
Orthotic Foot Devices and Therapeutic Shoes

MEDICAL POLICY NUMBER: 90

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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

Commercial

Medicaid/OHP*

Medicare**

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered “**not medically necessary**” for Medicare members.

COVERAGE CRITERIA

Orthopedic Footwear and Prosthetic Shoes

- I. Prosthetic shoes (L3250) may be considered **medically necessary** if they are an integral part of a prosthesis for a member with a partial foot amputation.
- II. Non-diabetic shoes (e.g., Oxford shoes [L3224, L3225], high top, depth inlay, or custom [L3649]) may be considered **medically necessary** if **all** of the following are met:
 - A. They are an integral part of a covered leg brace (L1900, L1920, L1980, L1990, L2000, L2005, L2010, L2020, L2030, L2050, L2060, L2080, or L2090), **and**
 - B. They are required for proper functioning of the leg brace, **and**
 - C. They are billed by the same supplier as the leg brace.
- III. Heel replacements (L3455, L3460), sole replacements (L3530, L3540), and shoe transfers (L3600-L3640) involving shoes on a covered brace may be considered **medically necessary**.
- IV. Inserts and other shoe modifications (L3000-L3170, L3300-L3450, L3465-L3520, L3550-L3595) may be considered **medically necessary** if they are on a shoe that is an integral part of a covered brace and when necessary for the proper functioning of the brace.
- V. Orthopedic footwear (including any components, accessories, and modifications) are considered **not medically necessary** when criteria I-IV are not met.
- VI. A matching shoe which is not attached to a brace and items related to that shoe are considered **not medically necessary**.

- VII. Shoes are considered **not medically necessary** when they are put on over a partial foot prosthesis or other lower extremity prosthesis (L5010-L5600) which is attached to the residual limb by other mechanisms.
- VIII. A foot pressure off-loading/supportive device (A9283) is considered **not medically necessary**.

Therapeutic Shoes for Persons with Diabetes

- IX. One pair of depth shoes (A5500) and up to three pairs of inserts (A5512-A5514) per calendar year may be considered **medically necessary** if **all** of the following criteria (A-E) are met:
 - A. The member has diabetes mellitus; **and**
 - B. The certifying physician has documented in the patient's medical record one or more of the following conditions within 6 months prior to delivery of the shoes/inserts and prior to or on the same day as signing the certification statement:
 - 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**
 - C. The certifying physician has certified that indications XI.A-B are met and that they are treating the member under a comprehensive plan of care for their diabetes and that the member needs diabetic shoes. The certifying physician must complete the following (1-2):
 - 1. Have an in-person visit with the member during which diabetes management is addressed within 6 months prior to delivery of the shoes/inserts; **and**
 - 2. Sign the certification statement on or after the date of the in-person visit and within 3 months prior to delivery of the shoe/inserts; **and**
 - D. Prior to selecting the specific items that will be provided, the supplier must conduct and document an in-person evaluation of the patient.
 - E. At the time of delivery of the items selected, the supplier must conduct an objective assessment of the fit of the shoe and inserts and document the results. A member's subjective statements regarding fit as the sole documentation of the in-person delivery does not meet this criterion.
- XII. Separate inserts may be considered **medically necessary** independently of diabetic shoes if the supplier of the shoes verifies in writing that the member has appropriate footwear into which the insert can be placed. This footwear must meet the definitions for depth shoes or custom-molded shoes (see the LCA A52501 for definitions).
- XIII. Inserts and/or modifications to therapeutic shoes may be considered **medically necessary** when all criteria for the therapeutic shoes (custom or depth) are met.

XIV. One pair of custom molded shoes (A5501) and up to two extra pairs of inserts (A5512-A5514) per calendar year may be considered **medically necessary** when clinical documentation supports **both** of the following:

- A. All of criteria IX are met, **and**
- B. The member has a foot deformity of a nature and severity that cannot be accommodated by a depth shoe.

XV. A custom molded shoe is considered **not medically necessary** if any of criteria IX. are not met or if documentation does not support the medical need for customization.

Limitations and Non-coverage Criteria

XVI. Therapeutic shoes, inserts and/or modifications will be considered **not medically necessary** if criterion IX is not met, including but not limited to quantities of shoes and inserts which exceed medically necessary limits.

XVII. A modification of a custom molded or depth shoe may be considered **medically necessary** as a substitute for an insert. Examples of common shoe modifications include, but are not limited to, the following:

- A. Rigid rocker bottoms (A5503),
- B. Roller bottoms (A5503),
- C. Wedges (A5504),
- D. Metatarsal bars (A5505),
- E. Offset heels (A5506),
- F. Flared heels.

