



Dear Doctor,

Your patient, \_\_\_\_\_, recently had a diabetic foot screening that indicated probable increased risk for ulceration. If so, Medicare may provide coverage for a pair of protective shoes. Please use the accompanying forms, as required by Medicare, when evaluating the patient in order to document diabetes management and qualifying conditions, if present.

Also attached is a letter from Paul J. Hughes, MD, Medicare Senior Medical Director, et al. that describes the medical doctor's responsibility under the Therapeutic Shoe Program.

Ulcerative foot risk assessment may qualify as a billable visit.

Please complete the following forms, as indicated, and fax them to \_\_\_\_\_:

- Physician Notes on Qualifying Condition(s)
- Statement of Certifying Physician for Therapeutic Shoes
- Prescription for Diabetic Shoes and Inserts

Your cooperation is very much appreciated. If you have any questions or need additional information, please contact us at \_\_\_\_\_  
*Supplier phone number*

Sincerely,

Please Fax to \_\_\_\_\_  
Supplier to enter.

Please fax this back with attached "Statement of Certifying Physician" and "Prescription for Therapeutic Shoes" and keep original in your patient's chart.

## Physician Notes on Qualifying Condition(s) for Therapeutic Shoes

• Please complete ALL Steps as indicated. • As required by Medicare, save in patients chart.

Name of Person to contact if there are any questions: \_\_\_\_\_

Patient Name: \_\_\_\_\_ HICN: \_\_\_\_\_ Date of Evaluation \_\_\_\_/\_\_\_\_/\_\_\_\_  
Supplier to enter Supplier to enter Supplier to enter

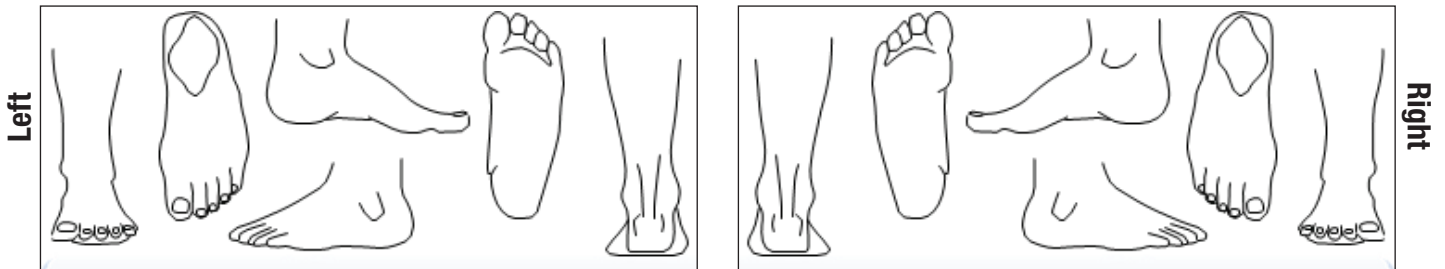
**Diabetes Management:** (Required to support discussion of diabetes management.)

**Plan of Care:**  Diet  Oral Meds  Injection  Pump Treatment Plan: Start date: \_\_\_\_\_  
Duration of DM: \_\_\_\_\_ Date of Last FBS: \_\_\_\_\_

**Physical Exam** - Please refer to the findings when noting secondary risk factor(s) on "Statement of Certifying Physician"

