DOCUMENTATION OVERVIEW – PRIMARY CARE FIRST

CERTIFYING PHYSICIAN	PRESCRIBING PHYSICIAN	SUPPLIER
Role		
Responsible for diagnosing and treating the beneficiary's diabetic systemic condition through a comprehensive plan of care	Performs foot exam and writes the Prescription/Detailed Written Order for therapeutic shoes and inserts	Furnishes the shoes and/or inserts to the beneficiary and bills Medicare
Who		
• Doctor of Medicine (MD) • Doctor of Osteopathy (DO) • Nurse Practitioner (NP)	• Doctor of Medicine (MD) • Doctor of Osteopathy (DO) • Physician's Assistant (PA) • Nurse Practitioner (NP) • Clinical Nurse Specialist (CNS) • Podiatrist (DPM)	• Pedorthist (CPED) • Orthotist (CO) • Prosthetist (CP) • Prosthetist/Orthotist (CPO) • Other qualified individual
Documentation		
1. Diabetes Management Exam Note • Documents diabetes management through plan of care • Within 6 months of delivery 2. Statement of Certifying Physician • Within 3 months of delivery of shoes and inserts	3. Diabetic Foot Exam • If not completed by MD/DO/NP, MD/DO/NP must sign-off and indicate agreement by other PRESCRIBING PHYSICIAN • Within 6 months of delivery 4. Prescription for Therapeutic Shoes and Inserts • Detailed Written Order	5. Patient Evaluation and Shoe Selection 6. Proof of Delivery/Warranty/Break In and Care Instructions 7. Medicare Supplier Standards 8. Dispensing Note • a) Prefabricated Heat Moldable Inserts • b) Custom Fabricated Inserts • c) Customs and Toe Filler

*MD/DO/NP can be both the CERTIFYING PHYSICIAN and PRESCRIBING PHYSICIAN

DOCUMENT PACK SUMMARY

Prior to Dispensing

- ☐ 0. Cover Letter: Fax to MD/DO managing the Patient's diabetes.
- ☐ 1. Diabetes Management Exam Note: Must be from MD/DO/NP who signs the *Statement of Certifying Physician*. Signed and dated by the MD/DO only.
- ☐ 2. Statement of Certifying Physician: Fax to MD/DO/NP. Must be signed by MD/DO/NP only and dated after foot exam.
- ☐ 3. Diabetic Foot Exam: May be included in the *Diabetes Management Exam Note* by MD/DO/NP. Otherwise it's performed, signed and dated by PA, CNS, DPM, and then agreed with, signed and dated by the MD/DO/NP who signed the *Statement of Certifying Physician*.
- ☐ 4. Prescription for Therapeutic Shoes and Inserts (Detail Written Order): Written by MD, DO, NP, PA, CNS, or DPM. Must be signed and dated by MD, DO, NP, PA, CNS, DPM who performed the *Diabetic Foot Exam* identifying the qualifying conditions.
- ☐ 5. In-Person Evaluation and Shoe Selection: Performed by the Supplier, in-person with the patient, when shoes are selected.

Dispensing Documents

- ☐ 6. Proof of Delivery/Warranty/Break In and Care Instructions: Signed by the patient. Copy given to the patient and the original is saved in the patient's chart.
- ☐ 7. Medicare Supplier Standards: Copy is given to the patient.
- ☐ 8. Dispensing Note: SOAP note written and signed by the qualified fitter delivering the shoes and inserts.

Additional Documents

- ☐ Invoice/Packing slip: Save in patient's chart to show proof of purchase.
- ☐ ABN: When indicated.

General Information	
Date:	

Provider Information	
Full Name:	
Phone Number:	
Fax Number:	

Patient Information	
Full Name:	
MBI:	
Date of Birth:	
Address:	

Primary Care Information	
Full Name:	
NPI:	
Address:	

Order Information	
Shoe Qty: (Pairs)	1
Insert Qty: (Pairs)	3

Submit and Print

Date:

Patient Name:

MBI#:

Dear Dr. ,

Your patient, , recently received a preliminary diabetic foot evaluation which indicated that they have a significant risk of developing diabetes related foot complications and may qualify for footwear and inserts under the Medicare Therapeutic Shoe Bill.

To qualify for Medicare reimbursement, a patient's Primary Care Physician/Practitioner (MD, DO or NP) is required to certify that the patient meets one or more of the qualifying conditions listed on the *Statement of Certifying Physician* (included).

To satisfy this requirement, we ask you to please send the patient's most recent *Diabetes Management Exam Notes* (**1**) and complete and return the attached forms (**2 and 3**):

1. **Diabetes Management Exam Note** (Including Foot Exam)
    - Signed and dated by **MD, DO or NP only**
    - Within last 6 months; Signed and Dated.
    - Foot findings must support items checked on the *Statement of Certifying Physician*
2. **Statement of Certifying Physician**
    - Complete, Sign, and Date by **MD, DO or NP only**
3. **Prescription for Diabetic Shoes and Inserts**
    - Complete, Sign, and Date

Please fax the completed forms back to us at and place a copy of this information in the patient's chart. Your cooperation is very much appreciated. If you have any questions or need additional information, please contact us at – .

