

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: ____/____/____