**Diagnosis code** - Coding Tip: Please refer to this exam when completing Statement of Certifying Physician.

Vascular	Right	Left	Neurological (LOPS)	Right	Left
Dorsalis Pedis	<input type="checkbox"/> normal <input type="checkbox"/> diminished	<input type="checkbox"/> normal <input type="checkbox"/> diminished	Vibration perception (tuning fork)	<input type="checkbox"/> normal <input type="checkbox"/> diminished	<input type="checkbox"/> normal <input type="checkbox"/> diminished
Posterior Tibial	<input type="checkbox"/> normal <input type="checkbox"/> diminished	<input type="checkbox"/> normal <input type="checkbox"/> diminished	Loss of Protective Sensation (LOPS)	<input type="checkbox"/> toes <input type="checkbox"/> mets <input type="checkbox"/> heel	<input type="checkbox"/> toes <input type="checkbox"/> mets <input type="checkbox"/> heel
Capillary Refill Time	<input type="checkbox"/> < 3 sec. <input type="checkbox"/> > 3 sec	<input type="checkbox"/> < 3 sec. <input type="checkbox"/> > 3 sec	DTR	<input type="checkbox"/> normal <input type="checkbox"/> diminished	<input type="checkbox"/> normal <input type="checkbox"/> diminished
Edema Present	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no	Sharp/Dull	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no
Other					



Please indicate bunions, swelling, redness, deformities, amputation or wounds using the symbol key below

Callus **C** | Bunion **B** | Swelling **S** | Redness **R** | Deformity **D** | Hammer/Claw Toe **HC** | Amputation **A** | Wound **W**

Condition	Type 1 Diabetes	Type 2 Diabetes
<input type="checkbox"/> Diabetes mellitus without complications	<input type="checkbox"/> E10.9	<input type="checkbox"/> E11.9
<input type="checkbox"/> Diabetes mellitus with diabetic polyneuropathy	<input type="checkbox"/> E10.42	<input type="checkbox"/> E11.42
<input type="checkbox"/> Diabetes mellitus with diabetic peripheral angiopathy without gangrene	<input type="checkbox"/> E10.51	<input type="checkbox"/> E11.51
<input type="checkbox"/> Diabetes mellitus with foot ulcer	<input type="checkbox"/> E10.621	<input type="checkbox"/> E11.621

**\* Certifying Physician Acknowledgment**

I am the MD/DO supervising the patient under a comprehensive plan of care for Diabetes Mellitus.  
I have personally conducted this foot examination or have authorized an eligible prescriber to conduct this exam on my behalf and agree with the findings.  
I have incorporated this exam as part of my medical records. Part of the comprehensive plan of care for this patient includes therapeutic shoes and insoles.

Physician Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
(Stamped signature nor date not allowable) Stamped date not allowable. Shoes must be dispensed not more than 90 days from when dated

Physician Name (Printed): \_\_\_\_\_ Physician NPI #: \_\_\_\_\_  
Supplier to enter



Please Fax to \_\_\_\_\_

Supplier to enter.

Supplier to enter. Please fax this back with attached "Physician Notes" and "Prescription for Therapeutic Shoes" and keep original in your patient's chart.

### Statement of Certifying Physician for Therapeutic Shoes

- Ensure that physical exam includes a qualifying risk factor
- Ensure that if neuropathy indicated as qualifying condition that physical exam also determines there to be callus present.
- Ensure that condition notes is consistent with clinical findings noted on physical exam.
- Ensure that physician has signed and dated form. Stamps not allowed.
- Ensure that form not completed by NP or PA.
- Ensure that for note dated not more than 90 days prior to when shoes dispensed.

Name of Person to contact if there are any questions: \_\_\_\_\_

Patient Name: \_\_\_\_\_ HICN: \_\_\_\_\_ DOB: \_\_\_\_/\_\_\_\_/\_\_\_\_  
*Supplier to enter* *Supplier to enter* *Supplier to enter*

Please indicate all risk factors for diabetic foot ulcerations.

**When completing and signing this form, please make certain that the following checked condition(s) are the same as you indicated on the Physician Notes on Qualifying Condition(s).**

I certify that all the following statements are true:

1. The patient has diabetes mellitus.
2. This patient has one or more of the following conditions (indicate all that apply)
  - Foot Deformity
  - History of partial or complete amputation of the foot
  - History of preulcerative callus
  - History of previous foot ulceration
  - Peripheral neuropathy with evidence of callus formation
  - Poor circulation/PAD

**Acknowledgment Statement:**

I am treating this patient's diabetes under a comprehensive plan of care. This patient requires diabetic shoes and heat-molded or custom-molded inserts to help prevent ulcers and further complications.

