Coverage Statement: Shoes and foot orthotics are covered when Medicare coverage criteria is met.

Guidelines/Notes:

1. Orthopedic Shoe

Orthopedic shoe is covered only if an integral part of a covered leg brace, including shoe inserts, heel/sole replacements, or shoe modification, when medically necessary for the proper functioning of the brace. Orthopedic shoes for subluxations of the foot are not covered.

See the Medicare Benefit Policy Manual, Chapter 15, §290 – Foot Care. (Accessed September 6, 2018)

Also see the DME MAC LCDs for Orthopedic Footwear (L33641). Compliance with these policies is required where applicable. (Accessed September 6, 2018)
2. **Prosthetic Shoe**

Prosthetic shoe (a device used when all or a substantial portion of the front of the foot) is **covered** when used as a structural device to replace all of a foot or when a large portion of the member’s forefoot (front part) is missing.

*See the NCD for Prosthetic Shoe (280.10). (Accessed September 6, 2018)*

*See the DME MAC LCDs for Orthopedic Footwear (L33641). Compliance with these policies is required where applicable. (Accessed September 6, 2018)*

3. **Therapeutic Shoe**

Therapeutic shoe, along with inserts are **covered** for diabetics when the following criteria are met:

a. The shoes must be prescribed, fitted and furnished by a podiatrist or other qualified individual (e.g., a pedorthist, orthotist or prosthetist)

b. The shoes must meet this policy’s definition for depth or custom-molded shoes

Custom-molded shoes are shoes that are constructed over a positive model of the member’s foot; made from leather or other suitable material of equal quality, have removable inserts that can be altered or replaced as the member’s condition warrants; and have some form of shoe closure.

Depth shoes are shoes that have a full-length heel-to-toe filler that, when removed, provides a minimum of 3/16 inch of additional depth used to accommodate custom molded or customized inserts, are made of leather or other suitable material of equal quality, have some form of foot closure, and are available in full and half sizes with a minimum of 3 widths so that the sole is graded to the size and width of the upper portions of the shoes according to the American standard last sizing schedule (the numerical shoe sizing system used for shoes sold in the United States or its equivalent).

c. The managing physician who is responsible for diagnosing and treating the member’s systemic condition, must do all the following:

1) Document in the medical record that the member has diabetes

2) Certify that the member is being treated under a comprehensive plan of care for his/her diabetes

3) Certify that the member needs therapeutic shoes

4) Document in the member’s record that the member has **one or more** of the following conditions:

   a) Peripheral neuropathy with the evidence of callus formation

   b) History of previous ulceration

   c) History or pre-ulcerative calluses

   d) Foot deformity

   e) Previous amputation of the foot or part of the foot

   f) Poor Circulation

**Limitations**

For each individual, coverage of the footwear and inserts is limited to one of the following within one calendar year:

a. No more than one (1) pair of custom-molded shoes (which includes inserts provided with
the shoes) and two (2) additional pairs of inserts
b. No more than one (1) pair of depth shoes and three (3) pairs of inserts (not including the non-customized removal inserts provided with such shoes)
c. Inserts
Inserts may be covered and dispensed independently of diabetic shoes if the supplier of the shoes verifies in writing that the patient has appropriate footwear into which the insert can be placed. This footwear must meet the definitions found above for depth shoes and custom-molded shoes.

Inserts are total contact, multiple density, removable inlays that are directly molded to the patient’s foot or a model of the patient’s foot or directly carved from a patient-specific, rectified electronic model and that are made of suitable material with regard to the patient’s condition.
d. Substitution of Modifications for Inserts
An individual may substitute modification(s) of custom-molded or depth shoes instead of obtaining a pair of inserts in any combination. Payment for the modification(s) may not exceed the limit set for the inserts for which the individual is entitled. Examples include but are not limited to: rigid rocker bottoms, roller bottoms (sole or bar), metatarsals bars, wedges (posting), offset heels, flared heels, Velcro closures, inserts for missing toes.

Notes:
• A pair of therapeutic shoes is covered even if only one foot suffers from diabetic foot disease (each shoe is equally equipped so that the affected limb, as well as the remaining limb, is protected).
• Therapeutic shoes for diabetics are not durable medical equipment (DME) and are not considered DME nor orthotics, but a separate category of coverage under Part B.
• In situations in which an individual qualifies for both diabetic shoes and a leg brace, these items are covered separately.

