



Therapeutic Shoes for Persons With Diabetes

REQUIRED DOCUMENTATION

All Claims

Standard Written Order

Beneficiary's name or Medicare Beneficiary Identifier (MBI)

General description of the item

The description can be either a general description (e.g., wheelchair or hospital bed), a HCPCS code, a HCPCS code narrative, or a brand name/model number

For equipment - In addition to the description of the base item, the SWO may include all concurrently ordered options, accessories or additional features that are separately billed or require an upgraded code (List each separately).

For supplies – In addition to the description of the base item, the DMEPOS order/prescription may include all concurrently ordered supplies that are separately billed (List each separately)

Quantity to be dispensed, if applicable

Order Date

Treating Practitioner Name or NPI

Treating Practitioner's signature

Practitioner's signature on the written order meets [CMS Signature Requirements](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf) (<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf>)

Standard Written Order was obtained prior to submitting the claim to Medicare.

The order is dated on or after a documented beneficiary visit with the prescribing practitioner.

Changes/corrections to the order have been initialed/signed and dated.

NOTE: If the prescribing practitioner is the supplier, a separate order is not required, but the items provided must be clearly noted in the beneficiary's record.

Delivery Documentation

Beneficiary's name

Delivery address

Quantity delivered

A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number.

Signature of person accepting delivery (if the signature is illegible, print the name underneath)

Relationship to beneficiary

Delivery date

Signed and dated Certifying Physician Statement (physician managing the beneficiary's systemic diabetes condition) that specifies the beneficiary meets ALL the criteria listed below:

Certifying Physician is an M.D. (Medical Doctor) or D.O. (Doctor of Osteopathy)



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NOTE: Exceptions to MD/DO as Certifying Physician

“Incident to” - NPs or PAs providing ancillary services as auxiliary personnel could meet the “incident to” requirements in their provision of therapeutic shoes to beneficiaries with diabetes if all of the following criteria are met:

1. The supervising physician has documented in the medical record that the patient is diabetic and has been, and continues to provide, the patient follow-up under a comprehensive management program of that condition; and,
2. The NP or PA certifies that the provision of the therapeutic shoes is part of the comprehensive treatment plan being provided to the patient; and,
3. The supervising physician must review and verify (sign and date) all of the NP or PA notes in the medical record pertaining to the provision of the therapeutic shoes, acknowledging their agreement with the actions of the NP or PA.

In states where the NP may practice independently, the NP’s employment situation would require compliance with Medicare “incident to” rules in order to serve as the certifying physician. Please refer to the applicable A/B MAC for further information.

“Primary Care First (PCF) Model Demonstration Project” - If a Nurse Practitioner is enrolled in the PCF Model Demonstration Project they can refer or certify the beneficiary until December 31, 2025.

Has diabetes

Has one of the following conditions:

- a. Previous amputation of the other foot, or part of either foot, or
- b. History of previous 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

Is being treated under a comprehensive plan of care for his/her diabetes, and needs diabetic shoes.

The certification statement was signed on or after the date of the in-person visit and within 3 months prior to delivery of the shoes/inserts.

Signature on the Certifying Physician Statement meets [CMS Signature Requirements](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf) (<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf>)

Clinical evaluation documenting the management of the beneficiary’s diabetes

Evaluation was performed by the Certifying Physician, or entity meeting the “Incident to” requirements;

Visit occurred within 6 months prior to delivery; and

Signature meets [CMS Signature Requirements](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf) (<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf>)

Clinical evaluation documenting that the beneficiary has one or more of the qualifying conditions, a-f, listed above

Evaluation was either personally performed by the certifying physician **OR** the certifying physician obtained, initialed, dated, and indicated agreement with information from the medical records of an in-person visit with a podiatrist, other M.D or D.O., physician assistant, nurse practitioner, or clinical nurse specialist.



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Evaluation was performed and/or reviewed by the Certifying Physician prior to completion of the Statement of Certifying Physician;

Visit to document the qualifying foot condition occurred within 6 months prior to delivery; and

Signature meets [CMS Signature Requirements](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf) (<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf>)

Supplier in-person evaluation conducted prior to or at the time of selection of items includes at least 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/modifications;

Measurements of the beneficiary's feet; and

For custom molded shoes and inserts, information regarding taking impressions, making casts, or obtaining CAD-CAM images of the beneficiary's feet that will be used in creating positive models of the feet.

Supplier in-person visit, at the time of delivery, which assesses the fit of the shoes and inserts with the beneficiary wearing them

Claims for Custom Molded Shoes (A5501)

Supplier's evaluation documents all of the following:

Beneficiary has a foot deformity that cannot be accommodated by a depth shoe;

The nature and severity of the deformity is described in detail; and

Visit included taking impressions, making casts, or obtaining CAD – CAM images of the beneficiary's feet in order to create positive models of the feet.

Claims for Prefabricated Multiple Density Inserts (A5512)

The inserts are listed in the Product Classification List (PCL) on the Pricing, Data Analysis, and Coding (PDAC) contractor website.

Claims for Custom Molded or Milled Inserts (A5513 or A5514)

The inserts are listed in the PCL on the PDAC contractor website, or

The supplier must provide a list of the materials that were used and a description of the custom fabrication process on request.

REMINDERS

- Items with no physician or other licensed health care provider order must be submitted with an "EY" modifier added to each affected HCPCS code.
- Suppliers **must** add a KX modifier to codes for shoes, inserts, and modification only if coverage criteria have been met. This documentation **must** be available upon request. The Statement of Certifying Physician form is not sufficient to meet this requirement.
- If all coverage criteria have not been met, the GY modifier **must** be added to each code.
- If a KX or appropriate GA, GY or GZ modifier is not included on the claim line, the claim line will be rejected as missing information.
- The right (RT) and/or left (LT) modifiers must be used when billing shoes, inserts, or modifications. If bilateral items are billed on the same date of service, bill each item on two separate claim lines using the RT and LT modifiers and 1 unit of service (UOS) on each claim line.
- 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.
- A new order is not required for the replacement of an insert or modification within one year of the order on file. However, the supplier's records should document the reason for the replacement.



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- A new order is required for the replacement of any shoe.

ONLINE RESOURCES

- **TSPD Resources**
 - **JB:** https://www.cgsmedicare.com/jb/mr/tsd_resources.html
 - **JC:** https://www.cgsmedicare.com/jc/mr/tsd_resources.html
- **DME MAC Supplier Manual**
 - **JB:** <https://www.cgsmedicare.com/jb/pubs/supman/index.html>
 - **JC:** <https://www.cgsmedicare.com/jc/pubs/supman/index.html>
- **Local Coverage Determinations (LCDs) and Policy Articles**
 - **JB:** <https://www.cgsmedicare.com/jb/coverage/lcdinfo.html>
 - **JC:** <https://www.cgsmedicare.com/jc/coverage/LCDinfo.html>
- **Primary Care First Model Demonstration Project Until December 31, 2025**
 - **JB:** <https://www.cgsmedicare.com/jb/pubs/news/2020/11/cope19408.html>
 - **JC:** <https://www.cgsmedicare.com/jc/pubs/news/2020/11/cope19408.html>

NOTE: It is expected that the beneficiary's medical records will reflect the need for the care provided. These records are not routinely submitted to the DME MAC but must be available upon request. Therefore, while it is not a requirement, it is a recommendation that suppliers obtain and review the appropriate medical records and maintain a copy in the beneficiary's file.

DISCLAIMER

This document was prepared as an educational tool and is not intended to grant rights or impose obligations. This checklist may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either written law or regulations. Suppliers are encouraged to consult the *DME MAC Supplier Manual* and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.