Physician Signature: \_\_\_\_\_  
*(Stamped signature not allowable)*

Date: \_\_\_\_\_  
*Stamped date not allowable. Shoes must be dispensed not more than 90 days from when dated*

Physician Name (Printed): \_\_\_\_\_  
*NP, PA not permitted.*

Physician NPI #: \_\_\_\_\_

Physician Address: \_\_\_\_\_

Physician Phone: \_\_\_\_\_



Please Fax to \_\_\_\_\_

Please fax this back with the attached "Prescription" and "Physician Notes on Qualifying Conditions" and keep original in your patient's chart.

### Prescription for Therapeutic Shoes and Inserts

- Confirm if indicate both a pair of shoes and three pair of either prefabricated or custom molded inserts.
- Ensure that condition and primary diagnosis code is noted and consistent with findings of physical exam.
- Ensure that condition(s) noted is consistent with clinical findings noted on physical exam.

Name of Person to contact if there are any questions: \_\_\_\_\_

Patient Name: \_\_\_\_\_ HICN: \_\_\_\_\_ DOB: \_\_\_\_/\_\_\_\_/\_\_\_\_  
Supplier to enter Supplier to enter Supplier to enter

Quantity (Please check)	HCPCS Code	Description
<input type="checkbox"/> 1	A5500	Diabetic Depth Shoes, pair
<input type="checkbox"/> 3 <input type="checkbox"/> 2 <input type="checkbox"/> 1	A5512	Prefabricated inserts pairs -multiple density , direct formed, molded to foot with external heat source (i.e. heat gun). Medicare allows up to three pairs of inserts per year.

**OR**

<input type="checkbox"/> 3 <input type="checkbox"/> 2 <input type="checkbox"/> 1	A5513	Custom-molded inserts - multiple, density, molded to model of patient's foot. Medicare allows up to three pairs of inserts per year.
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**OR**

1 Left Partial Foot Filler (L5000)  3 Right Custom Inserts  1 Right Partial Foot Filler (L5000)  3 Left Custom Inserts

Please confirm that the entered Diagnosis Code matches your charting documentation.

Condition	Type 1 Diabetes	Type 2 Diabetes
Diabetes mellitus without complications	<input type="checkbox"/> E10.9	<input type="checkbox"/> E11.9
Diabetes mellitus with diabetic polyneuropathy	<input type="checkbox"/> E10.42	<input type="checkbox"/> E11.42
Diabetes mellitus with diabetic peripheral angiopathy without gangrene	<input type="checkbox"/> E10.51	<input type="checkbox"/> E11.51
Diabetes mellitus with foot ulcer	<input type="checkbox"/> E10.621	<input type="checkbox"/> E11.621

Duration of usage: 12 Months

Prescriber Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
(Stamped signature not allowable) Stamped date not allowable

Prescriber Name (Printed): \_\_\_\_\_ Physician NPI #: \_\_\_\_\_



November 2010

**Therapeutic Shoes for Diabetics – Physician Documentation Requirements**

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:

- An M.D. or D.O. (termed the “certifying physician”) must be managing the patient’s diabetes under a comprehensive plan of care and must certify that the patient needs therapeutic shoes.
- That certifying physician must document that the patient has one or more of the following qualifying conditions:
  - Foot deformity
  - Current or previous foot ulceration
  - Current or previous pre-ulcerative calluses
  - Previous partial amputation of one or both feet or complete amputation of one foot
  - Peripheral neuropathy with evidence of callus formation
  - Poor circulation

According to Medicare national policy, it is not sufficient for a podiatrist, physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS) to provide that documentation (although they are permitted to sign the order for the shoes and inserts) .The certifying physician must be an M.D. or D.O.

