

Therapeutic Shoes for Persons with Diabetes

A Collaborative Webinar
presented by the
A/B and DME Medicare
Administrative Contractors

October 17, 2023



Disclaimer

The A/B and DME MAC Provider Outreach and Education (POE) staff have produced this material as an informational reference for providers furnishing services in our contract jurisdictions to Medicare beneficiaries.

Although every reasonable effort has been made to assure the accuracy of the information within these pages at the time of publication, the Medicare program is constantly changing, and it is the responsibility of each provider to remain abreast of the Medicare program requirements. Any regulations, policies and/or guidelines cited in this publication are subject to change without further notice. Current Medicare regulations can be found on the Centers for Medicare & Medicaid Services (CMS) website at <http://www.cms.gov>.

As a reminder, CMS does not allow recording of education opportunities such as this.

Participants

- **CGS Administrators, LLC**
- **First Coast Service Options, Inc.**
- **National Government Services**
- **Noridian Healthcare Solutions, LLC**
- **Novitas Solutions**
- **Palmetto GBA**
- **WPS Government Health Administrators**

Agenda

- Certifying Physician
 - Nurse Practitioners (NPs) and Physician Assistants (Pas) as Certifying Physicians
 - Primary Care First (PCF) Model
- Coverage Criteria
- Documentation Requirements
- Frequently Asked Questions (FAQs)
- References
- Resources
- Questions




Certifying Physician

Certifying Physician

Certifying Physician is defined as doctor of medicine (M.D.) or doctor of osteopathy (D.O.)

- Responsible for diagnosing and treating beneficiary's diabetic systemic condition through comprehensive plan of care
- Certifying physician may not be podiatrist or clinical nurse specialist



Nurse Practitioners and Physician Assistants as Certifying Physicians

October 17, 2023

© 2023 Copyright. This is collaborative education
presented by the four DME MAC jurisdictions.

NP and PA as Certifying Physician for Therapeutic Shoes and Inserts

CMS guidance delegation

- Certifying physician (MD or DO) comprehensive management of diabetes responsibilities to NP and PA

Clarification specific

- NPs/PAs practicing under supervision of MD or DO
 - i.e., “incident to”
- Does not extend to NPs who practice independently (i.e., bill under their own NPI)

NP and PA as Certifying Physician for Therapeutic Shoes and Inserts (2)

NPs or PAs could meet “incident to” requirements if all criteria are met:

- Supervising physician (MD or DO) documented in medical record, patient is diabetic, has been, continues to provide patient follow-up under comprehensive management program; and
- NP or PA certifies provision of therapeutic shoes part of comprehensive treatment plan provided; and
- Supervising physician review/verify (sign/date) NP/PA notes in medical record pertaining to provision of therapeutic shoes and inserts, acknowledging agreement with NP/PA

CMS guidance addresses

- NP or PA performing role of certifying physician
- Supervising MD or DO billing for service under NPI



Primary Care First (PCF) Model Demonstration Project

Primary Care First (PCF) Model Demonstration Project

January 1, 2021 through December 31, 2025

- CMS will utilize PCF model
- Allow NPs to certify order for diabetic shoes

CMS launched PCF model in 26 regions

Only NPs participating in PCF demonstration eligible to serve as certifying physician

- Participants are listed with group or organization

Information on PCF Model

<https://www.cms.gov/priorities/innovation/innovation-models/primary-care-first-model-options>

- Bottom of page under PCF Participant List

PCF Regions

Statewide

- Alaska, Arkansas, California, Colorado, Delaware, Florida, Hawaii, Louisiana, Maine, Massachusetts, Michigan, Montana, Nebraska, New Hampshire, New Jersey, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, Tennessee, Virginia

Regional

- New York Greater Buffalo region, Kansas and Missouri Greater Kansas City region, Pennsylvania Greater Philadelphia region, New York North Hudson-Capital region, Kentucky Ohio and Northern Kentucky region



Coverage Criteria

October 17, 2023

© 2023 Copyright. This is collaborative education
presented by the four DME MAC jurisdictions.

