

Therapeutic Shoes for Persons with Diabetes

DOCUMENTATION CHECKLIST

Required Documentation in Supplier's File*

Documentation of a Dispensing Order (preliminary written or verbal order) that contains:

Description of the item	Date of the order
Name of the beneficiary	Physician signature (for written orders) or supplier signature (for verbal orders)
Name of the physician	

NOTE: Only required if the items are dispensed prior to obtaining the detailed written order.

Detailed Written Order That Contains:

- Beneficiary's name
- List of all separately billable items ordered
- Quantity to be dispensed (for inserts)
- The treating physician's signature
- The date the treating physician signed the order (must be personally entered by physician)
- The date of the order

Physician's signature on the written order meets **CMS Signature Requirements**

<http://www.cgsmedicare.com/jc/pubs/news/2010/0410/cope12069.html>

Order was obtained prior to submitting the claim to Medicare.

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

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

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

Direct Delivery

- Beneficiary's name
- Delivery address
- Quantity delivered
- Detailed description of item(s)
- Brand
- Signature of person accepting delivery
- 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:

- Has diabetes
- Has one of the following conditions
 - Previous amputation of the other foot, or part of either foot, or
 - History of previous 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
 - Poor circulation in either foot

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



Signature on the Certifying Physician Statement meets **CMS Signature Requirements**

<http://www.cgsmedicare.com/jc/pubs/news/2010/0410/cope12069.html>

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

Clinical evaluation documenting the management of the patient's diabetes

Evaluation was performed by the Certifying Physician;

Visit occurred within 6 months prior to delivery (if DOS is on or after 01/01/11); and

Signature meets **CMS Signature Requirements**

<http://www.cgsmedicare.com/jc/pubs/news/2010/0410/cope12069.html>

Clinical evaluation documenting that the beneficiary met one or more of criteria a – f listed above

Evaluation was either personally performed by the certifying physician OR the certifying physician obtained documentation from another clinician, reviewed the information and indicated agreement with the information by initialing and dating the record;

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 (if DOS is on or after 01/01/11); and

Signature meets **CMS Signature Requirements**

<http://www.cgsmedicare.com/jc/pubs/news/2010/0410/cope12069.html>

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 patient's feet; and

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

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

Verification that the supplier disclosed Supplier Standards to the beneficiary

Claims for Custom Molded Shoes (A5501)

Supplier's evaluation documents all of the following:

Patient 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 patient's feet in order to create positive models of the feet.

Claims for Custom Molded Inserts (A5513)

PDAC website lists the insert as HCPCS code A5513 or the supplier has the following documentation:

List of materials that were use; and

A description of the custom fabrication process.

Reminders

- Suppliers should not submit claims to the DME MAC prior to obtaining a valid written order. Items billed to the DME MAC before a signed and dated order has been received 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 GY modifier is not included on the claim line, it will be rejected as missing information.
- The certifying physician must be an M.D. or D.O and may not be a podiatrist, physician assistant, nurse practitioner, or clinical nurse specialist.
- 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.
- A new order is required for the replacement of any shoe.

Additional Information References on the Web

- TSD Resources http://www.cgsmedicare.com/jc/coverage/mr/TSD_Resources.html
- Supplier Documentation Requirements <http://www.cgsmedicare.com/jc/pubs/pdf/Chpt3.pdf>
- Local Coverage Determinations (LCDs) and Policy Articles <http://www.cgsmedicare.com/jc/coverage/LCDinfo.html>

NOTE: It is expected that the patient'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 Jurisdiction C Supplier Manual* and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.