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 detailed written order. This can be prepared by the supplier but must be signed and dated by you to indicate agreement.
2. A copy of an office visit note from your medical records that shows that you are managing the patient’s diabetes. This note should be within 6 months prior to delivery of the shoes and inserts.
3. Either (a) a copy of an office visit note from your medical records that describes one of the qualifying conditions or (b) an office visit note from another physician (e.g., podiatrist) or from a PA, NP, or CNS that describes one of the qualifying conditions .If option (b) is used, you must sign, date, and make a note on that document indicating your 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. It must describe (examples not all-inclusive):

- The specific foot deformity (e.g., 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 – e.g., 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 are not by themselves 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 you after the visits described in #2 and 3 .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. **However, this form is not sufficient by itself to show that the coverage criteria have been met, but must be supported by other documents in your medical records – as noted in #2 and 3.**

New documentation is required yearly in order for Medicare to pay for replacement shoes and inserts.

Physicians can review the complete Local Coverage Determination and Policy Article titled Therapeutic Shoes for Persons with Diabetes on the NAS web site at [www.noridianmedicare.com/dme](http://www.noridianmedicare.com/dme). It may also be viewed in the local coverage section of the Medicare Coverage Database at [www.cms.hhs.gov/mcd/search.asp](http://www.cms.hhs.gov/mcd/search.asp).

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 is in compliance with the HIPPA Privacy Rule. No specific authorization is required from your patient .Also note that you may not charge the supplier or the beneficiary to provide this information.

Please cooperate with the supplier so that they can provide the therapeutic shoes and inserts that are needed by your patient.

Sincerely,

Paul J. Hughes, M.D.  
Medical Director, DME MAC, Jurisdiction A

Robert D. Hoover, Jr., MD, MPH, FACP Medical  
Director, DME MAC, Jurisdiction C

Adrian M. Oleck, M.D.  
Medical Director, DME MAC, Jurisdiction B

Richard W. Whitten, MD, MBA, FACP  
Medical Director, DME MAC, Jurisdiction D

# Non-Physician Supplier Medicare Compliance Documentation Guide

## Shoe Fitter Responsibility/Actions

1. Complete "Patient Evaluation Prior to Shoe Selection".
2. Select Shoe Size and Style.
  - Measure feet and use display stand to select shoe according the 4 S's: Size, Shape, Stability, Style.
3. Print up "Physician's Packet" at [Apexfoot.com/dealer-resources](http://Apexfoot.com/dealer-resources) and complete:
  - Prescription.
  - Physician Notes on Qualifying Condition(s).
  - Statement of Certifying Physician.

Give customized forms to patient to be signed by Certifying Physician.  
Make appointment for patient with MD / DO.

4. Alternatively, print out in advance, "Physician's Packet" from "Forms" section of [Apexfoot.com/dealer-resources](http://Apexfoot.com/dealer-resources)
5. Click on "Dispensing Docs" to print out "Patient Receipt", "Dispensing Chart Notes" and "Supplier Standards". Save in patient's chart until patient returns to pick up shoes.

## Patient Responsibility/Actions

6. Patient visits MD / DO, has foot evaluation with discussion of diabetes management.
  - Following evaluation, physician completes forms, signs, dates and faxes to supplier.

## Supplier Responsibility/Actions

7. Supplier evaluates forms, reviews to ensure Medicare compliance and orders shoes and inserts.
  - If compliance forms incomplete or inaccurate, supplier follows up with certifying physician.
  - Once forms determined to be accurate and complete, non-physician supplier places order for shoes and inserts with apex via phone or fax. Shoes and inserts shipped.

## Shoe Fitter Responsibility/Actions

8. Supplier contacts patient, fits shoes and signs compliance documentation.
9. Supplier goes to [Apexfoot.com](http://Apexfoot.com) to print out Medicare compliance documentation including: Patient Receipt, Supplier Standards and Dispensing SOAP Note.

Print additional copies of this form by logging onto [Apexfoot.com/dealer-resources](http://Apexfoot.com/dealer-resources) and selecting the "Forms" section.

