Clarifying and Strengthening Coordination of Care in Medicare's Therapeutic Shoes for Persons with Diabetes Program

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August 8, 2014

Marilyn Tavenner, Administrator
Center for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: Meeting request concerning Medicare Therapeutic Shoes for individuals with diabetes

Dear Administrator Tavenner:

On behalf of the members of the American Podiatric Medical Association (APMA), the national organization representing the vast majority of America's estimated 15,000 doctors of podiatric medicine (DPMs), I write to request a meeting with you and relevant CMS officials concerning ongoing problems experienced in the prescribing and furnishing of Medicare therapeutic shoes for individuals with diabetes.

Statement of the Problem

Stemming from the way Medicare auditors are interpreting current law, there is increasing health-care provider confusion and frustration in the process by which Medicare diabetic patients qualify for and obtain medically necessary therapeutic shoes.

Several years ago APMA met with contractor medical directors (CMDs) and CMS officials to discuss these issues and problems, and even though they were empathetic, they offered no reasonable solutions that could better clarify existing statutory language.

Since that time, APMA has received increasing numbers of member accounts of payments to suppliers of the therapeutic shoes and inserts being denied or retracted, many of which go on to be overturned upon appeal. Based on our review of the podiatrists' records, including the contractor, auditors, and administrative law judge determinations, it was apparent that confusion surrounds interpretation of statutory language regarding the role of the prescribing health-care provider. The result has been increasing frustration on the part of podiatrist prescribers, MD/DO certifiers of therapeutic shoe medical necessity, and suppliers (including podiatrist suppliers).

The CMDs' interpretations of statutory language have resulted in a number of adverse consequences brought to the attention of APMA:

- Confusion, increased audits and administrative burdens particularly for the shoe suppliers (where many shoe providers/suppliers are filing claims and go through a lengthy appeals process, diverting precious time and resources from patient care; and many of these appeals are being appealed and overturned by Administrative Law Judges);

- Reports of more difficulty for patients in obtaining the therapeutic shoes and inserts, including situations where some beneficiaries are receiving shoes in a timely fashion, while others may have to wait longer periods for no well-articulated reason;
- Reports of patient receiving the wrong shoes/inserts, and thus unnecessarily increasing Medicare program costs without the expected clinical benefits;
- Increased frustration on the part of podiatrist-suppliers;
- Increasing reports of certifying MD/DOs who are frustrated with the increased work burden—real or perceived—involved with the therapeutic shoe program and who are refusing to participate;
- Increased costs to the Medicare program for evaluation and management services added in requiring the MD/DOs examine patients after the specialists have already examined the patients.

Our goal has been to work with CMS and the DME MACs to identify the reasons for these common denials for medically necessary items. It is our belief that the medical records and determination of diabetic/therapeutic shoe medical necessity by DPMs or orthopedists are not being accepted as part of the sum total of the records required by the supplier, and in many cases are provoking a disqualification for the diabetic shoes.

In addition, when a DPM or other medical provider sends his/her medical records to the certifying MD/DO, the MDs/DOs are reluctant to sign-off on them (as required under the current scheme) because they are put in the unsavory position of having to agree with the work of another specialist provider.

History

In conversations with the CMDs, APMA was specifically told that statutory language regarding the therapeutic shoe program precluded the prescribing doctor's medical records from being supplementary, contributory, and/or relevant toward meeting the requirements for qualifying one or more of the 6 lower extremity conditions or the medical necessity for the therapeutic shoes in the first place. APMA has argued, pointing to the language of the Social Security Act, that the statute does not support this presumption, but rather the CMDs' position is one based solely on CMD interpretation.

APMA argued and did get agreement from the CMDs that the prescribing doctor (whether a podiatrist or orthopedist) was the specialist most qualified to evaluate the patient's lower extremities, and probably the specialist to whom the primary care physician sent the patient for this problem in the first place. The association also received an understanding from the CMDs that medical necessity for a prescription—any prescription written by a doctor—must be determined prior to the writing of a prescription.

The CMDs said that although they appreciated this basic medical provider process, statutory language (SSA §1861(s)(12)(A) et seq.) merely says that prescribing doctors prescribe and that the certifying doctor would be the sole determiner of the qualifying lower extremity condition and medical necessity (even though statutory language does not specifically say that, and it

could be subject to the CMD discretion to include the medical records of the prescribing doctor). (*Please see attached statutory side-by-side summary.*)

APMA also attained agreement (which is embodied in Local Coverage Determinations), albeit as a temporary solution, that if the prescribing doctor performs the lower extremity examination, the certifying doctor would need to agree to those findings.

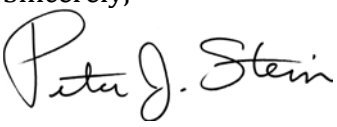
Statutory language only notes the certifying doctor is the only one that can certify (sign the statement of certification). The CMDs have said that the statute does not recognize that medical records from both the certifying doctor and prescribing doctor could be relevant in the certifying doctor's determination of medical necessity and clinical findings qualifying the diabetic patient for therapeutic shoes. However, in but one specific example of inconsistency, DME MAC Noridian has written in Q&A for providers that "*Medical records include but are not limited to the podiatrist's records that discuss the condition of the foot and MD/DO records that discuss the condition of the foot …*"

Solutions

APMA has been working on a legislative solution to these problems, embodied in Sec. 3 of the *Helping Ensure Life- and Limb-Saving Access to Podiatric Physicians (HELLPP) Act* (HR 1761 / S 1318). We would very much appreciate your technical advice and counsel as to whether these issues could be resolved through a clearer National Coverage Determination interpretation of existing statutory language, or if this legislative language could achieve the desired policy resolution to remove regulatory inconsistencies and provider confusion in the way Medicare therapeutic shoes are prescribed and furnished to individuals with diabetes. (*Please see the attached side-by-side comparison of current law with the HELLPP Act provisions in this area.*)

APMA appreciates your time and attention to these important issues, and looks forward to hearing from you about scheduling a meeting in the very near future to discuss them.

Sincerely,



Peter J. Stein
Director, Legislative Advocacy

Attachment: Side by Side Comparison of Current Law vs. HELLPP Act (HR 1761 / S 1318)

cc: Sean Cavanaugh, Deputy Administrator & Director, Center for Medicare
Laurence Wilson, Director, Chronic Care Policy Group
Scott Haag, Director, APMA Health Policy & Practice

Overview of Issues

ISSUE BRIEF

Clarifying and Strengthening Coordination of Care in the Medicare Diabetic Shoe Program

In order for a patient to be eligible for Medicare's Diabetic Shoe Program, a physician (MD or DO) must certify that the patient has diabetes mellitus, that the patient is being treated under a comprehensive plan of care for diabetes, and that it would be medically necessary for the diabetic patient to have therapeutic diabetic shoes.

The MD or DO physician who is treating the patient's systemic diabetes condition must currently also certify that the patient qualifies at least one of six lower extremity conditional findings for diabetic shoes/inserts eligibility:

a. Previous amputation of the other foot, or part of either foot; or
b. History of previous foot ulceration of either foot; or
c. History of pre-ulcerative calluses of either foot; or
d. Peripheral neuropathy with evidence of callus formation of either foot; or
e. Foot deformity of either foot; or
f. Poor circulation in either foot.

