Medical Review

Therapeutic Shoes – Documentation Requirements

The National Government Services, Jurisdiction B Medical Review department recently conducted a widespread post pay probe for HCPCS codes A5500, A5501, A5512, and A5513. A widespread post pay probe is a selection of paid claims reviewed for medical necessity based on a particular service from multiple suppliers. The suppliers who had claims selected and reviewed for this probe have been sent final probe determination letters. The letter indicates the probe review findings and any overpayment(s) identified. The claims that were found to have been paid in error have been adjusted and a demand letter has been generated.

The following are the most common errors found during the recent medical review audit of therapeutic shoes and inserts and clarification of documentation requirements.

Medical records fail to document coverage criteria
The supplier must provide information from the patient's medical record (e.g., physician office notes, nursing home records, hospital records, etc.) from prior to the date of service on the claim which documents the need for therapeutic shoes. The documentation must clearly indicate that (1) the patient is being treated for diabetes mellitus and (2) the patient has one of the following qualifying conditions:

1. Previous amputation of the other foot, or part of either foot, or
2. History of previous foot ulceration of either foot, or
3. History of pre-ulcerative calluses of either foot, or
4. Peripheral neuropathy with evidence of callus formation of either foot, or
5. Foot deformity of either foot, or
6. Poor circulation in either foot; and

For criterion (d), suppliers should note that there must be documentation of both the peripheral neuropathy of the legs and a callus. For criterion (e), the specific type of deformity (e.g., bunion, hammer toes, etc.) must be documented. For criterion (f), there must be symptoms, signs, or a diagnosis of small or large vessel arterial insufficiency in the legs.

As stipulated in the national policy, **this documentation must be from the records of the M.D. or D.O. who is treating the patient's diabetes**. Documentation by other practitioners – e.g., a podiatrist, physician assistant, nurse practitioner, or clinical nurse specialist who is ordering physician – can be submitted but it is not sufficient to meet this national policy requirement.

A signed Statement of Certifying Physician form is not sufficient by itself to show that coverage criteria have been met.

Certification form is not obtained yearly
The national policy requires that the M.D. or D.O. who is managing the patient's diabetes must certify that:

- He/she is treating the patient's diabetes under a comprehensive plan of care, and
- The patient has one of the qualifying conditions listed above, and
- The patient needs diabetic shoes

The local coverage determination (LCD) specifies that this certification must be obtained on a yearly basis.

An example of a form that can be used for this certification is attached to the LCD. A similar document created by the supplier would be acceptable if it contains all of the required elements.

The certification statement must be signed and dated by the M.D. or D.O. who is treating the patient for diabetes. Signature and date stamps are not acceptable.

It is important to note that this certification statement is not a substitute for either documentation in the patient's medical record (as described above) or the detailed written order.

No valid detailed written order
For therapeutic shoes, the detailed written order must include:

- Beneficiary name
- Description of the items provided
- Narrative description (e.g., diabetic shoes, custom inserts, etc.) or the specific manufacturer and product name/number of the shoe/insert
- If a custom item is provided, the order must state "custom fabricated." If not, payment will be based on the allowance for a prefabricated shoe/insert.
- Specific listing of any separately billed shoe modification – e.g., rocker bottom, wedge, metatarsal bar, etc.

- Quantity dispensed
- Length of need
- Physician signature and signature date
- Start date of the order, if the signature date is after the date of delivery

The use of signature or date stamps is not acceptable

The beneficiary name, description of items provided, and quantity dispensed may be completed by the supplier, but must be reviewed, signed, and dated by the physician.

The ordering physician may be an M.D., D.O., podiatrist, physician assistant, nurse practitioner, or clinical nurse specialist.

If the ordering physician is the supplier, a separate order is not required, but the item provided must be clearly noted in the patient's record.

A new order is not required for the replacement of an insert or modification within one year of the order on file. However, the supplier's records should document the reason for the replacement. A new order is required for the replacement of any shoe. A new order is also required for the replacement of an insert or modification more than one year from the most recent order on file.

The Statement of Certifying Physician form that is attached to the LCD cannot serve as the detailed written order because it does not contain all of the required elements.

Supplier records fail to document necessity for custom fabricated shoes
According to the LCD, a custom molded shoe (A5501) is covered when the patient has a foot deformity that cannot be accommodated by a prefabricated depth shoe. The nature and severity of the deformity must be well documented in the physician's or supplier's records.

Information not provided to confirm correct coding of inserts
The following items must be listed in the DME Coding System (DMECS) Product Classification List on the Pricing, Data Analysis, and Coding (PDAC) contractor Web site:

1. All products billed with code A5512 (prefabricated insert)
2. Products that are billed with code A5513 (custom molded insert) that utilize a manufactured multi-density blank

Products that are custom fabricated by a practitioner (e.g., pedorthist, orthotist, prosthetist) from individual single density sheets of material for dispensing directly to their patients do not require PDAC Coding Verification Review. However, during an audit, the contractor may ask the supplier to describe their process for custom fabrication and the materials used.

If a product does not fall into one of the categories described above, it must be billed with code A5510 or A9270.

Information not provided to confirm correct coding of shoes
There is no requirement for products billed with code A5500 (prefabricated therapeutic shoe) or A5501 (custom fabricated therapeutic shoe) to be listed in the DMECS Product Classification List.

For prefabricated shoes (A5500), in an audit suppliers must provide the manufacturer and product name/number of the shoe . If the shoes are not on the DMECS Product Classification List, the supplier may be asked to provide a specification sheet from the manufacturer verifying that the coding guidelines in the Policy Article have been met.

For custom fabricated shoes (A5501) that are not on the DMECS Product Classification List, suppliers may be asked to provide information describing their process for custom fabrication and the materials that are used.

Medical necessity not documented for patients in nursing facilities
Patients in nursing facilities typically have very limited ambulation and often use footwear other than shoes. The medical record should clearly document the extent and frequency of the patient's ambulation and the medial necessity for therapeutic shoes.

No delivery slip
Suppliers are required to maintain proof of delivery documentation in their files. Refer to the Chapter 8 of the *DME MAC Supplier Manual* on the National Government Services Web site.

No documentation received
Failure to respond to a documentation request results in a denial of the claim.

It is important for suppliers to be familiar with the documentation requirements and correct coding. Suppliers can review the Therapeutic Shoes for Persons with Diabetes LCD on the National Government Services Web site at www.NGSMedicare.com Web site. Correct manufacturer and coding information may be found on the PDAC Web site at www.dmepdac.com  under the DME Coding System

(DMECS).

Please ensure when submitting additional documentation requests that all supporting medical necessity documentation is provided and respond in a timely manner. Suppliers have 30 days from the date on the additional documentation request letter to respond. If you received a denial due to the post pay probe you have the right to file a redetermination. You can find information regarding how to file a redetermination request in the *Jurisdiction B Supplier Manual*, Chapter 20.

A letter to physicians explaining their responsibilities for documentation of the coverage criteria for therapeutic shoes in their medical record and completion of the yearly certification form is being developed. A notice will be sent by list serve and posted to the www.NGSMedicare.com Web site when that is available.