XVIII. Inserts with compression molding to the patient's foot over time through the heat and pressure generated by wearing a shoe with the insert present (A5510) are considered **not medically necessary**.

XIX. Inserts and/or modifications used in non-covered shoes are considered **not medically necessary**.

XX. Deluxe features of diabetic shoes (A5508; e.g., style, color, type of leather, etc.) are considered **not medically necessary** because they do not contribute to the therapeutic function of the shoe.

XXI. Separate charges for any of the following are **not separately reimbursable**:

- A. Fitting of the shoes, inserts or modifications, **or**
- B. The certification of need or prescription of the footwear.

Link to [Evidence Summary](#)

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

This policy may be primarily based on the following Center for Medicare and Medicaid Services (CMS) guidances:

- Local Coverage Determination (LCD) L33641: Orthopedic Footwear¹
- Local Coverage Determination (LCD) L33369: Therapeutic Shoes for Persons with Diabetes²
- Local Coverage Article (LCA) A52481: Orthopedic Footwear³
- Local Coverage Article (LCA) A52501: Therapeutic Shoes for Persons with Diabetes⁴

Definitions

Depth Shoe: A depth shoe (A5500) is one that:

1. Has a full length, heel-to-toe filler that when removed provides a minimum of 3/16" of additional depth used to accommodate custom-molded or customized inserts; and
2. Is made from leather or other suitable material of equal quality; and
3. Has some form of shoe closure; and
4. Is available in full and half sized with a minimum of three widths so that the sole is graded to the upper portions of the shoe according to the American standard last sizing schedule of its equivalent.

The shoe may or may not have an internally seamless toe.

Custom-molded shoe: A custom-molded shoe (A5501) is one that:

1. Is constructed over a positive model of the patient's foot; and
2. Is made from leather or other suitable material of equal quality; and
3. Has removable inserts that can be altered or replaced as the patient's condition warrants; and
4. Has some form of shoe closure.

This shoe may or may not have an internally seamless toe.

Rigid rocker bottoms (A5503) are exterior elevations with apex position for 51 percent to 75 percent distance measured from the back end of the heel. The apex is a narrowed or pointed end of an anatomical structure. The apex must be positioned behind the metatarsal heads and tapering off sharply to the front tip of the sole. Apex height helps to eliminate pressure at the metatarsal heads. Rigidity is ensured by the steel in the shoe. The heel of the shoe tapers off in the back in order to cause the heel to strike in the middle of the heel.

Roller bottoms (sole or bar) (A5503) are the same as rocker bottoms, but the heel is tapered from the apex to the front tip of the sole.

Wedges (posting) (A5504) are either of hind foot, fore foot, or both and may be in the middle or to the side. The function is to shift or transfer weight bearing upon standing or during ambulation to the opposite side for added support, stabilization, equalized weight distribution, or balance.

Metatarsal bars (A5505) are exterior bars which are placed behind the metatarsal heads in order to remove pressure from the metatarsal heads. The bars are of various shapes, heights, and construction depending on the exact purpose.

Offset heel (A5506) is a heel flanged at its base either in the middle, to the side, or a combination, that is then extended upward to the shoe in order to stabilize extreme positions of the hind foot.

BACKGROUND

Orthotic foot devices are orthopedic appliances used to support, align, prevent, and correct deformities or to improve function of the foot. Examples of orthotic foot devices may include:

- Therapeutic shoes
- Insoles
- Arch supports
- Wedges and lifts

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, physician assistant, nurse practitioner, or clinical nurse specialist.

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.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

BILLING GUIDELINES AND CODING

Orthopedic Footwear and Prosthetic Shoes

- Depth-inlay or custom molded shoes **for diabetics** (A5500-A5501) and related inserts and modifications (A5503-A5511) are billed using these A codes regardless of whether or not the shoe is an integral part of a brace. Shoes and other footwear for **non-diabetics** use different HCPCS codes and are subject to different coverage requirements.
- Code L3250 may be used only for a shoe that is custom fabricated from a model of a patient and has a removable custom fabricated insert designed for toe or distal partial foot amputation. The shoe serves to hold the insert on the leg. Code L3250 must not be used for a shoe that is put on other types of leg prostheses (L5010-L5600) that are attached to the residual limb by other mechanisms.
- Please see LCA: Orthopedic Footwear - Policy Article (A52481) for additional coding guidelines.