In practice, a podiatrist — a doctor of podiatric medicine (DPM) — or an orthopedist, is the one who performs the patient's detailed lower extremity examination qualifying at least one of these six conditional findings. In doing so, it is the podiatrist or orthopedist who typically identifies medical necessity (and writes the prescription/order for diabetic shoes/inserts) and initiates contact with and reports requisite information to the patient's physician (e.g., the certifying MD/DO).

Podiatrists/orthopedists are finding that their medical records, which contain more detailed lower extremity examination findings than the MD/DO's records, are either being discounted or completely ignored by the DME Medicare Administrative Contractors (DMACs), Contractor Medical Directors, and auditors when records are submitted for qualifying their patient for the therapeutic shoe and insert benefit. Refunds are being asked from the suppliers (both podiatrist-suppliers and commercial suppliers). Recent rates of audit claims error/denials are alarmingly high. Some recent reviews reveal 85% to 97% of the audited claim submissions are being denied by regulators and auditors who have been following narrow DMAC Local Coverage Determination policies. (APMA has received anecdotal evidence that a large number of these decisions are being overturned "favorably" by administrative law judges.)

For several years, APMA has discussed these problems with CMS and the DMACs, and while they are sympathetic, they have said that any remedy must come from a statutory change.

APMA members are becoming increasingly frustrated with this status quo, with a number now dropping their participation in the Medicare Diabetic Shoe Program and many others considering no longer serving as suppliers. The anticipated consequences include reduced or progressively difficult access to this medically necessary and appropriate benefit for diabetic patients.

APMA has identified some minor balanced improvements to clarify provider roles and remove confusion and regulatory inconsistencies in the provision of this medically necessary benefit. These clarifications would preserve the integrity of the checks and balances in the diabetic shoe/insert program. MDs or DOs who are treating the patient's diabetes would certify that the patient is under a comprehensive program of management of the disease; podiatrists/orthopedists would determine medical necessity for diabetic therapeutic shoes and inserts and prescribe those shoes and inserts; suppliers would fit, provide, and evaluate fit of the shoes and inserts. Under this proposal, the roles of the MD, DO, and DPM would, however, be clarified, thereby strengthening their coordination of care and communication in treating Medicare diabetic patients.

These targeted reforms would amend § 1861(s)(12) of the Social Security Act to clarify roles and improve communications among medical providers. They will significantly reduce the frustrations of the physicians and suppliers over the current administrative policies of the Medicare Diabetic Shoe Program, help ensure that those Medicare patients who are most at risk and eligible for this benefit receive it, and obviate Medicare diabetic patients making additional office visits, which in turn would save money for patients/beneficiaries and the Medicare program.

Prepared by the American Podiatric Medical Association,
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Therapeutic Shoes and Inserts for Persons with Diabetes

Current Law:

"Therapeutic Shoes for Individuals with Severe Diabetic Foot Disease" ("Medicare Diabetic Shoe Program") became a Medicare benefit in May 1993 after the Secretary of the U.S. Department of Health and Human Services reported to Congress a demonstration project finding the program's cost-effectiveness.[1] The statutory language placed a "check and balance" on the benefit qualification by defining the roles of three separate entities: 1) the certifying physician (MD/DO managing the patient's diabetes and documenting the medical necessity for the patient to receive the therapeutic shoes and inserts); 2) the prescribing podiatrist or other qualified physician; and 3) the supplier of the therapeutic shoes and inserts—the prescribing podiatrist or a qualified individual, such as a pedorthist or orthotist.[2]

The Medicare Diabetic Shoe Program allows qualified diabetic beneficiaries one (1) pair of shoes (HCPCS A5500 or A5501) and three (3) sets of inserts (HCPCS A5510, A5512, or A5513) each calendar year.

National qualifying coverage criteria is found in the Medicare Benefit Policy Manual (Internet-only Pub. 100-2, Chapter 15, §140), and limits the benefit to qualified beneficiaries with diabetic foot disease. The section defines what is considered to be acceptable/reimbursable custom-molded shoes, depth shoes, and inserts. In addition, terms for substituting shoe modifications (and what those modifications can be) for otherwise reimbursable inserts are listed. Medicare Benefit Policy Manual, Chapter 15, §140 expands the statutory definition of "certification", "prescription", and "furnishing footwear" as follows:

> C. Certification
>
> The need for diabetic shoes must be certified by a physician who is a doctor of medicine or a doctor of osteopathy and who is responsible for diagnosing and treating the patient's diabetic systemic condition through a comprehensive plan of care. This managing physician must:
>
> - document in the patient's medical record that the patient has diabetes;
> - certify that the patient is being treated under a comprehensive plan of care for diabetes, and that the patient needs diabetic shoes; and
> - document in the patient's record that the patient has one or more of the following conditions:
>   - peripheral neuropathy with evidence of callus formation;
>   - history of pre-ulcerative calluses;
>   - history of previous ulceration;
>   - foot deformity;
>   - previous amputation of the foot or part of the foot; or
>   - poor circulation.

[1] Omnibus Budget Reconciliation Act of 1987 (OBRA), § 4072(e)(1)-(2)(B)(i)
[2] OBRA § 4072(e)(12)

D. 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.

E. Furnishing Footwear

The footwear must be fitted and furnished by a podiatrist or other qualified individual such as a pedorthist, an orthotist, or a prosthetist. The certifying physician may not furnish the diabetic shoes unless the certifying physician is the only qualified individual in the area. It is left to the discretion of each carrier to determine the meaning of "in the area.

Current Issues [Specific to Podiatrist-Prescribers; Podiatrist-Suppliers]:

The current Local Coverage Determinations (LCDs) for Therapeutic Shoes for Patients with Diabetes[3] policy requires the MD/DO to: 1) initiate the referral to the prescribing doctor; 2) provide documentation that they (the MD/DO) perform a detailed lower extremity examination that qualified at least one of the six conditional findings; 3) complete the Statement of Certification; and 4) maintain copies of all the paperwork while sending originals to the supplier. These requirements have caused regulatory inconsistencies and provider confusion in the provision of this medically necessary benefit.

The Medicare Diabetic Shoe Program's requirement that the MD/DO managing the patient's diabetes determines the medical necessity for the therapeutic shoe/insert benefit. But it is actually the podiatrist who normally identifies medical necessity, writes the prescription/order, and initiates contact with the patient's primary care physician (PCP). In this role, podiatrists will inform the PCP that: 1) their mutual patient is likely eligible for the therapeutic shoe/insert benefit; 2) a medical necessity exists for the shoes/inserts; and 3) the MD/DO needs to provide certain documentation in order to satisfy Medicare's requirements for supplier reimbursement.

Usually, the podiatrist-prescriber provides the patient's MD/DO with the qualifying lower extremity finding(s), a Statement of Certification with an explanation on how to complete it, and instructions on providing copies of the patient's medical record documenting that he or she is a person with diabetes and under a comprehensive program of care for this condition. This documentation is copied and forwarded to the supplier (whether a podiatrist-supplier or commercial supplier). Unlike several years ago when documentation demands were met by having the certifying MD/DO complete, sign, and date the "statement of certification," that form alone no longer satisfies the documentation requirements (according to the "Therapeutic Shoes for Patients with Diabetes" LCDs).