## Medicare Compliance Documentation Pointers:

- Save the "Patient Evaluation" as required by Medicare. It may be requested in event of audit.
- Give patient: Physician Notes of Qualifying Condition(s), Statement of Certifying Physician, and Prescription for Therapeutic Shoes and Inserts. Tell patient to bring forms to MD/DO managing their diabetes.

Questions?  
Contact One of Our Retail Specialists

## Patient Evaluation Prior to Shoe Selection

- Ensure that patient is eligible for coverage for shoes and inserts by Medicare, Medicaid or a private insurer
- Ensure that patient has qualifying risk factor for therapeutic shoes

Patient Name: \_\_\_\_\_ HICN: \_\_\_\_\_ DOB: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Does the patient have Medicare as the primary insurance?:  Yes  No

Has the patient received shoes under the Medicare Therapeutic Shoe Program this calendar year?:  Yes  No

### Assessment

Which feet does patient have?  Both  Left  Right

**Callus:**  Yes  No

**Amputation:**  Yes  No

**Deformities:**  None  Bunion  Hammer toes

Scarring  Clawing  Overlapping

Other: \_\_\_\_\_

**Edema:**  None  Present / Describe: \_\_\_\_\_

**Fat Pads:**  Normal  Inadequate / Describe: \_\_\_\_\_

**Joint Stability:**  Normal  Flattened longitudinal arch  Cavus

**Vascularity:**  Normal  Limited / Describe: \_\_\_\_\_

**Foot Color:**  Normal  Bluish  Red

**Range of Motion:**  Normal  Abnormal

**Muscle Testing:**  Normal  Abnormal

**Skin Integrity:**  Normal  Abnormal

**Skin Temperature:**  Normal  Abnormal

**Cognitive Awareness:**  Normal  Abnormal

Has patient worn therapeutic footwear?  Yes  No

#### Functional goals for patient services (check all that apply)

- Protection of sensation-compromised foot  
 Provision of appropriate footwear for protection, support, stability, and comfort  
 Refer to MD/DO follow-up  
 Other: \_\_\_\_\_

### Shoe Ordering Information

Shoe Size based on measuring device, fit of currently worn shoes and try-on sample:

Length: \_\_\_\_\_ Width: \_\_\_\_\_

Selected Shoe Brand:  Selected Shoe Model / Sku: \_\_\_\_\_

Selected Inserts:  Prefabricated heat molded  Custom molded Insert Quantity (Prs):  3  2  1

If Partial Foot Filler is required:  1 Left Partial Foot Filler (L5000)  3 Right Custom Inserts  1 Right Partial Foot Filler (L5000)  3 Left Custom Inserts

Qualified Fitter's Signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Qualified Fitter's Name (Printed): \_\_\_\_\_

Neurological (Use Y or N)	Right	Left
Loss of Vibration Perception		
Loss of Vibration Perception		



Note corns, calluses or deformities using symbol key below:

Corn/Callus (C)	Wound (W)	Bunion (B)	Redness (R)
Swelling (S)	Hammer/Claw toe (HC)		Amputation (A)

If patient has previously received shoes covered by Medicare, are they worn and in need of replacement?  Yes  No

If patient has previously received inserts covered by Medicare, are they worn and in need of replacement?  Yes  No



# Delivery Documentation and Break-In Instructions

Congratulations on receiving your new shoes. In accordance with Medicare regulations, they have been selected to provide you with optimum comfort and protection.

Getting used to your shoes? People with decreased feeling in their feet may have a false sense of security as to how much at risk their feet actually are. An ulcer on the foot can develop in a couple of hours when the shoes are expertly fit. In order to best avoid irritation, adhere to the following break-in schedule:

- FIRST DAY**      Wear One Hour
- SECOND DAY**    Wear Two Hours – Check feet after first hour
- THIRD DAY**      Wear Three Hours
- FOURTH DAY**    Wear Four Hours – Check feet after two hours
- FIFTH DAY**      Wear Full Day – Check after lunch

- IF AT ANY TIME YOU SEE RED SPOTS OR DARKNESS ON THE TOES OR OTHER BONY AREAS: Discontinue wearing the shoes for the rest of the day and start routine again the next day beginning with one hour of wear.
- IF A RED SPOT OR DARKNESS APPEARS WITH EVERY WEARING – DO NOT WEAR SHOES. Call this office for an adjustment appointment.
- BE SURE TO INSPECT YOUR FEET EVERY DAY.