Therapeutic Shoes for Persons with Diabetes

- Deluxe features must be coded using A5508.
- Code A5507 is only to be used for not otherwise specified therapeutic modifications to the shoe or for repairs to a diabetic shoe(s).
- Codes for inserts or modifications (A5503-A5508, A5510, A5512 and A5513) may only be used for items related to **diabetic** shoes (A5500, A5501). These codes must not be used for items related to footwear coded with codes L3215-L3253. Inserts and modifications used with L coded footwear must be coded using L codes (L3000-L3649).
- Inserts for missing toes or partial foot amputation should be coded L5000 (*Partial foot, shoe insert with longitudinal arch, toe filler*) or L5999 (*Lower extremity prosthesis, not otherwise specified*), whichever is applicable.

Please see Local Coverage Article: A52501: Therapeutic Shoes for Persons with Diabetes for additional coding guidelines.⁴

| CODES* | | |
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| HCPCS | A5508 | For diabetics only, deluxe feature of off-the-shelf depth-inlay shoe or custom molded shoe, per shoe |
| | A5510 | For diabetics only, direct formed, compression molded to patient's foot without external heat source, multiple-density insert(s) prefabricated, per shoe |
| | A9283 | Foot pressure off loading/supportive device, any type, each |
| Orthopedic Footwear | | |
| | L3000 | Foot, insert, removable, molded to patient model, UCB type, Berkeley shell each |
| | L3001 | Foot, insert, removable, molded to patient model, Spenco, each |
| | L3002 | Foot, insert, removable, molded to patient model, Plastazote or equal, each |
| | L3003 | Foot, insert, removable, molded to patient model, silicone gel, each |
| | L3010 | Foot, insert, removable, molded to patient model, longitudinal arch support, each |
| | L3020 | Foot, insert, removable, molded to patient model, longitudinal/metatarsal support, each |
| | L3030 | Foot, insert, removable, formed to patient foot, each |
| | L3031 | Foot, insert/plate, removable, addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite each |
| | L3040 | Foot, arch support, removable, premolded, longitudinal |
| | L3050 | Foot, arch support, removable, premolded, metatarsal, each |
| | L3060 | Foot, arch support, removable, premolded, longitudinal/metatarsal, |
| | L3070 | Foot, arch support, non-removable attached to shoe, longitudinal, each, |
| | L3080 | Foot, arch support, non-removable attached to shoe, metatarsal, each |
| | L3090 | Foot, arch support, non-removable attached to shoe, Longitudinal/ metatarsal, each |
| | L3100 | Hallus-Valgus night dynamic splint, prefabricated, off-the-shelf |
| | L3140 | Foot, abduction rotation bar, including shoes |
| | L3150 | Foot, abduction rotation bar, without shoes |
| | L3160 | Foot, adjustable shoe-styled positioning devices |
| | L3170 | Foot, plastic, silicone or equal, heel stabilizer, prefabricated, off-the-shelf, |
| | L3201 | Orthopedic shoe, Oxford with supinator or pronator, infant |
| | L3202 | Orthopedic shoe, Oxford with supinator or pronator, child |
| | L3203 | Orthopedic shoe, Oxford with supinator or pronator, junior |
| | L3204 | Orthopedic shoe, hightop with supinator or pronator, infant |
| | L3206 | Orthopedic shoe, hightop with supinator or pronator, child |
| | L3207 | Orthopedic shoe, hightop with supinator or pronator, junior |
| | L3208 | Surgical boot, each, infant |
| | L3209 | Surgical boot, each, child |
| | L3211 | Surgical boot, each, junior |
| | L3212 | Benesch boot, pair, infant |
| | L3213 | Benesch boot, pair, child |
| | L3214 | Benesch boot, pair, junior |
| | L3215 | Orthopedic footwear, ladies shoe, Oxford, each |
| | L3216 | Orthopedic footwear, ladies shoe, depth inlay, each |
| | L3217 | Orthopedic footwear, ladies shoe, hightop, depth inlay, each |
| | L3219 | Orthopedic footwear, men's shoe, Oxford, each |