See the Medicare Benefit Policy Manual, Chapter 15, §140 - Therapeutic Shoes for Individuals with Diabetes. (Accessed September 6, 2018)

Local Coverage Determinations (LCDs) exist and compliance with these policies is required where applicable. See the DME MAC LCDs for Therapeutic Shoes for Persons with Diabetes (L33369). (Accessed September 6, 2018)
09/18/2018  Annual review with the following updates:

Guideline 2 (Prosthetic Shoe) – added from the definition of prosthetic shoe under the Definition section. “a device used when all or a substantial portion of the front of the foot”

Guideline 3 (Therapeutic Shoe)
- Added “along with inserts” based on the Medicare Benefit Policy Manual, Chapter 15, §140 - Therapeutic Shoes for Individuals with Diabetes
- Deleted “shoe inserts (also known as foot orthotics) and/or modifications to therapeutic shoes”; cannot find the Medicare reference source

Guideline 3.a & 3.b (Limitations) - added “No more than” to the following based on the Medicare Benefit Policy Manual, Chapter 15, §140 - Therapeutic Shoes for Individuals with Diabetes
- No more than one (1) pair of custom-molded shoes (which includes inserts provided with the shoes) and two (2) additional pairs of inserts
- No more than one (1) pair of depth shoes and three (3) pairs of inserts (not including the non-customized removal inserts provided with such shoes)

Guideline 3.c (Inserts)
- Deleted the following language; cannot find the Medicare reference source:
  Separate inserts independent of the therapeutic shoes are covered when the member meets the coverage criteria above and the prescribing provider verifies in writing that the member has the appropriate footwear into which the insert can be placed.

- Replaced with the following language from the Medicare Benefit Policy Manual, Chapter 15, §140 - Therapeutic Shoes for Individuals with Diabetes.
  Inserts may be covered and dispensed independently of diabetic shoes if the supplier of the shoes verifies in writing that the patient has appropriate footwear into which the insert can be placed. This footwear must meet the definitions found above for depth shoes and custom-molded shoes.

- Moved the following from the following definition and updated to include “or directly carved from a patient-specific, rectified electronic model”; based on definition from the Medicare Benefit Policy Manual, Chapter 15, §140 - Therapeutic Shoes for Individuals with Diabetes.
  Inserts are total contact, multiple density, removable inlays that are directly molded to the patient’s foot or a model of the patient’s foot or directly carved from a patient-specific, rectified electronic model and that are made of suitable material with regard to the patient’s condition.

Guideline 3.d (Substitution of Modifications for Inserts)
- Deleted the following language; cannot find the Medicare reference source:
  Modifications of custom-molded or depth shoes (e.g., wedges, offset heels or shoe lifts, Velcro closures, inserts for missing toes, etc.) instead of obtaining a
A pair of inserts in any combination are covered when the member meets the above coverage criteria.

- Replaced with the following language from the Medicare Benefit Policy Manual, Chapter 15, §140 - Therapeutic Shoes for Individuals with Diabetes.

An individual may substituted modification(s) of custom-molded or depth shoes instead of obtaining a pair of inserts in any combination. Payment for the modification(s) may not exceed the limit set for the inserts for which the individual is entitled. Examples include but are not limited to: rigid rocker bottoms, roller bottoms (sole or bar), metatarsals bars, wedges (posting), offset heels or shoe lifts, flared heels, Velcro closures, inserts for missing toes.

- Added the following notes from the Medicare Benefit Policy Manual, Chapter 15, §140 - Therapeutic Shoes for Individuals with Diabetes.

蓬勃发展的鞋子被糖尿病患者视为耐用医疗设备 (DME) 而且不能被认为是 DME 或矫形器，但是一个单独的覆盖类别在 Part B.

In situations in which an individual qualifies for both diabetic shoes and a leg brace, these items are covered separately.

Definitions

- Custom-Molded Shoes - moved definition to Guideline 3 (Therapeutic Shoe)
- Depth Shoes - moved definition to Guideline 3 (Therapeutic Shoe)
- Foot Orthotics – deleted definition; can’t find a Medicare reference source
- Inserts - moved definition to Guideline 3 (Therapeutic Shoe)
- Orthopedic Shoe – deleted definition; can’t find a Medicare reference source
- Peripheral Neuropathy - deleted definition; can’t find a Medicare reference source
- Prosthetic Shoe - moved to Guideline 2 (Prosthetic Shoe)
- Therapeutic Shoe – deleted definition; not needed; already included in the guideline section

09/19/2017 Annual review with the following updates:

Guideline 3.c.4.f (Poor circulation) – removed “vascular insufficiency” from guideline (updated language to be consistent with the referenced Medicare Benefit Policy Manual).

Guideline 3 (Limitations) - updated language to be consistent with the referenced Medicare Benefit Policy Manual.

09/20/2016 Annual review; no updates.

10/20/2015 Annual review; no updates.

10/21/2014 Annual review with following updates:

- Guideline #2 (Prosthetic Shoe) – Removed reference link to the retired LCDs for Prosthetic Shoe.

- Updated the definitions of (added reference link to the Medicare Benefit Coverage Manual (Pub. 100-2), Chapter 15, Section 140 Therapeutic Shoes for Individuals with Diabetes):
  - Custom-Molded Shoes
  - Depth Shoes
• Foot Orthotics
• Inserts
• Orthopedic Shoe
• Peripheral Neuropathy
• Therapeutic Shoe

- Updated the definition of “Prosthetic Shoe”; also added reference link to the NCD for Prosthetic Shoe (280.10)

10/24/2013 Annual review; no updates.
10/31/2012 Annual review; no updates.
10/13/2011 Annual review; no updates.