**Follow-Up** - You should have regularly scheduled visits with your foot care doctor. Please direct any questions about these shoes or inserts to this office. Billing questions may be directed to your Medicare carrier. Every four months remove the inserts in your shoes and replace with a new pair. In one year, you will receive a reminder to return to your foot care provider to evaluate the condition of these shoes.

**Return Policy** Shoes that are unsuitable may be returned within one week of dispensing. The shoes must be in good condition, i.e., no scuffmarks, outside dirt or obvious wear on the soles and in original packaging. We strongly urge you to wear these shoes in your home for the first week. Substandard shoes may also be returned as all warranties, expressed and implied under applicable State law will be honored.

I certify that I have received the item(s) marked below in good condition. The Fitter has explained, in detail, the proper use and care of these shoes and inserts and has fit them to me. The Fitter has told me to call the office if I encounter any problems or if I have any questions. I have been informed of the Medicare DMEPOS Supplier Standards. I agree to receive reminders by mail, email or telephone to determine if appropriate to be fit with replacement shoes and inserts.

**Description of items provided** - 1 Pair - Depth Shoes, 3 Pairs - custom molded insert(s)

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Patient Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Shoe brand and model: \_\_\_\_\_  
\_\_\_\_\_



## Medicare Supplier Standards

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements and cannot contract with an individual or entity to provide licensed services.
2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
3. An authorized individual (one whose signature is binding) must sign the application for billing privileges.
4. A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal procurement or non-procurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.
6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.
7. A supplier must maintain a physical facility on an appropriate site. This standard requires that the location is accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.
8. A supplier must permit CMS, or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours, and must maintain a visible sign and posted hours of operation.
9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.
10. A supplier must have comprehensive liability insurance in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.
11. A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from contacting a Medicare beneficiary based on a physician's oral order unless an exception applies.
12. A supplier is responsible for delivery and must instruct beneficiaries on use of Medicare covered items, and maintain proof of delivery.
13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.
14. A supplier must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare covered items it has rented to beneficiaries.
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.
16. A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare covered item.
17. A supplier must disclose to the government any person having ownership, financial, or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number i.e., the supplier may not sell or allow another entity to use its Medicare billing number.
19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
21. A supplier must agree to furnish CMS any information required by the Medicare statute and implementing regulations.
22. All suppliers must be accredited by a CMS approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment of those specific products and services (except for certain exempt pharmaceuticals). Implementation Date October 1, 2009
23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.
24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.
25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.
26. Must meet the surety bond requirements specified in 42 C.F.R. 424.57(c). Implementation date May 4, 2009
27. A supplier must obtain oxygen from a state-licensed oxygen supplier.
28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 C.F.R. 424.516(f).
29. DMEPOS suppliers are prohibited from sharing a practice location with certain other Medicare providers and suppliers.
30. DMEPOS suppliers must remain open to the public for a minimum of 30 hours per week with certain exceptions.



# Dispensing Chart Notes for Therapeutic Shoes, Custom Molded Inserts

Patient Name: \_\_\_\_\_ HICN: \_\_\_\_\_ DOB: \_\_\_\_/\_\_\_\_/\_\_\_\_

Diagnosis: \_\_\_\_\_

### Dispensing Chart Notes:

S: Patient presents for dispensing of depth shoes and three pair of custom molded inserts to prevent diabetic ulceration.