Sincerely,

PLEASE FAX TO:

STATEMENT OF CERTIFYING PHYSICIAN FOR THERAPEUTIC SHOES AND INSERTS

Patient Name:		**MBI#:**		**DOB:**	

Please complete this Statement of Certifying Physician for the patient listed above so that we may provide them with therapeutic shoes and inserts.

To qualify for Medicare reimbursement, it is required that the Primary Care Physician certify that the patient meets one or more of the conditions listed below.

I certify that all of the following statements are true:

1. This patient has diabetes mellitus.
2. This patient has one or more of the following conditions (indicate all that apply):
   - ☐ History of partial or complete amputation of the foot
   - ☐ History of previous foot ulceration
   - ☐ History of pre-ulcerative callus
   - ☐ Peripheral neuropathy with evidence of callus formation
   - ☐ Foot deformity
   - ☐ Poor circulation

   Please make certain these condition(s) are consistent with and supported by clinical findings noted in the patient's Diabetes Management Exam Notes
3. I am treating this patient under a comprehensive plan of care for diabetes.
4. This patient needs special shoes to help prevent complications resulting from diabetes.

Primary Care Signature: (MD, DO or NP ONLY)		**Date:**	
Physician Name: (Printed)		**NPI:**	
Physician Address:			

Please ensure this form is not completed by a NP or PA, it **must be signed by a MD, DO or NP. No stamped signatures permitted.*

Please fax back the completed form <u>along with the exam note from the patient's chart supporting what's noted above</u>. The original should be saved in the patient's chart.

PLEASE FAX TO:

PRESCRIPTION FOR THERAPEUTIC SHOES AND INSERTS

Patient Name:		**MBI#:**		**DOB:**	

Quantity	**HCPCS Code**	**Description**
1	A5500	Anodyne Diabetic Extra-Depth Shoes, pair
3	A5512	Anodyne Prefabricated Heat Moldable Inserts, pair

Other:

Therapeutic Objectives:

☐ Prevent Ulceration and other pedal complications

☐ Distribute weight, balance, and plantar pressure

Duration of Usage: 12 Months

Physician Signature:		**Date:**	
Physician Name: (Printed)		**NPI:**	
Physician Address:			

**Please ensure this form is completed only by a DPM, MD, DO, PA, NP or CNS. No stamped signatures permitted.*

IN-PERSON EVALUATION AND SHOE SELECTION

Patient Name:		**MBI#:**		**DOB:**	

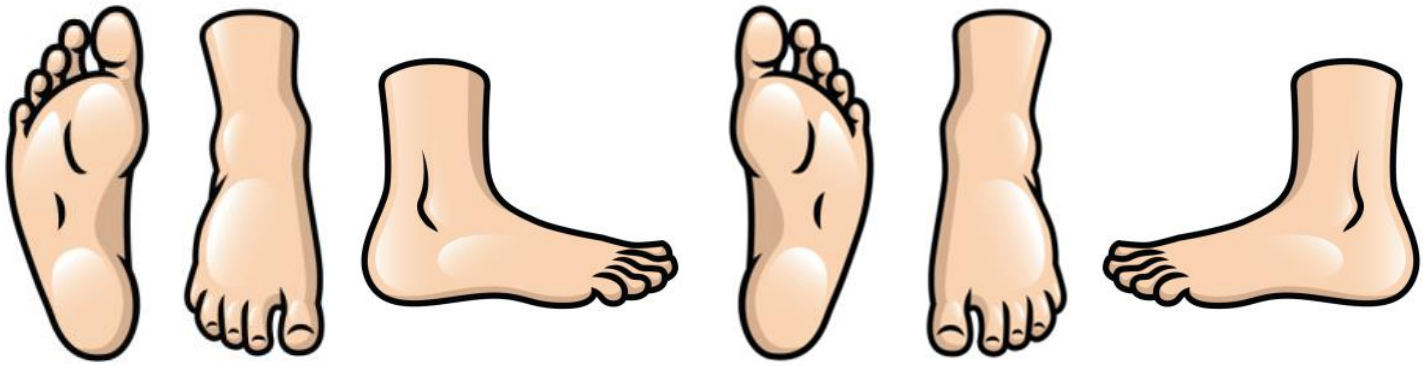
Does the patient have Diabetes? ☐ Yes ☐ No

Does the patient have Medicare as their primary insurance? ☐ Yes ☐ No

Had the patient received shoes under the Medicare Therapeutic Shoe Program this calendar year? ☐ Yes ☐ No

Assessment

RIGHT FOOT **LEFT FOOT**



Note deformities on the images above using the symbol key below:

A: Amputation **B**: Bunions **C**: Callus **H**: Hammer Toes **R**: Redness **S**: Swelling **W**: Wound/Ulcer

