The Centers for Medicare and Medicaid Services (CMS) have specific documentation necessary prior to dispensing diabetic footwear.

- The Therapeutic Shoes for Persons with Diabetes (TSD) was passed in 1993.
- The bill was designed to help prevent lower limb ulcers, amputation, and other complications in people who are diagnosed with diabetes.

**Documentation**
Definitions:
The *Certifying Physician* provides the medical care for and manages the beneficiary’s systemic diabetic condition.

- The Certifying Physician must be a D.O. or M.D.
- The Certifying Physician may not furnish shoes unless he/she is in a defined rural area or health professional shortage area.
- The Certifying Physician cannot be a podiatrist.
Definitions:
The *Prescribing Physician* writes the order for the therapeutic shoes, modifications, and inserts.

- May be podiatrist, M.D., D.O., Physician Assistant, Nurse Practitioner, or a Clinical Nurse Specialist.
- Must be knowledgeable in diabetic shoes and inserts
- The Prescribing Physician *can* be the supplier.

Documentation
Definitions:
The *supplier* is the actual entity that furnishes the shoe, modification, and/or insert and bills Medicare.

- The supplier may be a podiatrist or other qualified individual
- The Prescribing Physician may be the supplier
- The Certifying Physician may be the supplier only if he/she is practicing in a defined rural area or a defined health care professional shortage area.
For an item to be covered by Medicare a written signed and dated order must be on file with the following criteria:

1) The patient has diabetes mellitus (ICD-9 code 249.00-250.93); AND

(This information is documented on the Statement of Certifying Physician)
2) The patient has one or more of the following conditions:
   a) Previous amputation of the foot or part of either foot, or
   b) History of previous foot ulceration, or
   c) History of pre-ulcerative calluses of either foot, or
   d) Peripheral neuropathy with evidence of callous formation, or
   e) Foot deformity, or
   f) Poor circulation, AND
3) The certifying physician who is managing the patient’s systematic diabetes has certified that indications 1) and 2) are met and that he/she is treating the patient under a comprehensive plan of care for his/her diabetes and that the patient needs diabetic shoes.
Prescription:
Following certification by the physician managing the patient’s systemic diabetic condition, a podiatrist or other qualified physician who is knowledgeable in the fitting of diabetic shoes and inserts may prescribe the particular type of footwear necessary.

The prescription should contain:
Patient Information (Name, DOB, Chart #...)
Current Diagnosis (Diabetes, Neuropathy, Previous amputations...)
Devices being prescribed (Custom/Non-custom Shoes and inserts, and/or toe filler)
Physician information (name and contact info, signature and date)
Medicare requires:

The Statement of Certifying Physician (SCP) must be signed and dated within **3 months** prior to dispensing footwear.

The Prescription must be signed and dated within **6 months** prior to dispensing footwear.

The physician treating the diabetes must conduct a clinical foot assessment within **6 months** and document the foot conditions. Clinical notes should be reflected on the SCP.

Supplier will have clinical notes on file, or have access to those notes.
✓ Statement of Certifying Physician (SCP)

Signed by Certifying Physician

Documented diagnosis of Diabetes Mellitus by the MD or DO treating the condition
Physician Notes on Qualifying Physician

Progress notes dictated during the clinical examination of the foot. Notes should include diagnosed foot condition, observations, follow up, treatment plan, and/or management. PCP notes are made available to the supplier or allowed access to them. Electronic? Consider printed copies with signature documentation.
✓ Prescription for Diabetic Shoes and Inserts

Signed by Prescribing Physician—can be a Certifying Physician or medical professional with prescription-writing privileges

A likely scenario is Certifying Physician completes prescription

Educate on well-written scripts
✓ Documentation of Initial In-Person Fitting

Medicare requires an in-person, diagnosis-specific foot assessment completed by the supplier

To determine appropriate need for shoes and to properly dispense footwear that addresses specific issues (e.g., swelling, deformities)

Aids in footwear selection
• **Documentation Reminder - Therapeutic Shoes**

  • Claim denials by NHIC Medical Review staff have resulted from failure of the supplier to document the fitting of the shoes. In many cases, these claims have an attestation from the beneficiary about the quality of the shoe and/or insert fit; however, there is no objective assessment from the supplier of the shoes regarding fit. This objective assessment by the supplier is a critical component of the delivery process.

  • Medicare and the DME MACs view the supplier of the shoe as a skilled professional with training in the proper assessment of fit and the relationship of the shoe and/or insert to correction of the underlying foot condition. Reliance solely on a beneficiary's statement about fit and comfort as documentation that the supplier performed an in-person fitting and assessment is inappropriate and will result in claim denials. Subjective statements from the beneficiary are only one component of fit assessment; the supplier must make an independent, objective assessment of the fit as well. Both components must be documented to meet the Medicare policy requirements.
✓ Documentation of Exact Items Dispensed

Footwear must be dispensed IN PERSON; try on shoes, heat mold inserts, assess fit

Keep records of your inventory or orders placed from manufacturer

Dispensed items match inventoried items match billing

Dr. Comfort
Authorization of Payment and Warranty

Once footwear is dispensed, patient signs and dates the authorization allowing supplier to bill their Medicare/private insurance.

