#### **SHP Diabetic Shoes**

AUTH: SHP Durable Medical Equipment 20 v3 (AC)

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# Coverage

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- · Coverage limitations for footwear and inserts for individuals with diabetes or vascular disease are limited to one of the following in a calendar year:
  - · One pair of custom molded shoes (including inserts provided with shoes) and two additional pairs of inserts
  - · One pair of extra-depth shoes (not including inserts provided with shoes) and three pairs of inserts
  - A member may substitute modification of the custom molded or extra-depth shoes instead of obtaining 1 pair of inserts. The most common modifications are: rigid rocker bottoms, roller bottoms, metatarsal bars, wedges, offset heels, or foot pressure off loading/supportive device
- Coverage limitations for diabetic foot care for Optima Virginia Medicaid Plans: Routine foot care visits, one pair of therapeutic shoes, or two shoe inserts per year (up to \$150 annually). Must use the approved network.
- · See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.

# **Application to Products**

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Policy is applicable to all products.

#### Authorization Requirements

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Pre-certification by the Plan is required.

### **Description of Item or Service**

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- Diabetic shoes aid in the prevention of foot ulcers by minimizing pressure points on the foot.
- For Medicare Plans, the Certifying Physician is defined as a doctor of medicine (M.D.) or a doctor of osteopathy (D.O.) who is responsible for diagnosing and treating the beneficiary's diabetic systemic condition through a comprehensive plan of care. The certifying physician may not be a podiatrist or clinical nurse specialist. Consequent to the M.D. or D.O. restriction, a nurse practitioner (NP) and a physician assistant (PA) may not serve in the role of the certifying physician, unless practicing "incident to" the supervising physician's authority, as described below.
- NPs or PAs providing ancillary services as auxiliary personnel could meet the "incident to" requirements in their provision of therapeutic shoes to beneficiaries with diabetes if all of
  the following criteria are met:
  - The supervising physician has documented in the medical record that the patient is diabetic and has been, and continues to provide, the patient follow-up under a comprehensive management program of that condition
  - The NP or PA certifies that the provision of the therapeutic shoes is part of the comprehensive treatment plan being provided to the patient
  - The supervising physician must review and verify (sign and date) all of the NP or PA notes in the medical record pertaining to the provision of the therapeutic shoes, acknowledging their agreement with the actions of the NP or PA
- In states where the NP may practice independently, the NP's employment situation would require compliance with Medicare "incident to" rules in order to serve as the certifying
  physician. Please refer to the applicable A/B MAC for further information.
- The Prescribing Practitioner is the person who actually writes the order for the therapeutic shoe, modifications and inserts. This practitioner must be knowledgeable in the fitting of diabetic shoes and inserts. The prescribing practitioner may be a podiatrist, M.D., D.O., physician assistant, nurse practitioner, or clinical nurse specialist. The prescribing practitioner may be the supplier (i.e., the one who furnishes the footwear).
- The Supplier is the person or entity that actually furnishes the shoe, modification, and/or insert to the beneficiary and that bills Medicare. The supplier may be a podiatrist, pedorthist, orthotist, prosthetist or other qualified individual. The Prescribing Practitioner may be the supplier. The Certifying Physician may only be the supplier if the certifying physician is practicing in a defined rural area or a defined health professional shortage area.

#### **Exceptions and Limitations**

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- There is insufficient scientific evidence to support the medical necessity of the following as they are not shown to improve health outcomes upon technology review:
  - Deluxe Diabetic shoes (A5508)
- There is insufficient scientific evidence to support the medical necessity of diabetic shoes for uses other than those listed in the clinical indications for procedure section.

## **Clinical Indications for Procedure**

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- Diabetic shoes may be indicated when **1 or more** of the following are present:
  - Individual has Optima Commercial Plan or Optima Virginia Medicaid Plan and ALL of the following
    - Individual has diabetes mellitus
    - Prevention of foot ulceration or amputation needed
    - Foot condition, as indicated by 1 or more of the following
      - Foot deformity (eg, hammer toe deformity, mallet toe deformity, Charcot arthropathy)
      - History of pre-ulcerative calluses