Pre- and post-payment audits (which appear to be increasing in numbers) have largely found lack of sufficient documentation either in the supplier records or in the MD/DO's medical records in order to qualify patients for diabetic shoe and insert benefits. Podiatrists are finding that their medical records, which contain more detailed lower extremity examination findings than the MD/DO's medical records, are either being discounted or completely ignored by the DME

[3] See appendix A

Medicare Administrative Contractors (DMACs), Contractor Medical Directors (CMDs), and auditors when attempting to qualify their patients for therapeutic shoe and insert benefits.

These entities are requesting refunds from both podiatrist-suppliers and commercial suppliers primarily because auditors are trying to follow the above-referenced statutory language documentation demands incorporated into the LCDs, ostensibly to prevent and limit fraud and abuse. However, this process has had a chilling effect on podiatrists as prescribers or suppliers in this area. In the spring of 2012, NGS DMAC conducted a prepayment targeted medical review for therapeutic shoes for persons with diabetes, which found a claims error rate of 86 percent. In November 2012, NGS DMAC reported its third quarter 2012 prepayment review finding – a claims error rate of 95 percent. Jurisdiction D DME MAC (Noridian) Medical Review Department recently conducted a widespread service-specific probe complex review, based on CERT review analysis, of HCPCS code A5500 (off-the-shelf depth-inlay shoe) and A5512 (multiple density inserts), which found an overall "error ratio" of 97 percent. If this trend continues, the DMACs will approach 100 percent denials due to claim errors, where the vast majority are the result of a lack of medical necessity because of the documentation standards the CMDs set.

American Podiatric Medical Association (APMA) members who function both as prescribers and suppliers of therapeutic shoes are becoming increasingly frustrated with the administration of the Medicare Diabetic Shoe Program. The number of audits, requirement of refunds, and the time, effort, and cost necessary to appeal the audit results are resulting in increased frustration among the medical professionals working on behalf of patients. It is noteworthy that many podiatrist-suppliers who have been audited are filing an increasing number of administrative appeals. They have reported that administrative law judges (ALJs) have overturned the audit findings and refund demands. Despite these rulings in favor of the podiatrist-supplies, APMA members are frustrated because DMAC CMDs and CMS are increasing costs and lack efficiency, and as a result, they are no longer participating as suppliers. Many APMA members prefer to write prescriptions to be filled by a commercial supplier that will likely be denied reimbursement. APMA members have also explained that increasing numbers of MD/DOs are no longer willing to fulfill the certification requirements for their own patients for the Medicare Diabetic Shoe Program benefit, citing their increased patient loads, and the administrative work burdens (specifically the paperwork required to be provided to the supplier).

The Medicare Diabetic Shoe Program is well intentioned as it seeks to avoid serious consequences in a highly at-risk population <u>while still being</u> cost effective. However, this desired effect is not realized because increasing numbers of certifying MD/DOs and suppliers (especially podiatrist-suppliers) are not willing to participate or have stopped participating. The actual result has been reduced or increasingly difficult access for individuals with diabetes to the benefit.

Proposed Legislative Changes and Rationale:

For more than three years, APMA continually communicated with the DMAC CMDs and representatives at CMS with the goal of resolving these issues. A resolution was not reached as the DMACs and CMS conveyed that a change in the Medicare Diabetic Shoe Program must be made legislatively. APMA agrees with this notion and proposes legislative changes to section 1861(s)(12) of the Social Security Act that re-defines the roles of the certifying physician and the prescribing podiatrist or other qualified physician to achieve the goals of the program and reflect the process that actually takes place. The proposed changes to <insert citation again> are as follows:

C.Certification

The physician (doctor of medicine or doctor of osteopathy) is responsible for documenting that the patient has diabetes mellitus and for certifying his or her management of the patient's diabetic systemic condition through a comprehensive plan of care. This certifying physician must:

- document in the patient's medical record that the patient has diabetes mellitus;
- certify that the patient is being treated under a comprehensive plan of care for diabetes; and
- concur with the prescribing podiatrist or other qualified physician that it is medically necessary for the patient to receive diabetic therapeutic shoes and inserts/shoe modifications.

D. Prescription

A podiatrist or other qualified physician is responsible for the examination of the patient's lower extremities and for the determination of medical necessity for the patient to receive diabetic therapeutic shoes and inserts/shoe modifications. The prescribing physician must document in the patient's record that the patient has one or more of the following conditions:

- Peripheral neuropathy with evidence of callus formation (including significant clinical pathological findings)
- History of pre-ulcerative calluses (described)
- History of previous ulceration (described)
- Foot deformity (including a detailed description [with location]
- Previous amputation of the foot or part of the foot (described)
- Poor circulation (including significant clinical pathological findings)

The podiatrist or other qualified physician will write the prescription or order detailing the type of diabetic therapeutic shoes and type of inserts and/or shoe modifications the patient requires. The podiatrist or other qualified physician must communicate the findings and medical necessity with the MD/DO managing the patient's diabetes. The MD/DO is required to document concurrence of medical necessity of therapeutic shoes and inserts/shoe modifications within a completed Statement of Certification.

E. Furnishing Footwear

The diabetic therapeutic shoes and inserts/shoe modifications are dispensed and fitted by a supplier (podiatrist or other qualified individual. such as a pedorthist, an orthotist, or a prosthetist). The certifying physician may not furnish the diabetic shoes unless the certifying physician is the only qualified individual in the area. It is left to the discretion of each carrier to determine the meaning of "in the area." The supplier would be responsible for obtaining 1) the prescription or order from

the prescribing podiatrist or other qualified physician[4]; 2) a completed Statement of Certification from the certifying MD/DO managing the patient's diabetes; and 3) a copy of the prescribing doctor's medical records documenting one or more qualifying lower extremity conditions[5] (see D above) and medical necessity for the diabetic therapeutic shoes and inserts/shoe modifications.

Conclusion

Currently, a number of podiatrists, suppliers, and MD/DOs considering abstaining from participation in the Medicare Diabetic Shoe Program for the reasons discussed. If the demonstration project preceding the establishment of the program was correct in its findings, the therapeutic shoe/insert program is medically necessary, designed to reduce foot complications that can lead to limb loss, and is cost effective. The frustrations expressed by the certifying physicians, prescribing doctors, and suppliers, as well as the DMAC CMDs and CMS, appear to result from statutory language interpretation, burdensome documentation requirements, and attempts to reduce fraud and abuse.

Unfortunately, the current administration of the Medicare Diabetic Shoe Program is increasing Medicare costs in the form of audits, which are frequently overturned by ALJs, and additional E/M service encounters by the certifying MD/DOs and prescribing doctors. The program is also increasing administrative costs for all entities that take part in it. These increased costs result in reduced participation in the program by physicians and suppliers, as well as reduced qualified patient access to the Medicare Diabetic Shoe Program benefit. Ultimately, the Medicare beneficiaries with diabetes will unnecessarily suffer and require costly treatment for ailments that would have been prevented through a reformed administration of the program.

[4] If the podiatrist or other qualified doctor is both the prescriber and supplier, the prescription or order may be included within the body of the patient's medical records.

[5] If the podiatrist or other qualified doctor is both the prescriber and supplier, the documented details of the qualifying lower extremity conditions may be contained within the body of the patient's medical records.