Warranty information is provided by supplier

Acknowledges receipt of DMEPOS Quality Standards, Shoe Care Instructions, Break-In
Review the following patient documents:
1. 30 DMEPOS Quality Standards
2. Shoe Care Instructions
3. Break-In Procedure
4. Warranty and Return Policy

*Verbally review these documents with the patient.

Patient MUST receive these forms upon dispensing.
The patient’s medical records will reflect the need for the care provided. The documentation must demonstrate both medical necessity and the level of the service provided.

The patient’s medical records may include the physician's office records, hospital records, home health care records, records from other healthcare professional and test reports.

Therapeutic Shoes billed to the DMERC before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.
All documentation must be available to the DMERC upon request.

*Keep all documents for at least 7 years.*

*In Texas, keep at least 10.*

*Nationally, Medicare is considering 10 years.*
ABN:
The Advanced Beneficiary Notice is used to convey that Medicare is not likely to provide coverage in a certain case. A verbal review should also take place far enough in advance so the beneficiary is able to consider the options and make an informed decision.

The following information should be listed on the form:

**Patient Name**
**Reason for non-covered benefit**
**Patient Cost**
**Authorization of Patient**

Once signed, the GA modifier can be affixed on the claim to require payment by the patient. If not signed or missing modifier, the patient is NOT financially responsible.
Medicare Beneficiary Complaint Log:
The patient has the right to freely voice grievances and recommend changes in care or services without fear or reprisal or unreasonable interruption of services.

Complaints need to be documented in the Medicare Beneficiaries Complaint Log.

The log must contain the patient’s name, address, telephone number, and health claim number, a summary of the complaint, the date it was received, the name of the person receiving the complaint, and summary of the actions taken to resolve the complaint.
For patients meeting these criteria, coverage is limited to one of the following within one calendar year (January-December).

One pair of depth shoes (A5500) and 3 pairs of inserts (either A5512 or A5513).
What qualifies as a diabetic shoe (A5500)?

Several features have been identified to qualify to dispense and bill to Medicare beneficiaries.
Pricing Data Analysis and Coding (PDAC)
HCPCS coding contractor, effective Aug. 18, 2008
Formerly SADMERC
Contact for specific coding guidance

PDAC Website
http://www.dmepdac.com

DME Coding System (DMECS)
PDAC Contact Center
(877) 735-1326
- Provides a minimum of 3/16” of additional depth (7/16” for DRC shoes)
- Leather or other suitable material
- Closure
- Available in full and half sizes with a minimum of three widths
- The sole width is graduated to the width of the upper
A5500: Off the shelf depth-inlay shoe (accommodates multi-density insert per shoe).
A5501: Shoe molded from cast (s) of patient’s foot (custom molded shoe), per shoe
A5503-A5506: Modification of off-the-shelf depth-inlay shoe or custom-molded shoe with additional features
A modification of a custom molded or depth shoe will be covered as a substitute for an insert.

A5503: Rigid rocker bottoms or roller bottoms
A5504: Wedges
A5505: Metatarsal bars
A5507: Not otherwise specified modification of off-the-shelf depth inlay shoe or custom-molded shoe, per shoe
A5508: Deluxe feature of off-the-shelf depth inlay shoe or custom-molded shoe, per shoe
A5510: Direct-formed, compression molded to patient’s foot without external heat source, multi-density insert(s), prefabricated, per shoe

A5512: Multiple-density insert, direct-formed, molded to foot after external heat source of 230 degrees F, or higher, total contact with patient’s foot, including arch, base layer minimum of 1/4” material of Shore A 35 Durometer or 3/16” material of Shore A 40 Durometer (or higher), prefabricated, each
A5513: Multiple-density insert, custom-molded from model of patient’s foot, total contact with patient’s foot, including arch, base layer, minimum of 3/16” material of Shore A 35 Durometer (or higher), including arch filler and other shaping material, custom fabricated, each
L5000: Partial foot, shoe insert with longitudinal arch, toe filler

Lateral Column/Fifth Digital Amputation
Partial foot prosthesis. Provides lateral stability for proper bio-mechanical balance and support.

Documentation
Modifiers:
**KX**-Specific required documentation on file
  Must be appended to all claims for diabetic footwear
**LT** - Left Side
**RT** - Right Side
**EY** - No physician or other licensed health care provider order for this item or service
  Use if there is not a completed order
**GA** - Properly completed ABN on file (when applicable)
If a custom-made item was ordered but not furnished to a beneficiary because the individual died or because the order was canceled by the beneficiary or because the beneficiary’s condition changed and the item was no longer reasonable and necessary or appropriate, payment can be made based on the supplier’s expenses."

