above on a routine basis in order to assure that Medicare will pay for these items and that your patient will not be held financially liable. Providing this documentation to the supplier is in compliance with the Health Insurance Portability and Accountability Act Privacy Rule. No specific authorization is required from your patient. Also note that you may not charge the supplier or your patient to provide this information. Please cooperate with the supplier so that they may provide the therapeutic shoes and inserts that are needed by your patient.

Sincerely,

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