DMAC Data

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Clarifying and Strengthening Coordination of Care in the Medicare Diabetic Shoe Program

The *Helping Ensure Life- and Limb-Saving Access to Podiatric Physicians (HELLPP) Act* (HR 1761 / S 1318) contains a provision to remove regulatory inconsistencies and provider confusion in Medicare's Therapeutic Shoes for Diabetics program, thereby enabling providers to work more efficiently and seamlessly on behalf of the patients they serve.

Recent data from two DME Medicare Administrative Contractors strongly suggest a flawed and confusing process in the provision of Medicare diabetic shoes, and underscore the need for clarifications like the ones contained in the HELLPP Act.

Initial Claims Processing

	Region C (CIGNA Government Services)	**Region D (Noridian)**
	Q1 2014	
Denial Rate	80%	82%
Common Reasons for Denial	1) Medical records from the certifying physician were not provided. (40%) 2) The clinician foot examination was performed by a clinician (another physician, podiatrist, nurse practitioner, clinical nurse specialist, physician assistant) other than the certifying physician and the certifying physician did not signify that he/she reviewed and agreed with the exam findings by stating approval and signing and dating the examination notes. (32%) ** 3) Documentation did not include a clinical foot exam. (13%) 4) The supplier's in-person evaluation of the beneficiary's feet was missing one or both of the following required elements: (1) Description of the abnormalities the shoes/inserts/modification need to accommodate; or (2) Measurements of the beneficiary's feet. (12%) 5) Documentation provided by the supplier did not include a copy of a detailed written order. (12%)	1) Documentation of foot abnormalities by certifying physician not met 2) Documentation of diabetes management by certifying physician not met 3) No documentation was received 4) Documentation of in-person visit prior to selection of items not met

Error rates are generally calculated by reviewing each claim and determining if there was an error in any of the following, for example:

- Does the item/equipment fit a Medicare benefit category?
- Is the item/equipment statutorily excluded?
- Is the item/equipment medically reasonable and necessary?
- Is there documentation to support that the item/equipment was provided?
- Was the item/equipment coded and billed correctly?

Error rates of 80% or higher should be a concern to policymakers that either the review criteria is unclear or that the claims adjudication process itself is flawed. These error rates remain consistently high across the most recent quarters available (in excess of 75%).

** **The HELLPP Act would significantly improve some exceedingly high error rates by addressing Reason 2 under CIGNA (present in 32% of denials) and potentially Reason 1 under Noridian (percentages not available).**

Noridian Documentation Requirements

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 Noridian web site at 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.

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

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

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

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

Noridian

https://www.noridianmedicare.com/dme/train/presentations/therapeutic_shoes_q_a.html

Q&A Session for Therapeutic Shoes for Persons with Diabetes

Policy Requirements

Q: Can a Certified Pedorthist (CPED) do the evaluation for a M.D. or D.O. to certify?
A: No, the certifying physician must personally document one of the condition in criteria 2a-f within 6 months prior to the delivery of the shoes or obtain, initial, date (prior to signing the certification statement), and indicate agreement with information from the medical records of an in-person visit with a podiatrist, other M.D or D.O., physician assistant, nurse practitioner (NP), or clinical nurse specialist (CNS).

Q: Can an M.D. or D.O. counter sign an Family Nurse Practitioner's (FNP) visit or do they have to be the one who saw the patient?
A: The individual who is managing the patient's diabetic condition must be an M.D. or D.O. If the condition is only being managed by a FNP, that does not meet the policy requirements.

Q: Will a pair of shoes be provided even though one leg has been amputated below the knee?
A: If the beneficiary has a prosthesis then yes, as it would meet criteria 2a in the Policy Article as long as all other requirements are met.

Q: If the beneficiary is seen by the FNP for shoes and has a face-to-face documented visit regarding the condition of the beneficiary's feet, can the M.D. or D.O. (certifying physician) sign that evaluation indicating agreement with those findings?
A: Yes. If the certifying physician reviews, signs/dates and indicates agreement with the FNP record regarding the feet prior to signing the Certificate Statement, that would met criterion 2 (as long as one of the condition in 2a-f are documented during that visit). However the M.D. or D.O. must have an in-person visit with the beneficiary during which diabetes management is addressed within 6 months prior to delivery of the shoes/inserts.

Q: Medicare requires the primary care doctor involvement every time diabetic shoes are ordered?
A: Yes. Coverage criterion 3 states:

- The certifying physician has certified that indications (1) and (2) are met and that he/she is treating the beneficiary under a comprehensive plan of care for his/her diabetes and that the beneficiary needs diabetic shoes. For claims with dates of service on or after 01/01/2011, the certifying physician must:
    - Have an in-person visit with the beneficiary during which diabetes management is addressed within 6 months prior to delivery of the shoes/inserts; and
    - Sign the certification statement (refer to the Documentation Requirements section of the related Local Coverage Determination) on or after the date of the in-person visit and

within 3 months prior to delivery of the shoes/inserts.

Q: Where does the supplier inspect the shoes and fit the patient if delivered by mail delivery?
A: The Therapeutic Shoes for Persons with Diabetes (TSPD) policy requires an in-person evaluation of the beneficiary by the supplier at the time of delivery. If the supplier is shipping the shoes, this requirement cannot be met.

Q: Describe D.O. please?
A: A D.O. is a doctor of osteopathy.

Q: We have questions regarding custom shoes and inserts when it comes to our ABC/BOC/DR Comfort certified fitters. Is it the case that they can no longer fit for customs as of 1/1/14 and only a licensed orthotist, prosthestist or pedorthists can fit for these? This question is based off of - Effective 1/1/2014, the Iowa Board of Podiatry established the rules to license Orthotists, Prosthetists, and Pedorthists.
A: If this is a state requirement, you would need to follow any state regulations for your state.

Q: On the Certifying Physician Statement for Therapeutic Shoes number 2e) states, Foot deformity. What would be covered under foot deformity?
A: A foot deformity could be a bunion; hammertoes etc. but are not limited to these examples.

Q: Does the qualifying condition have to be written in the MDs record if it is written in the DPMs and the MD has signed and dated, agreeing with the DPMs records?
A: Only Criterion 2 would be met if the qualifying condition is noted in the DPMs records and the certifying MD/DO has indicated agreement with the findings & has signed & dated those records

Coding

Q: Is the insert that comes with the A5500 shoe considered a diabetic insert?
A: Only if it meets the definition of A5512 in the Policy Article. Medicare allows 3 pairs of inserts (A5512 or A5513) (not including the non-customized removable inserts provided with such shoes).

Q: Can any modifications for diabetic shoes be submitted with an "L" code or are they all "A" codes?
A: Only "A" codes listed in the Policy Article are considered modifications for TSPD. If there isn't a specific code for the modification you are conducting, use A5507 and describe the modification in the narrative section of your claim.

Q: Regarding the substitute for an inserts, if the beneficiary needed 1 A5512 and 1 A5503, can you do this as long as you do not exceed 3 per side?
A: Yes, that is fine. Be sure to use the appropriate modifiers for both A5512 and A5503 (LT and/or RT) identifying if the modification is for one or both feet.