Reimbursement is invoiced amount
DOS will be date of cancellation
You will submit invoice with claim
Medicare Benefit Policy Manual

Upgrades:

“An upgrade may be from one item to another within a single Health Insurance Common Procedure Coding System (HCPCS) code or may be from one HCPCS code to another. When an upgrade is within a single code, the upgraded item must include features that exceed the official code descriptor for that item.”

While **boots** achieve the same medical benefit, they are more expensive and have additional features that can be considered an upgrade. The provider can bill the boot as an upgrade for the difference. A signed ABN is required in this instance.
Selling reimbursable items for cash?

Cash Payment

**Pricing must be Medicare’s minimum allowable**

- **2013 Reimbursement for 1 pair A5500 shoes only:** $137.68
- **2013 Reimbursement for 6 individual A5512 inserts:** $168.48

The same care and level of service should be provided for each patient or cash paying customer.

Complete ABN, retain on file, and affix GA modifier to the claim.
The vendor should have an invoice for depth shoes and/or inserts which meet Medicare guidelines.

These forms can be found on the Dr. Comfort website under “Medicare Information.”
A provider of DMEPOS products must possess the following liability coverage:

**Professional Liability**—this is liability insurance for the services which are rendered

**Product Liability** – the liability for the devices or products dispensed from the office/clinic

**Property/Casualty**—the protection of the storefront
In addition to the documentation mentioned, the following can also be in the patients chart:

• Intake Form with Medical History
• Prescription/Order information
• Assessment
• Treatment Plan
• Follow Up
• Progress Notes/Performance Outcomes
HIPAA - health insurance portability and accountability act of 1996, mandates the use of standards for the exchange of health care data.

What is it?
It is protection for the privacy and security of Protected Health Information (PHI). It is also the standardization of electronic data interchange in health care transactions.
HIPAA
Covered entities may use PHI for the purposes of Treatment, Payment and health care Operations (TPO) without any special permission from the patient.

*Special permission, called an authorization, must be obtained for uses and disclosures other than for TPO.*
HIPAA (continued)
The purpose of HIPAA is to:
• Limit the unauthorized use and disclosure of PHI
• Give patients new rights to access their medical records and to know who else has accessed them
• Restrict most disclosure of health information to the minimum needed for the intended purpose
• Establish new criminal and civil sanctions for proper use or disclosure
• Establish new requirements for access to records by researchers and others
HIPAA (continued)
In a healthcare setting, the patient has the:
• Right to a notice of the covered entity privacy practices
• Right to request restrictions and confidential communications concerning PHI
• Right to obtain access to protected health information for inspection and copying
• Right to obtain an accounting of certain disclosures
• Right to request amendment of PHI
Standard components may be in the following form, known as, SOAP notes:

**S:** Subjective  
**O:** Objective  
**A:** Assessment  
**P:** Plan

The progress notes for each patient are used to keep record of the status, progress and plan of care.

They also provide legal protection should any problems arise with the patient.
S: Subjective:
This would include anything the patient tells you regarding the reason for the visit. It also may be on the initial patient paperwork you may have had patient fill out.

Chief complaint
Activity level
Employment status
Health Status
Social/Health Habits
Family History
Medical History
Medications
Goals

Sample Note:
Patient complains of burning and tingling in both feet. Denies any recent changes in medical history. She said that when she checked her blood sugar last week it was “over 290” during the day. Patient is currently not working and states that she does very little during the day. Patient would like to be able to work more without the burning.
O: Objective:
This would include the problem, diagnosis and reason for the visit with you today.
Also, add things that you find during the examination using only four senses:

What do you see?
What do you smell?
What do you feel?
What do you hear?

No tasting

Example:
68 year old female with history of DM since 2004, non-insulin dependant, was referred in today by her endocrinologist—Dr. Smith. Patient indicated that she smokes 1 pack of cigarettes a day and denies use of alcohol. Observed an unstable gait and a callus under the first met head. Upon examination, patient had no sensation on the plantar aspect of both feet using the monofilament test. No digital hair growth. Patient’s feet were hot to the touch.
A: Assessment
This would include any measurable data during the examination:

Results of testing
Temperature
ROM
Pulses
Measurements of wounds
Shoe measurements

Example:
Patient’s loss of sensation, tingling and burning as well as callus formation indicates she is a good candidate for diabetic shoe gear. She was also advised to revisit her podiatrist or PCP for further testing.
P: Plan
This would include any anticipated goals and progress that you would like seen. Also, any referrals that are necessary to obtain these outcomes. Also, be sure to include what was given or ordered today and any upcoming follow-up visits.

Example:
Measured for shoes and custom inserts to properly off load the area of callus formation. Due to her foot type, we decided on the Betty Black 8 ½ wide and she will be seen in 2 weeks to check proper fit. Along with her physician, we would like to see the callus debrided and no longer present.
S.O.A.P Notes
Sign and date the note.
Do not leave any empty space between your final notation and signature.
Note should have your full name and title.
Write legibly or dictate/type.
If a mistake is made when writing the note, draw a single line through the error, write the word “error” and initial the mistake.
Do NOT scribble out or attempt to erase it. Every word of a progress note must be readable or it may be suspect to alteration.

Documentation