Statutory Benefit

Therapeutic Shoes and inserts are covered under Therapeutic Shoes for Persons with Diabetes benefit (Social Security Act §1861(s)(12)).

- Statutory payment policy requirements are discussed in Local Coverage Article:
<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52501>

Coverage Criteria

1. Beneficiary has diabetes mellitus
2. Certifying physician documented in beneficiary's medical record one or more of conditions 2a-2f from Policy Article (A52501) **or** initialed, dated and indicated agreement with records of another practitioner who conducted foot exam
3. Certifying physician (MD or DO) completed Certifying Physician Statement and had an in-person visit with the beneficiary during which diabetes management is addressed within 6 months prior to delivery of shoes/inserts
 1. NP or PA may not serve in role of certifying physician, unless practicing "incident to" supervising physician's authority
 2. NP practicing independently under PCF demonstration
4. Supplier conducted and document in-person evaluation of beneficiary prior to selecting items Supplier conducted objective assessment of fit of shoe and inserts and document results at time of in-person delivery

Conditions 2A-2F

- A. Previous amputation of other foot, or part of either foot, or
- B. History of foot ulceration, or
- C. History of pre-ulcerative calluses, or
- D. Peripheral neuropathy with evidence of callus formation of either foot, or
- E. Foot deformity, or
- F. Poor circulation in either foot

Documentation must clearly indicate condition is of feet or foot

Allowance Per Calendar Year

One pair of custom molded shoes and two additional pairs of inserts

or

One pair of depth shoes and three pairs of inserts

- Not including non-customized removable inserts provided with shoes

Calendar year: January through December



Documentation Requirements

October 17, 2023

© 2023 Copyright. This is collaborative education
presented by the four DME MAC jurisdictions.

Roles

- **Certifying Physician**
 - Responsible for diagnosing and treating beneficiary's diabetic systemic condition through comprehensive plan of care
 - May not be podiatrist or clinical nurse specialist
- **Prescribing Practitioner**
 - Conducts foot exam
 - Certifying physician, other MD or DO, NP, PA, CNS, DPM
- **Supplier**
 - Provides diabetic shoes

Required Documentation Created by Physician/Practitioner

- From Certifying Physician:
 - Medical record of in-person visit with beneficiary during which diabetes management is addressed within 6 months prior to delivery of shoes/inserts
 - Medical record of in-person visit documenting one of the covered foot conditions (criteria 2A-F) within 6 months prior to delivery of shoes/inserts
 - Statement of Certifying Physician signed on or after date of in-person visit and within 3 months prior to delivery of shoes/inserts
- Prescribing Practitioner
 - Medical record of in-person visit within 6 months prior to delivery of shoes/inserts
 - Standard Written Order (SWO)

Standard Written Order (SWO) Elements

- SWO elements
 - Beneficiary's name or Medicare Beneficiary Identifier (MBI)
 - Order Date
 - General description of the item
 - Description can be either general description (e.g., diabetic shoes and inserts), HCPCS code, HCPCS code narrative, or brand name/model number
 - Quantity to be dispensed
 - Treating practitioner name or National Provider Identifier (NPI)
 - Treating practitioner's signature
- If prescriber is also supplier, separate order is not required
 - Items provided must be clearly noted in medical record

Documentation of Diabetes Management

- Support diagnosis of diabetes mellitus
- Document comprehensive plan of care
 - More than diagnosis in medical record
 - Numerous guidelines from clinical organizations related to diabetes care provide detailed information about various elements of care plan for persons with diabetes
- Must occur within 6 months prior to delivery of shoes/inserts
- Certification Statement by itself does not meet requirement for documentation in medical records

Who May Conduct the Evaluation for Diabetes Management

- MD or DO responsible for diagnosing and treating beneficiary's diabetic systemic condition through comprehensive plan of care
- NP practicing independently under Primary Care First Model Demonstration Project
- NP or PA practicing under supervision of MD or DO "incident to"
 - Supervising physician has documented that patient is diabetic and has been, and continues to provide, patient follow-up under comprehensive management program of that condition
 - Supervising physician must review and verify (sign and date) all NP or PA notes in medical record pertaining to provision of therapeutic shoes, acknowledging their agreement with actions of NP or PA