O: There is certification of therapeutic necessity from the physician managing the patient's diabetes in the chart. There is a signed copy of relevant medical records from the certifying physician attesting to the qualifying conditions for therapeutic footwear and that the patient is under a comprehensive plan of care for their diabetes. The inserts contain a base layer of 3/16 inch shore A durometer material. There was total contact between the plantar surface of each foot, including the arch and the insert.

- There are no bony prominences pushing through the shoe uppers, no slippage of heels and ample toe room
- Shoe is of appropriate length: there is approximately a thumb's width from end of toe to the end of shoe
- Shoe is of appropriate width: there is no significant pressure to the sides of the foot
- Shoes were delivered in same size as ordered
- Patient's feet are supported stably by heel counter

A: Patient ambulated 20 feet without complaint and met established goals. Good fit of therapeutic shoes and multi-density inserts.

P: Fitting of depth shoes with three pair of multiple density custom molded inserts to prevent diabetic ulceration. Proper use and care was given and the list of Durable Medical Equipment Supplier Guidelines. A follow up appointment to check the fit of shoes and inserts was made.

### Product List:

**1 pair** - Depth shoes (A5500) to prevent pedal ulceration

**3 pairs** - Inserts – custom molded to foot, multiple density, (A5513) to prevent pedal ulceration.

Signature of Qualified Shoe Fitter: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Print Name of Qualified Shoe Fitter: \_\_\_\_\_ Follow-up Appointment: \_\_\_\_/\_\_\_\_/\_\_\_\_



# Delivery Documentation and Break-In Instructions

Congratulations on receiving your new shoes. In accordance with Medicare regulations, they have been selected to provide you with optimum comfort and protection.

Getting used to your shoes? People with decreased feeling in their feet may have a false sense of security as to how much at risk their feet actually are. An ulcer on the foot can develop in a couple of hours when the shoes are expertly fit. In order to best avoid irritation, adhere to the following break-in schedule:

- FIRST DAY**      Wear One Hour
- SECOND DAY**    Wear Two Hours – Check feet after first hour
- THIRD DAY**      Wear Three Hours
- FOURTH DAY**    Wear Four Hours – Check feet after two hours
- FIFTH DAY**      Wear Full Day – Check after lunch

- IF AT ANY TIME YOU SEE RED SPOTS OR DARKNESS ON THE TOES OR OTHER BONY AREAS: Discontinue wearing the shoes for the rest of the day and start routine again the next day beginning with one hour of wear.
- IF A RED SPOT OR DARKNESS APPEARS WITH EVERY WEARING – DO NOT WEAR SHOES. Call this office for an adjustment appointment.
- BE SURE TO INSPECT YOUR FEET EVERY DAY.

**Follow-Up** - You should have regularly scheduled visits with your foot care doctor. Please direct any questions about these shoes or inserts to this office. Billing questions may be directed to your Medicare carrier. Every four months remove the inserts in your shoes and replace with a new pair. In one year, you will receive a reminder to return to your foot care provider to evaluate the condition of these shoes.

**Return Policy** Shoes that are unsuitable may be returned within one week of dispensing. The shoes must be in good condition, i.e., no scuffmarks, outside dirt or obvious wear on the soles and in original packaging. We strongly urge you to wear these shoes in your home for the first week. Substandard shoes may also be returned as all warranties, expressed and implied under applicable State law will be honored.

I certify that I have received the item(s) marked below in good condition. The Fitter has explained, in detail, the proper use and care of these shoes and inserts and has fit them to me. The Fitter has told me to call the office if I encounter any problems or if I have any questions. I have been informed of the Medicare DMEPOS Supplier Standards. I agree to receive reminders by mail, email or telephone to determine if appropriate to be fit with replacement shoes and inserts.