Amputation:	☐ Left ☐ Right	Cognitive Awareness:	☐ Normal ☐ Abnormal		
Bunions:	☐ Left ☐ Right	Fat Pads:	☐ Normal ☐ Abnormal		
Callus:	☐ Left ☐ Right	Foot Color:	☐ Normal ☐ Abnormal		
Hammer Toes:	☐ Left ☐ Right	Range of Motion:	☐ Normal ☐ Abnormal		
Redness:	☐ Left ☐ Right	Skin Temperature:	☐ Normal ☐ Abnormal		
Swelling:	☐ Left ☐ Right	Skin Integrity:	☐ Normal ☐ Abnormal		
Wound/Ulcer:	☐ Left ☐ Right				

	Foot Measurements	
	Left	Right
Heel to toe		
Heel to Ball		
Width		

Shoe Ordering Information [Size based on foot measuring device and fitting inventory]

Shoe Style No:	Color:	Size:	Width:
Insert Type:	Anodyne Heat Moldable Inserts	Insert Quantity (Pairs):	3

Shoe Fitter Signature:		**Shoe Fitter Name: (Printed)**		**Date:**	

PROOF OF DELIVERY/WARRANTY/BREAK IN AND CARE INSTRUCTIONS

Break-in Instructions:

6. In the comfort of your own home, put your shoes on and walk around for 30 minutes to 1 hour.
7. After the short wear, remove your shoes and socks, and examine your feet to make sure there are no signs of irritation, redness or dark spots. The mirror sticker on the inside of your Anodyne shoe box will help with this.
8. Wear your shoes indoors a few hours a day over the next couple days, while continually checking your feet for signs of irritation.
9. Once you feel comfortable that that your new shoes aren't causing any issues, go ahead and begin wearing them outside, full-time.
10. It is very important to continue to perform daily exams on your feet during and after the break-in process. In the event that there is ever any irritation, redness, or darks pots on your feet during or after the break-in process, discontinue wear of your shoes and contact your foot care specialist immediately.

Product Care Instructions:

6. Remove the heat moldable or custom inserts received with your shoes every four months and replace with a new pair.
7. Use a damp cloth to clean dirt and grime off of the shoe upper and outsole and allow to dry.
8. For leather shoes – soften, condition, and replenish leathers and color, by applying Anodyne Leather Conditioner (or a comparable leather cream or conditioner approved by your footcare specialist). Conditioner should be applied evenly with a clean, dry cloth.
9. The shoe lining and insert can be cared for by spraying Anodyne Anti-microbial Protectant (or a comparable cleaner approved by your footcare specialist).
10. For future protection of shoes, we recommend using Anodyne Stain Shield to help repel water and avoid staining. Regular care and cleaning will ensure a longer lifespan for your shoes.

Follow-Up: You should have regularly scheduled visits with your foot care specialist. Please direct any questions about these shoes or inserts to our office.

Warranty: Anodyne accepts the return of any undamaged Anodyne shoes in their original packaging within 30 days of the shoes being shipped.

I certify that I have received the item(s) marked below in good condition and authorize the Supplier to bill Medicare. The Fitter has explained, in detail, how to appropriately break-in and care for these shoes and inserts and has ensured that they fit properly. I was also instructed to call the office if I questions, comments, or concerns moving forward. I have received a copy of the Medicare DMEPOS Supplier Standards.

Description of items provided:

Quantity	HCPCS Code	Description
1	A5500	Anodyne Diabetic Extra-Depth Shoes, pair
3	A5512	Anodyne Prefabricated Heat Moldable Inserts, pair

Patient Signature:		**Patient Name:**		**Date:**	
Patient Address:					
Witness Signature:		**Witness Name:**		**Date:**	

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 AND INSERTS

Patient Name:		MBI#:		DOB:	

Dispensing Chart Notes:

S: Patient is present for dispensing of therapeutic shoes and inserts to prevent diabetic foot complications.

O: There is certification of medical necessity from the physician managing the patient's diabetes in the chart. There is a signed statement from the certifying physician attesting to the patient's qualifying conditions for diabetic, extra-depth shoes and multi density, direct-formed inserts, in addition to pertinent medical records indicating that the patient is under a comprehensive plan of care for their diabetes. Inserts are – multiple density inserts, direct formed, molder to foot after external heat source of 230 degrees Fahrenheit or higher, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore A 40 durometer (or higher), prefabricated, each.

A: Patient ambulated without issue and the shoes accommodate

- √ 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.
- √ Patient's feet are supported and stabilized by the heel counter.
- √ There are no bony prominences pushing through the shoe uppers, no slippage of heels, and ample toe room.
- √ Multi density, direct formed Inserts fit inside the shoes properly and make total contact with the patient's feet.

P: Fitting of diabetic, extra-depth shoes and multi density, direct formed inserts to prevent diabetic foot complications. Break-in and care instructions were provided to the patient, in addition to warranty information and Medicare DMPEOS Supplier Standards. A follow up appointment to check the fit of shoes and inserts was made.

Description of items provided:

Quantity	HCPCS Code	Description
1	A5500	Anodyne Diabetic Extra-Depth Shoes, pair
3	A5512	Anodyne Prefabricated Heat Moldable Inserts, pair

Shoe Fitter Signature:		Date:	
Shoe Fitter Name: (Printed)			