Documentation of Covered Foot Condition

- “Certifying physician” has documented in medical record one or more of following conditions:
 - Previous amputation of other foot, or part of either foot
 - History of previous foot ulceration on either foot
 - History of pre-ulcerative calluses of either foot
 - Peripheral neuropathy with evidence of callus formation of either foot
 - Foot deformity of either foot
 - » Include a description of deformity
 - Poor circulation in either foot
 - » Documented evidence of poor circulation
- Certification Statement by itself does not meet requirement for documentation in medical records

Certifying Physician's Responsibility for the Foot Examination Documentation

- Certifying physician must either:
 - Personally document one or more of criteria a – f in medical record of in-person visit within 6 months prior to delivery and prior to or on same day as signing certification statement
 - NP or PA practicing “incident to” supervising physician
 - » Supervising physician (MD or DO) must review, sign and date acknowledging agreement
 - Obtain, initial, date (prior to signing the certification statement), and indicate agreement with information from medical records of in-person visit within 6 months prior to delivery of shoes/inserts, that documents one or more of criteria a-f
 - Medical records of in-person visit may be with:
 - » Podiatrist (DPM),
 - » Other MD or DO
 - » PA, NP or CNS

Statement of Certifying Physician

- Certifying physician has certified
 - Indications (1) and (2) are met
 - Treating beneficiary for diabetes and beneficiary needs diabetic shoes
 - In-person visit during which diabetes management is addressed within six (6) months prior to delivery
 - Signs and dates certification statement on or after date of in-person visit and within three (3) months prior to delivery of shoes/inserts
 - NP or PA practicing “incident to” supervising physician
 - NP or PA completes, signs and dates statement
 - Supervising physician (M.D. or D.O.) must review and verify (sign and date) acknowledging agreement
- Certification statement is not sufficient to meet requirement for documentation in medical record

Example of Statement of Certifying Physician

Statement of Certifying Physician for Therapeutic Shoes for Persons with Diabetes

Patient Name: _____

MBI: _____

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. (Circle all that apply):
 - a. History of partial or complete amputation of the foot.
 - b. History of previous foot ulceration.
 - c. History of pre-ulcerative callus.
 - d. Peripheral neuropathy with evidence of callus formation.
 - e. Foot deformity.
 - f. Poor circulation.
3. I am treating this patient with a comprehensive plan of care for his/her diabetes.
4. This patient needs special shoes (depth or custom-molded shoes) because of his/her diabetes.

Physician signature: _____

Date signed: _____

Physician name (printed – MUST BE AN M.D. OR D.O.): _____



Frequently Asked Questions (FAQ)

FAQ #1

Q. If medical professional (DPM, NP, PA, CNS, another MD or DO) other than Certifying Physician conducts foot examination, does certifying physician also have to conduct a foot exam?

A. No. If the certifying physician does not personally conduct a foot examination, they must obtain, indicate agreement, sign and date foot examination completed by another medical professional. Foot examinations conducted by another medical professional are expected to be detailed and discuss qualifying foot condition(s).

FAQ #2

Q. Why does the DME supplier need copies of the medical records when a valid statement of certifying physician and written order is provided to the supplier?

A. Information contained directly in the contemporaneous medical record is the source required to justify payment.

- Templates and forms are subject to corroboration with information in the medical record.
- The certification statement is not sufficient to meet the requirement for documentation in the medical record.
- A prescription is not considered to be part of the medical record.

FAQ #3

Q. Who can sign the SWO for diabetic shoes?

A. The “Prescribing Practitioner” is the person who writes the order for the therapeutic shoes, modifications, and inserts. This practitioner must be knowledgeable in the fitting of diabetic shoes and inserts. The prescribing practitioner may be a

- Podiatrist (DPM)
- M.D. or D.O.
- Nurse Practitioner (NP)
- Clinical Nurse Specialist (CNS)
- Physician Assistant (PA)

The prescribing practitioner may be the supplier (i.e., the one who furnishes the footwear).



Questions?

Thank you for attending this A/B and
DME MAC collaborative education.