**Description of items provided** - 1 Pair - Extra Depth Shoes Depth Shoes, 3 Pairs - Heat Molded Insert(s)

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Patient Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Shoe brand and model: \_\_\_\_\_

\_\_\_\_\_

## Medicare Supplier Standards

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements and cannot contract with an individual or entity to provide licensed services.
2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
3. An authorized individual (one whose signature is binding) must sign the application for billing privileges.
4. A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, any State health care programs, or from any other Federal procurement or non-procurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.
6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.
7. A supplier must maintain a physical facility on an appropriate site. This standard requires that the location is accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.
8. A supplier must permit CMS, or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours, and must maintain a visible sign and posted hours of operation.
9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.
10. A supplier must have comprehensive liability insurance in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.
11. A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from contacting a Medicare beneficiary based on a physician's oral order unless an exception applies.
12. A supplier is responsible for delivery and must instruct beneficiaries on use of Medicare covered items, and maintain proof of delivery.
13. A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.
14. A supplier must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare covered items it has rented to beneficiaries.
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.
16. A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare covered item.
17. A supplier must disclose to the government any person having ownership, financial, or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number i.e., the supplier may not sell or allow another entity to use its Medicare billing number.
19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
21. A supplier must agree to furnish CMS any information required by the Medicare statute and implementing regulations.
22. All suppliers must be accredited by a CMS approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services, for which the supplier is accredited in order for the supplier to receive payment of those specific products and services (except for certain exempt pharmaceuticals). Implementation Date October 1, 2009
23. All suppliers must notify their accreditation organization when a new DMEPOS location is opened.
24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.
25. All suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.
26. Must meet the surety bond requirements specified in 42 C.F.R. 424.57(c). Implementation date May 4, 2009
27. A supplier must obtain oxygen from a state-licensed oxygen supplier.
28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 C.F.R. 424.516(f).
29. DMEPOS suppliers are prohibited from sharing a practice location with certain other Medicare providers and suppliers.
30. DMEPOS suppliers must remain open to the public for a minimum of 30 hours per week with certain exceptions.



# Dispensing Chart Notes for Therapeutic Shoes, Prefabricated Heat-Molded Inserts

Patient Name: \_\_\_\_\_ HICN: \_\_\_\_\_ DOB: \_\_\_\_/\_\_\_\_/\_\_\_\_

Diagnosis: \_\_\_\_\_

### Dispensing Chart Notes:

S: Patient presents for dispensing of depth shoes and three pair of prefabricated, heat molded inserts to prevent diabetic ulceration.

O: There is certification of therapeutic necessity from the physician managing the patient's diabetes in the chart. There is a signed copy of relevant medical records from the certifying physician attesting to the qualifying conditions for therapeutic footwear and that the patient is under a comprehensive plan of care for their diabetes. The inserts contain a base layer of 3/16 inch shore A durometer material. They were heated to over 230 degrees Fahrenheit and full weight bearing was performed on a foam pillow. During molding, the patient's feet were protected from the heated insole by socks. After molding, there was total contact between the plantar surface of each foot, including the arch and the insert.

- There are no bony prominences pushing through the shoe uppers, no slippage of heels and ample toe room.
- Shoe is of appropriate length: there is approximately a thumb's width from end of toe to the end of shoe.
- Shoe is of appropriate width: there is no significant pressure to the sides of the foot
- Shoes were delivered in same size as ordered
- Patient's feet are supported stably by heel counter.

A: Patient ambulated 20 feet without complaint and met established goals. Good fit of therapeutic shoes and multi-density inserts.

P: Fitting of depth shoes with three pair of prefabricated multiple density custom molded inserts to prevent diabetic ulceration. Proper use and care was given and the list of Durable Medical Equipment Supplier Guidelines. A follow up appointment to check the fit of shoes and inserts was made.

### Product List:

**1 pair** - Depth shoes (A5500) to prevent pedal ulceration

**3 pairs** - Inserts – direct formed, molded to foot with external heat source (i.e. heat gun) multiple density, prefabricated, per shoe (A5512) to prevent pedal ulceration.

Signature of Qualified Shoe Fitter: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Print Name of Qualified Shoe Fitter: \_\_\_\_\_ Follow-up Appointment: \_\_\_\_/\_\_\_\_/\_\_\_\_