Q: With the partial toe filler/insert L5000 the policy article does not state that it requires a KX modifier. However, when we asked a Noridian representative, we were told that it does. Does it or does it not require a KX modifier?
A: Codes A5512 or A5513 may not be billed in addition to code L5000. The L5000 is part of the Lower

Limb Prostheses LCD, which does not require the KX modifier.

Q: Can you provide a resource for the verbiage for coverage on the L5000, partial foot with toe filler. It is my understanding that a portion of the MT head must be involved - where can we find the exact language as to the specifics of this definition?
A: Please refer to this article. L5000 is part of the Lower Limb Prostheses LCD.
www.noridianmedicare.com/dme/news/docs/2012/06_jun/toe_fillers_and_diabetic_shoe_inserts_coding_clarification.html

Q: Can you please tell me is the HCPCS code for fabricated shoes for women and men the same? The reason I ask is because Medi-Cal has one HCPCS for women and another for men.
A: The HCPCS code is valid for either men's or women's shoes.

Documentation

Q: What items and/or diagnoses are being looked at within the certifying physician's documentation to show diabetes management?
A: The certifying physician's records need to support management of diabetes mellitus under a comprehensive plan of care.

Q: Can the certifying physician sign the certification statement the same day they sign off on the podiatrist notes stating he is in agreement with their medical records regarding coverage criteria 2a-f?
A: Yes, as long as the certifying physician does so prior to signing the certifying statement.

Q: Who signs the verbal order?
A: If the physician's office is calling the order into the supplier, then the verbal order would be signed by the person that took the order over the phone.

Q: How old can the prescription be to be accepted by the supplier?
A: The supplier should dispense the shoes within a reasonable time from receiving the order. Generally 3 months is acceptable from when the order is signed. This policy also requires that the Certifying Statement be completed within 3 months prior to dispensing the shoes.

Q: When a supplier delivers directly to a beneficiary in a skilled nursing facility (SNF) and they sign the delivery, does the delivery have to be signed by a nurse, etc as well?
A: If the beneficiary is able to sign the proof of delivery that would be valid. Medicare would also need upon request information from the nursing facility showing that the item(s) delivered for the beneficiary's use were actually provided to and used by the beneficiary.

Q: The need for custom shoe documentation comes from the supplier correct?
A: Correct. Coverage criterion 4 within the Policy Article states:
Prior to selecting the specific items that will be provided; the supplier must conduct and document an in-person evaluation of the beneficiary. (Refer to the related Local Coverage Determination, Documentation Requirements section, for additional information.)
And the LCD states:
The in-person evaluation of the beneficiary by the supplier at the time of selecting the items that will be

provided (refer to related Policy Article, Non-Medical Necessity Coverage and Payment Rules, criterion 4) must include at least the following:

- An examination of the beneficiary's feet with a description of the abnormalities that will need to be accommodated by the shoes/inserts/modifications.
- For all shoes, taking measurements of the beneficiary's feet.
- For custom molded shoes (A5501) and inserts (A5513), taking impressions, making casts, or obtaining CAD-CAM images of the beneficiary's fee that will be used in creating positive models of the feet.

Q: Recently we received a denial on our diabetic shoes stating that inserts were not ordered, does the physician need to state that the beneficiary needs insert when applicable?
A: The detailed written order must specify all items ordered that will be billed separately to Medicare.

Q: What other medical records are required besides the detailed written order and the Certifying Physician Statement form? Could we just use these two documents for now?
A: The medical record must substantiate the need and all other requirements in the LCD and Policy Article must be met. Medical records include but are not limited to the podiatrist's records that discuss the condition of the foot and MD/DO records that discuss the beneficiary's diabetic condition. www.noridianmedicare.com/dme/coverage/docs/lcds/current/therapeutic_shoes_for_persons_with_diabetes.htm

Billing

Q: When dispensing diabetic shoes, is the physician information submitted on the claim; the physician that filled out the "Statement of Certifying Physician" or the physician that signed the order?
A: The physician that signed the order for the shoes would be entered into the referring physician fields on the claim.

Q: How would we bill shoes for a beneficiary who is hospice?
A: If the item being dispensed is not related to the hospice condition, the item should be billed with the GW modifier.

Q: We have beneficiaries who purchase our diabetic shoes; however, they do not have diabetes. Since they're paying out of pocket, is it necessary to send a claim into Medicare with a GY modifier? Should the patient sign an ABN?
A: Yes, if they don't meet the Medicare requirement of having diabetes, you would bill with a GY modifier. Since this denies statutorily excluded/not a Medicare benefit for this policy, it denies patient responsibility, so you could provide a voluntary ABN to explain the denial. Suppliers must submit a claim if the beneficiary requests you to bill.

Payment Rules

Q: Why is Noridian the only contractor requiring all these burdensome standards? This is further unfair burden on the primary doctor.

A: This is a statutory policy. Most the rules discussed are written into the Social Security Act (SSA).

Q: Medicare Advantage plans do not require any of these over burdensome requirements for which Noridian DME requires, why is that?
A: The information being discussed in this training is for Medicare fee-for-service. Refer to the Medicare Advantage plan for questions and clarifications on their process for TSPD.

Q: If shoes are dispensed to a Medicare beneficiary in a SNF with POS 31 or 32, will they deny?
A: If the beneficiary is in a private pay situation, then the shoes should pay as long as they meet all of the coverage criteria. If the beneficiary's stay in the SNF is covered by Medicare Part A the shoes will deny as being included in the Part A reimbursement.

Q: Regarding the prescribing physician, what if the NP has assumed the duties of the certifying physician due to shortages of physicians in our area (Urban)?
A: An NP may be the prescribing physician and the supplier, but may not be the certifying physician.

Q: Can you tell me exactly where the statues are written by congress?
A: This is in the SSA. Chapter 9 of the Noridian Supplier Manual lists all citations. Specific to TSPD:
Section 1833(o)[42 USC Section 1395l(o)]
Section 1834(j)(5)(F)[42 USC Section 1395m(j)(5)(F)]
Section 1842(s)(2)(c)[42 USC Section 1395u(s)(2)(c)]
Section 1861(s)(12)[42 USC Section 1395x(s)(12)]

Q: Some persons with diabetes require two different size shoes. The vendors charge extra in this case, is there a way to be reimbursed for that higher cost?
A: The fee schedule for shoes is per shoe. If the supplier is non-participating they have the option of not accepting assignment and charging the beneficiary your reasonable cost. There is no additional reimbursement related to different size shoes.

Q: Are you aware of any lobbying and/or upcoming changes in the footwear bill that will allow NP's and PA's to be the Certifying Physician?
A: I am not aware of anything but you may want to contact your congressman/women or senator to see if they know.

Q: What is the reasoning for only allowing diabetes management to be certified by a M.D. or D.O., when Medicare pays NP and PA's to care for an individual with diabetes?
A: That is a statutory requirement per the benefit category which is written in the SSA.

Q: Do these rules apply to a hospital based SNF unit for the payment of the shoes?
A: It would as long as Medicare Part A is not paying for that beneficiary's stay in the SNF. If Medicare Part A is paying for the beneficiary's stay, then reimbursement would be included in the Part A consolidated payment.

Q: Are TSPD included in the competitive bid?
A: The CBIC website is www.dmecompetitivebid.com. TSPD are not currently listed as a product category for competitive bidding.