- Peripheral arterial disease
- Peripheral neuropathy with evidence of callus formation
- Previous amputation of foot or part of foot
- · Previous diabetic foot ulcer
- Therapeutic shoe type is 1 or more of the following
  - · Custom-molded shoes
  - Depth shoes
- Provider with appropriate expertise in individual's condition has evaluated individual and recommended therapeutic diabetic shoe
- No active plantar foot ulcer
- Individual has Optima Medicare Plan and request is for Therapeutic shoes, inserts and/or modifications to therapeutic shoes with ALL of the following
  - Individual has diabetes mellitus
  - The certifying physician has documented in the individual's medical record 1 or more of the following conditions
    - · Previous amputation of the other foot, or part of either foot
    - · History of previous foot ulceration of either foot
    - History of pre-ulcerative calluses of either foot
    - Peripheral neuropathy with evidence of callus formation of either foot
    - Foot deformity of either foot
    - Poor circulation in either foot
  - The certifying physician is treating the individual under a comprehensive plan of care for his/her diabetes and that the individual needs diabetic shoes. For claims with dates of service on or after 01/01/2011, the certifying physician must have ALL of the following
    - · Have an in-person visit with the individual during which diabetes management is addressed within 6 months prior to delivery of the shoes/inserts
    - · Sign the certification statement on or after the date of the in-person visit and within 3 months prior to delivery of the shoes/inserts
  - Prior to selecting the specific items that will be provided, the supplier must conduct and document an in-person evaluation of the individual
  - At the time of in-person delivery to the individual of the items selected, the supplier must conduct an objective assessment of the fit of the shoe and inserts and document the results. A beneficiary's subjective statements regarding fit as the sole documentation of the in-person delivery does not meet this criterion

# **Document History**

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- Revised Dates:
  - 2022: October
  - o 2020: June
  - o 2016: May
  - o 2015: May, October
  - o 2014: May
  - o 2013: May
  - 2012: September
  - o 2011: May
  - 2009: May
  - 2008: May
  - 2006: October
  - 2005: December
  - o 2002: October
  - · 2000: September
- · Reviewed Dates:
  - 2021: November
  - 2020: November 2019: October, November
  - o 2018: August
  - o 2017: November
  - o 2012: May
  - · 2010: May
  - o 2004: December
  - 2003: November
- · Effective Date: May 1993

#### Coding Information

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- · CPT/HCPCS codes covered if policy criteria is met:
  - · HCPCS A5500 For diabetics only, fitting (including follow-up), custom preparation and supply of off-the-shelf depth-inlay shoe manufactured to accommodate multidensity insert(s), per shoe
  - HCPCS A5501 For diabetics only, fitting (including follow-up), custom preparation and supply of shoe molded from cast(s) of patient's foot (custom molded shoe), per shoe
     HCPCS A5503 For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with roller or rigid rocker bottom, per shoe

  - HCPCS A5504 For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with wedge(s), per shoe
  - HCPCS A5505 For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with metatarsal bar, per shoe · HCPCS A5506 - For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with off-set heel(s), per shoe
  - HCPCS A5507 For diabetics only, not otherwise specified modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe, per shoe
  - HCPCS A5510 For diabetics only, direct formed, compression molded to patient's foot without external heat source, multiple-density insert(s) prefabricated, per shoe
  - . HCPCS A5512 For diabetics only, multiple density insert, direct formed, molded to foot after external heat source of 230 degrees Fahrenheit or higher, total contact with patient's foot, including arch, base layer minimum of 1/4 inch material of shore a 35 durometer or 3/16 inch material of shore a 40 durometer (or higher), prefabricated, each
  - HCPCS A5513 For diabetics only, multiple density insert, custom molded from model of patient's foot, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore a 35 durometer or higher), includes arch filler and other shaping material, custom fabricated, each
  - HCPCS A5514 For diabetics only, multiple density insert, made by direct carving with cam technology from a rectified cad model created from a digitized scan of the patient, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore a 35 durometer (or higher), includes arch filler and other shaping material, custom fabricated, each
- CPT/HCPCS codes considered not medically necessary per this Policy:
  - · HCPCS A5508 For diabetics only, deluxe feature of off-the-shelf depth-inlay shoe or custom molded shoe, per shoe

# References

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References used include but are not limited to the following:

Specialty Association Guidelines; Government Regulations; Winifred S. Haves, Inc. Uptodate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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LCD: Therapeutic Shoes for Persons with Diabetes (L33369). (2020, Jan 01). Retrieved Aug 02, 2022, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=Crisis+Stabilization&keywordType=starts&areald=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all

Product Classification. (2022, Aug 08). Retrieved Aug 08, 2022, from Food and Drug Administration: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm? start\_search=1&DeviceName=&ProductCode=&ThirdParty=&DeviceClass=1&SUBMISSION\_TYPE\_ID=4&GMPExempt=N&Panel=&RegulationNumber=890.3475&PAGENUM=10&SortColumn=DeviceNam

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### Codes

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HCPCS: A5500, A5501, A5503, A5504, A5505, A5506, A5507, A5508, A5510, A5512, A5513, A5514

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