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| L3221 | Orthopedic footwear, men's shoe, depth inlay, each |
| L3222 | Orthopedic footwear, men's shoe, hightop, depth inlay, each |
| L3224 | Orthopedic footwear, woman's shoe, Oxford, used as an integral part of a brace (orthosis) |
| L3225 | Orthopedic footwear, man's shoe, Oxford, used as an integral part of a brace (orthosis) |
| L3230 | Orthopedic footwear, custom shoe, depth inlay, each |
| L3250 | Orthopedic footwear, custom molded shoe, removable inner mold, prosthetic shoe, each |
| L3251 | Foot, shoe molded to patient model, silicone shoe, each |
| L3252 | Foot, shoe molded to patient model, Plastazote (or similar), custom fabricated, each |
| L3253 | Foot, molded shoe Plastazote (or similar) custom fitted, each |
| L3254 | Non-standard size or width |
| L3255 | Non-standard size or length |
| L3257 | Orthopedic footwear, additional charge for split size |
| L3260 | Surgical boot/shoe, each |
| L3265 | Plastazote sandal, each |
| L3300 | Lift, elevation heel, tapered to metatarsals, per inch |
| L3310 | Lift, elevation, heel and sole, neoprene, per inch |
| L3320 | Lift, elevation, heel and sole, cork, per inch |
| L3330 | Lift, elevation, metal extension (skate) |
| L3332 | Lift, elevation, inside shoe, tapered, up to one-half inch |
| L3334 | Lift, elevation, heel, per inch |
| L3340 | Heel wedge, SACH |
| L3350 | Heel wedge |
| L3360 | Sole wedge, outside sole |
| L3370 | Sole wedge, between sole |
| L3380 | Clubfoot wedge |
| L3390 | Outflare wedge |
| L3400 | Metatarsal bar wedge, rocker |
| L3410 | Metatarsal bar wedge, between sole |
| L3420 | Full sole and heel wedge, between sole |
| L3430 | Heel, counter, plastic reinforced |
| L3440 | Heel, counter, leather reinforced |
| L3450 | Heel, SACH cushion type |
| L3455 | Heel, new leather, standard |
| L3460 | Heel, new rubber, standard |
| L3465 | Heel, Thomas with wedge |
| L3470 | Heel, Thomas extended to ball |
| L3480 | Heel, pad and depression for spur |
| L3485 | Heel, pad, removable for spur |
| L3500 | Orthopedic shoe addition, insole, leather |
| L3510 | Orthopedic shoe addition, insole, rubber |
| L3520 | Orthopedic shoe addition, insole, felt covered with leather |
| L3530 | Orthopedic shoe addition, sole, half |
| L3540 | Orthopedic shoe addition, sole, full |

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| | L3550 | Orthopedic shoe addition, toe tap, standard |
| | L3560 | Orthopedic shoe addition, toe tap, horseshoe |
| | L3570 | Orthopedic shoe addition, special extension to instep (leather with eyelets) |
| | L3580 | Orthopedic shoe addition, convert instep to Velcro closure |
| | L3590 | Orthopedic shoe addition, convert firm shoe counter to soft counter |
| | L3595 | Orthopedic shoe addition, march bar |
| | L3600 | Transfer of an orthosis from one shoe to another, caliper plate, existing |
| | L3610 | Transfer of an orthosis from one shoe to another, caliper plate, new |
| | L3620 | Transfer of an orthosis from one shoe to another, solid stirrup existing |
| | L3630 | Transfer of an orthosis from one shoe to another, solid stirrup, new |
| | L3640 | Transfer of an orthosis from one shoe to another, Dennis Browne, splint (Riveton), both shoes |
| | L3649 | Orthopedic shoe, modification, addition or transfer, not otherwise specified |
| Therapeutic Shoes | | |
| | 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 |
| | A5501 | For diabetics only, fitting (including follow-up), custom preparation and supply of shoe molded from cast(s) of patients foot (custom molded shoe), per shoe |
| | 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 |
| | A5504 | For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with wedge(s), per shoe |
| | A5505 | For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with metatarsal bar, per shoe |
| | 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 |
| | A5507 | For diabetics only, not otherwise specified modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe, per shoe |
| | 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 ¼ inch material of shore a 35 durometer or 3/16 inch material of shore a 40 durometer (or higher), prefabricated, each |
| | 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 of material of shore a 35 durometer or higher, includes arch filler and other shaping material, custom fabricated, each |
| | 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 |

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for

medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.

- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Centers for Medicare & Medicare Services. Local Coverage Determination (LCD): Orthopedic Footwear (L33641). <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33641>. Accessed 2/26/2023.
2. Centers for Medicare & Medicare Services. Local Coverage Determination (LCD): Therapeutic Shoes for Persons with Diabetes (L33369). <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33369>. Accessed 2/26/2023.
3. Centers for Medicare & Medicare Services. Local Coverage Article: Orthopedic Footwear - Policy Article (A52481). <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52481>. Accessed 2/26/2023.
4. Centers for Medicare & Medicare Services. Local Coverage Article: Therapeutic Shoes for Persons with Diabetes - Policy Article (A52501). <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52501>. Accessed 2/26/2023.

POLICY REVISION HISTORY

| DATE | REVISION SUMMARY |
|--------|--|
| 2/2023 | Converted to new policy template. |
| 4/2023 | Annual Update, no changes to criteria. |