Q: We understood shoes could be delivered every 12 months, not calendar year. Is it calendar

year? One pair could be delivered in November and another pair in January?
A: Correct. TSPD have a calendar year allowance. Per the Policy Article:
For beneficiaries meeting the coverage criteria, coverage is limited to one of the following within one calendar year (January – December):

- One pair of custom molded shoes (A5501) (which includes inserts provided with these shoes) and 2 additional pairs of inserts (A5512 or A5513); or
- One pair of depth shoes (A5500) and 3 pairs of inserts (A5512 or A5513) (not including the non-customized removable inserts provided with such shoes).

Replacement

Q: I have a customer that got a pair of shoes from us. We billed Medicare and about a month or so later she returned them wanting a different pair because they were rubbing on one of her foot wrong. Do I need a new order from the doctor on that?
A: A new order is not required for the replacement of an insert or modification within one year of the order on file. However, a new order is required for the replacement of any shoe.

Last Updated: June 4, 2014

Social Security Act

Statutory Provisions

Section 1833(o)[42 USC Section 1395l(o)]

(o)(1) In the case of shoes described in section 1861(s)(12)—

(A) no payment may be made under this part, with respect to any individual for any year, for the furnishing of—

(i) more than one pair of custom molded shoes (including inserts provided with such shoes) and 2 additional pairs of inserts for such shoes, or

(ii) more than one pair of extra-depth shoes (not including inserts provided with such shoes) and 3 pairs of inserts for such shoes, and

(B) with respect to expenses incurred in any calendar year, no more than the amount of payment applicable under paragraph (2) shall be considered as incurred expenses for purposes of subsections (a) and (b).

Payment for shoes (or inserts) under this part shall be considered to include payment for any expenses for the fitting of such shoes (or inserts).

(2)(A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra-depth shoes, and inserts shall be the amount determined for such items by the Secretary under section 1834(h).

(B) The Secretary may establish payment amounts for shoes and inserts that are lower than the amount established under section 1834(h) if the Secretary finds that shoes and inserts of an appropriate quality are readily available at or below the amount established under such section.

(C) In accordance with procedures established by the Secretary, an individual entitled to benefits with respect to shoes described in section 1861(s)(12) may substitute modification of such shoes instead of obtaining one (or more, as specified by the Secretary) pair of inserts (other than the original pair of inserts with respect to such shoes). In such case, the Secretary shall substitute, for the payment amount established under section 1834(h), a payment amount that the Secretary estimates will assure that there is no net increase in expenditures under this subsection as a result of this subparagraph.

(3) In this title, the term “shoes” includes, except for purposes of subparagraphs (A)(ii) and (B) of paragraph (2), inserts for extra-depth shoes.

Section 1834(j)(5)(F)[42 USC Section 1395m(j)(5)(F)]

(j) Requirements for Suppliers of Medical Equipment and Supplies.—

(1) Issuance and renewal of supplier number.—

(A) Payment.—Except as provided in subparagraph (C), no payment may be made under this part after the date of the enactment of the Social Security Act Amendments of 1994 for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number.

(B) Standards for possessing a supplier number.—A supplier may not obtain a supplier number unless—

(i) for medical equipment and supplies furnished on or after the date

of the enactment of the Social Security Act Amendments of 1994 and before January 1, 1996, the supplier meets standards prescribed by the Secretary in regulations issued on June 18, 1992; and

(ii) for medical equipment and supplies furnished on or after January 1, 1996, the supplier meets revised standards prescribed by the Secretary (in consultation with representatives of suppliers of medical equipment and supplies, carriers, and consumers) that shall include requirements that the supplier—

(I) comply with all applicable State and Federal licensure and regulatory requirements;

(II) maintain a physical facility on appropriate site;

(III) have proof of appropriate liability insurance; and

(IV) meet such other requirements as the Secretary may specify.

(C) Exception for items furnished as incident to a physician's service.—Subparagraph (A) shall not apply with respect to medical equipment and supplies furnished incident to a physician's service.

(D) Prohibition against multiple supplier numbers.—The Secretary may not issue more than one supplier number to any supplier of medical equipment and supplies unless the issuance of more than one number is appropriate to identify subsidiary or regional entities under the supplier's ownership or control.

(E) Prohibition against delegation of supplier determinations.—The Secretary may not delegate (other than by contract under section 1842) the responsibility to determine whether suppliers meet the standards necessary to obtain a supplier number.

(2) Certificates of medical necessity.—

(A) Limitation on information provided by suppliers on certificates of medical necessity.—

(i) In general.—Effective 60 days after the date of the enactment of the Social Security Act Amendments of 1994, a supplier of medical equipment and supplies may distribute to physicians, or to individuals entitled to benefits under this part, a certificate of medical necessity for commercial purposes which contains no more than the following information completed by the supplier:

(I) An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished.

(II) A description of such medical equipment and supplies.

(III) Any product code identifying such medical equipment and supplies.

(IV) Any other administrative information (other than information relating to the beneficiary's medical condition) identified by the Secretary.

(ii) Information on payment amount and charges.—If a supplier distributes a certificate of medical necessity containing any of the information permitted to be supplied under clause (i), the supplier shall also list on the certificate of medical necessity the fee schedule amount and the supplier's charge for the medical equipment or supplies being furnished prior to distribution of such certificate to the physician.

(iii) Penalty.—Any supplier of medical equipment and supplies who knowingly and willfully distributes a certificate of medical necessity in violation of clause (i) or fails to provide the information required under clause (ii) is subject to a civil money penalty in an amount not to exceed $1,000 for each such certificate of medical necessity so distributed. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1128A(a).

(B) Definition.—For purposes of this paragraph, the term "certificate of medical necessity" means a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(3) Coverage and review criteria.—The Secretary shall annually review the coverage and utilization of items of medical equipment and supplies to determine whether such items should be made subject to coverage and utilization review criteria, and if appropriate, shall develop and apply such criteria to such items.

(4) Limitation on patient liability.—If a supplier of medical equipment and supplies (as defined in paragraph (5))—

(A) furnishes an item or service to a beneficiary for which no payment may be made by reason of paragraph (1);

(B) furnishes an item or service to a beneficiary for which payment is denied in advance under subsection (a)(15); or

(C) furnishes an item or service to a beneficiary for which payment is denied under section 1862(a)(1);

any expenses incurred for items and services furnished to an individual by such a supplier not on an assigned basis shall be the responsibility of such supplier. The individual shall have no financial responsibility for such expenses and the supplier shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected from the individual for such items or services. The provisions of subsection (a)(18) shall apply to refunds required under the previous sentence in the same manner as such provisions apply to refunds under such subsection.

(5) Definition.—The term "medical equipment and supplies" means—

(A) durable medical equipment (as defined in section 1861(n));

(B) prosthetic devices (as described in section 1861(s)(8));

(C) orthotics and prosthetics (as described in section 1861(s)(9));

(D) surgical dressings (as described in section 1861(s)(5));

(E) such other items as the Secretary may determine; and

(F) for purposes of paragraphs (1) and (3)—

(i) home dialysis supplies and equipment (as described in section 1861(s)(2)(F)),

(ii) immunosuppressive drugs (as described in section 1861(s)(2)(J)),

(iii) therapeutic shoes for diabetics (as described in section 1861(s)(12)),

(iv) oral drugs prescribed for use as an anticancer therapeutic agent (as described in section 1861(s)(2)(Q)), and

(v) self-administered erythropoetin (as described in section 1861(s)(2)(P)).

Section 1842(s)(2)(c)[42 USC Section 1395u(s)(2)(c)]

(s)(1)(A) Subject to paragraph (3), the Secretary may implement a statewide or other area wide fee schedule to be used for payment of any item or service described in paragraph (2) which is paid on a reasonable charge basis.

(B) Any fee schedule established under this paragraph for such item or service shall be updated—

(i) for years before 2011—

(I) subject to subclause (II), by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year; and

(II) for items and services described in paragraph (2)(D) for 2009, section 1834(a)(14)(J) shall apply under this paragraph instead of the percentage increase otherwise applicable; and

(ii) for 2011 and subsequent years—

(I) the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, reduced by—

(II) the productivity adjustment described in section 1886(b)(3)(B)(xi)(II).

The application of subparagraph (B)(ii)(II) may result in the update under this paragraph being less than 0.0 for a year, and may result in payment rates under any fee schedule established under this paragraph for a year being less than such payment rates for the preceding year.

(2) The items and services described in this paragraph are as follows:

(A) Medical supplies.

(B) Home dialysis supplies and equipment (as defined in section 1881(b)(8)).

(C) Therapeutic shoes.

(D) Parenteral and enteral nutrients, equipment, and supplies.

(E) Electromyogram devices.

(F) Salivation devices.

(G) Blood products.

(H) Transfusion medicine.

(3) In the case of items and services described in paragraph (2)(D) that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)—

(A) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program; and

(B) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise applicable under paragraph (1) for an area that is not a competitive acquisition area under section

1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.

Section 1861(s)(12)[42 USC Section 1395x(s)(12)]

(s) The term "medical and other health services" means any of the following items or services:

(1) physicians' services;

(2)(A) services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills (or would have been so included but for the application of section 1847B);

(B) hospital services (including drugs and biologicals which are not usually self-administered by the patient) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services;

(C) diagnostic services which are—

(i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital, and

(ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study;

(D) outpatient physical therapy services and outpatient occupational therapy services;

(E) rural health clinic services and Federally qualified health center services;

(F) home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies, and, for items and services furnished on or after January 1, 2011, renal dialysis services (as defined in section 1881(b)(14)(B));

(G) antigens (subject to quantity limitations prescribed in regulations by the Secretary) prepared by a physician, as defined in section 1861(r)(1), for a particular patient, including antigens so prepared which are forwarded to another qualified person (including a rural health clinic) for administration to such patient, from time to time, by or under the supervision of another such physician;

(H)(i) services furnished pursuant to a contract under section 1876 to a member of an eligible organization by a physician assistant or by a nurse practitioner (as defined in subsection (aa)(5)) and such services and supplies furnished as an incident to his service to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service; and

(ii) services furnished pursuant to a risk-sharing contract under section 1876(g) to a member of an eligible organization by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(2)), and such services and supplies furnished as an incident to such clinical psychologist's services or clinical social worker's services to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service;

(I) blood clotting factors, for hemophilia patients competent to use such factors to control bleeding without medical or other supervision, and items related to the administration of such factors, subject to utilization controls deemed necessary by the Secretary for the efficient use of such factors;

(J) prescription drugs used in immunosuppressive therapy furnished, to an individual who receives an organ transplant for which payment is made under this title;

(K)(i) services which would be physicians' services and services described in subsections (ww)(1) and (hhh) if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a physician assistant (as defined in subsection (aa)(5)) under the supervision of a physician (as so defined) and which the physician assistant is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services,

(ii) services which would be physicians' services and services described in subsections (ww)(1) and (hhh) if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a nurse practitioner or clinical nurse specialist (as defined in subsection (aa)(5)) working in collaboration (as defined in subsection (aa)(6)) with a physician (as defined in subsection (r)(1)) which the nurse practitioner or clinical nurse specialist is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as an incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services;

(L) certified nurse-midwife services;

(M) qualified psychologist services;

(N) clinical social worker services (as defined in subsection (hh)(2));

(O) erythropoietin for dialysis patients competent to use such drug without medical or other supervision with respect to the administration of such drug, subject to methods and standards established by the Secretary by regulation for the safe and effective use of such drug, and items related to the administration of such drug;

(P) prostate cancer screening tests (as defined in subsection (oo));

(Q) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an anticancer chemotherapeutic agent for a given indication, and containing an active ingredient (or ingredients), which is the same indication and active ingredient (or ingredients) as a drug which the carrier determines would be covered pursuant to subparagraph (A) or (B) if the drug could not be self-administered;

(R) colorectal cancer screening tests (as defined in subsection (pp));

(S) diabetes outpatient self-management training services (as defined in subsection (qq));

(T) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an acute anti-emetic used as part of an

anticancer chemotherapeutic regimen if the drug is administered by a physician (or as prescribed by a physician)—

(i) for use immediately before, at, or within 48 hours after the time of the administration of the anticancer chemotherapeutic agent; and

(ii) as a full replacement for the anti-emetic therapy which would otherwise be administered intravenously;

(U) screening for glaucoma (as defined in subsection (uu)) for individuals determined to be at high risk for glaucoma, individuals with a family history of glaucoma and individuals with diabetes;

(V) medical nutrition therapy services (as defined in subsection (vv)(1)) in the case of a beneficiary with diabetes or a renal disease who—

(i) has not received diabetes outpatient self-management training services within a time period determined by the Secretary;

(ii) is not receiving maintenance dialysis for which payment is made under section 1881; and

(iii) meets such other criteria determined by the Secretary after consideration of protocols established by dietitian or nutrition professional organizations;

(W) an initial preventive physical examination (as defined in subsection (ww));

(X) cardiovascular screening blood tests (as defined in subsection (xx)(1));

(Y) diabetes screening tests (as defined in subsection (yy));

(Z) intravenous immune globulin for the treatment of primary immune deficiency diseases in the home (as defined in subsection (zz));

(AA) ultrasound screening for abdominal aortic aneurysm (as defined in subsection (bbb)) for an individual—

(i) who receives a referral for such an ultrasound screening as a result of an initial preventive physical examination (as defined in section 1861(ww)(1));

(ii) who has not been previously furnished such an ultrasound screening under this title; and

(iii) who—

(I) has a family history of abdominal aortic aneurysm; or

(II) manifests risk factors included in a beneficiary category recommended for screening by the United States Preventive Services Task Force regarding abdominal aortic aneurysms; and

(BB) additional preventive services (described in subsection (ddd)(1));

(CC) items and services furnished under a cardiac rehabilitation program (as defined in subsection (eee)(1)) or under a pulmonary rehabilitation program (as defined in subsection (fff)(1)); and

(DD) items and services furnished under an intensive cardiac rehabilitation program (as defined in subsection (eee)(4));

(EE) kidney disease education services (as defined in subsection (ggg)); and

(FF) personalized prevention plan services (as defined in subsection (hhh)).

(3) diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of

such tests meets such conditions relating to health and safety as the Secretary may find necessary and including diagnostic mammography if conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act[217]), diagnostic laboratory tests, and other diagnostic tests;

(4) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;

(5) surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;

(6) durable medical equipment;

(7) ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations;

(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens;

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition;

(10)(A) pneumococcal vaccine and its administration and, subject to section 4071(b) of the Omnibus Budget Reconciliation Act of 1987[218], influenza vaccine and its administration; and

(B) hepatitis B vaccine and its administration, furnished to an individual who is at high or intermediate risk of contracting hepatitis B (as determined by the Secretary under regulations);

(11) services of a certified registered nurse anesthetist (as defined in subsection (bb));

(12) subject to section 4072(e) of the Omnibus Budget Reconciliation Act of 1987[219], extra-depth shoes with inserts or custom molded shoes with inserts for an individual with diabetes, if—

(A) the physician who is managing the individual's diabetic condition (i) documents that the individual has peripheral neuropathy with evidence of callus formation, a history of pre-ulcerative calluses, a history of previous ulceration, foot deformity, or previous amputation, or poor circulation, and (ii) certifies that the individual needs such shoes under a comprehensive plan of care related to the individual's diabetic condition;

(B) the particular type of shoes are prescribed by a podiatrist or other qualified physician (as established by the Secretary); and

(C) the shoes are fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist, as established by the Secretary) who is not the physician described in subparagraph (A) (unless the Secretary finds that the physician is the only such qualified individual in the area);

(13) screening mammography (as defined in subsection (jj));

(14) screening pap smear and screening pelvic exam; and

(15) bone mass measurement (as defined in subsection (rr)).

No diagnostic tests performed in any laboratory, including a laboratory that is part of a rural health clinic, or a hospital (which, for purposes of this sentence, means an

institution considered a hospital for purposes of section 1814(d)) shall be included within paragraph (3) unless such laboratory—

(16) if situated in any State in which State or applicable local law provides for licensing of establishments of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing establishments of this nature, as meeting the standards established for such licensing; and

(17)(A) meets the certification requirements under section 353 of the Public Health Service Act;[220] and

(B) meets such other conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.

There shall be excluded from the diagnostic services specified in paragraph (2)(C) any item or service (except services referred to in paragraph (1)) which would not be included under subsection (b) if it were furnished to an inpatient of a hospital. None of the items and services referred to in the preceding paragraphs (other than paragraphs (1) and (2)(A)) of this subsection which are furnished to a patient of an institution which meets the definition of a hospital for purposes of section 1814(d) shall be included unless such other conditions are met as the Secretary may find necessary relating to health and safety of individuals with respect to whom such items and services are furnished.

Helping Ensure Life- and Limb-Saving Access to Podiatric Physicians (HELLPP) Act

Legislative Language

Side by Side Comparison of Current Law vs. HELLPP Act (HR 1761 / S 1318)

Current Law	HR 1761 / S 1318	Codification
§ 1861(s)(12), Social Security Act ***[42 U.S.C. 1395x]***	**SEC. 3. CLARIFYING MEDICARE DOCUMENTATION REQUIREMENTS FOR THERAPEUTIC SHOES FOR PERSONS WITH DIABETES.** (a) IN GENERAL.—Section 1861(s)(12) of the Social Security Act (42 U.S.C. 1395x(s)(12)) is amended to read as follows:	***[42 U.S.C. 1395x]***
(12) subject to section 4072(e) of the Omnibus Budget Reconciliation Act of 1987[515], extra-depth shoes with inserts or custom molded shoes with inserts for an individual with diabetes, if—	(12) subject to section 4072(e) of the Omnibus Budget Reconciliation Act of 1987, extra-depth shoes with inserts or custom molded shoes with inserts (in this paragraph referred to as 'therapeutic shoes') for an individual with diabetes, if —	(12) subject to section 4072(e) of the Omnibus Budget Reconciliation Act of 1987[515], extra-depth shoes with inserts or custom molded shoes with inserts (in this paragraph referred to as 'therapeutic shoes') for an individual with diabetes, if —
(A) the physician who is managing the individual's diabetic condition — (i) documents that the individual has peripheral neuropathy with evidence of callus formation, a history of pre-ulcerative calluses, a history of previous ulceration, foot deformity, or previous amputation, or poor circulation, and (ii) certifies that the individual needs such shoes under a comprehensive plan of care related to the individual's diabetic condition;	(A) the physician who is managing the individual's diabetic condition — (i) documents that the individual has diabetes; (ii) certifies that the individual is under a comprehensive plan of care related to the individual's diabetic condition; and (iii) documents agreement with the prescribing podiatrist or other qualified physician (as established by the Secretary) that it is medically necessary for the individual to have such extra-depth shoes with inserts or custom molded shoes with inserts;	(A) the physician who is managing the individual's diabetic condition — (i) documents that the individual has diabetes; ~~peripheral neuropathy with evidence of callus formation, a history of pre-ulcerative calluses, a history of previous ulceration, foot deformity, or previous amputation, or poor circulation~~, ~~and~~ (ii) certifies that the individual is ~~needs such shoes~~ under a comprehensive plan of care related to the individual's diabetic condition, and (iii) documents agreement with the prescribing podiatrist or other qualified physician (as established by the Secretary) that it is medically necessary for the individual to have such extra-depth shoes with inserts or custom molded shoes with inserts;
(B) the particular type of shoes are prescribed by a	(B) the therapeutic shoes are prescribed by a	(B) the ~~particular type of~~ therapeutic shoes are

Side by Side Comparison of Current Law vs. HELLPP Act (HR 1761 / S 1318)

Current Law	HR 1761 / S 1318	Codification
podiatrist or other qualified physician (as established by the Secretary); and	podiatrist or other qualified physician (as established by the Secretary) who—	prescribed by a podiatrist or other qualified physician (as established by the Secretary)~~; and~~ who—
	(i) examines the individual and determines the medical necessity for the individual to receive the therapeutic shoes; and	(i) examines the individual and determines the medical necessity for the individual to receive the therapeutic shoes; and
	(ii) communicates in writing the medical necessity to a certifying doctor of medicine or osteopathy for the individual to have therapeutic shoes along with findings that the individual has peripheral neuropathy with evidence of callus formation, a history of pre-ulcerative calluses, a history of previous ulceration, foot deformity, previous amputation, or poor circulation (or any combination thereof); and	(ii) communicates in writing the medical necessity to a certifying doctor of medicine or osteopathy for the individual to have therapeutic shoes along with findings that the individual has peripheral neuropathy with evidence of callus formation, a history of pre-ulcerative calluses, a history of previous ulceration, foot deformity, previous amputation, or poor circulation (or any combination thereof); and
(C) the shoes are fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist, as established by the Secretary) who is not the physician described in subparagraph (A) (unless the Secretary finds that the physician is the only such qualified individual in the area);	(C) the therapeutic shoes are fitted and furnished by a podiatrist or other qualified supplier individual (as established by the Secretary), such as a pedorthist or orthotist, who is not the physician described in subparagraph (A) (unless the Secretary finds that the physician is the only such qualified individual in the area);''.	(C) the therapeutic shoes are fitted and furnished by a podiatrist or other qualified supplier individual (as established by the Secretary), such as a pedorthist or orthotist, ~~as established by the Secretary)~~ who is not the physician described in subparagraph (A) (unless the Secretary finds that the physician is the only such qualified individual in the area);
	(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to items and services furnished on or after January 1, 2014.	