# **Medicare Medical Policy**

## **Orthotic Foot Devices and Therapeutic Shoes**

#### MEDICARE MEDICAL POLICY NUMBER: 298

Effective Date: 5/1/2025	MEDICARE COVERAGE CRITERIA	2
Last Review Date: 4/2025	POLICY CROSS REFERENCES	
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**INSTRUCTIONS FOR USE:** Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

**SCOPE:** Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

Kedicare Only

## **MEDICARE COVERAGE CRITERIA**

**IMPORTANT NOTE:** More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

**Note:** This policy does not address ankle-foot orthoses commonly referred to as a walking boot, which are used to provide immobilization as treatment for an orthopedic condition or following orthopedic surgery (L4360, L4361, L4386, L4387 and L4631). For these devices, see the separate Medicare medical policy for *Ankle-Foot and Knee-Ankle-Foot Orthotics* (see policy cross references below).

Service		Medicare Guidelines	HCPCS Code(s)
Non-Covered Shoes and Footwear	•	HCPCS codes L3215, L3216, L3217, L3219, L3221, L3222: Local Coverage Article (LCA): Orthopedic Footwear - Policy Article (A52481) (Medicare coverage requires shoes be an integral part of a covered leg brace. Shoes which are <b>not</b> part of a leg brace must be billed with codes L3215, L3216, L3217, L3219, L3221, or L3222, making these codes non-covered by nature of not meeting Medicare's basic coverage requirement).	A5508, A5510, A9283, L3215, L3216, L3217, L3219, L3221, L3222
	•	HCPCS code A9283: Local Coverage Article (LCA): Orthopedic Footwear - Policy Article (A52481) and LCA: Ankle-Foot/Knee-Ankle- Foot Orthoses – Policy Article (A52457) HCPCS codes A5508, A5510: LCA:	
		Therapeutic Shoes for Persons with Diabetes – Policy Article (A52501)	
Prosthetic Shoe	•	National Coverage Determination (NCD): Prosthetic Shoe ( <u>280.10</u> )	L3250
	•	Local Coverage Determination (LCD): Orthopedic Footwear ( <u>L33641</u> ) (See also the associated LCA <u>A52481</u> for relevant ICD-10 codes; however, presence of an ICD-10 alone is not sufficient to guarantee coverage.)	

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Orthopedic Footwear	LCA: Orthopedic Footwear - Policy Article	L3000, L3001, L3002,
	( <u>A52481</u> )	L3003, L3010, L3020,
		L3030, L3031, L3040,
	IMPORTANT NOTES:	L3050, L3060, L3070,
	1. While there is an LCD for orthopedic	L3080, L3090, L3100,
	footwear, statutory coverage criteria for	L3140, L3150, L3160,
	these items are found in the related Policy	L3170, L3201, L3202,
	Article (LCA). Thus, the LCA is the primary	L3203, L3204, L3206,
	Medicare Guidance source for these items.	L3207, L3208, L3209,
	2. Orthopedic footwear in this category can	L3211, L3212, L3213,
	only be considered for coverage when	L3214, L3224, L3225,
	provided as an integral part of a covered leg	L3230, L3251, L3252,
	brace described by codes L1900, L1920,	L3253, L3254, L3255,
	L1980, L1990, L2000, L2005, L2010, L2020,	L3257, L3260, L3265,
	L2030, L2050, L2060, L2080, or L2090 <u>AND</u>	L3300, L3310, L3320,
	the footwear must also be medically	L3330, L3332, L3334,
	necessary for the proper functioning of the	L3340, L3350, L3360,
	leg brace. <sup>1</sup> Both the leg brace and the	L3370, L3380, L3390,
	footwear must be billed by the same	L3400, L3410, L3420,
	supplier.	L3430, L3440, L3450,
	1. Products which cannot be used as an integral	L3455, L3460, L3465,
	part to a leg brace are not covered benefits	L3470, L3480, L3485,
	under Medicare (see non-covered row	L3500, L3510, L3520,
	above).	L3530, L3540, L3550,
		L3560, L3570, L3580,
		L3590, L3595, L3600,
		L3610 ,L3620, L3630,
		L3640, and L3649
Therapeutic Shoes for	For HCPCS code A5501:	A5500, A5501, A5503,
Persons with Diabetes	• LCD: Therapeutic Shoes for Persons with	A5504, A5505, A5506,
	Diabetes ( <u>L33369</u> )	A5507, A5512, A5513,
		A5514,
	For all others, as well as frequency limitations	
	for all codes, including A5501:	
	• LCA: Therapeutic Shoes for Persons with	
	Diabetes – Policy Article (A52501)	
	<b>NOTE:</b> While there is an LCD for therapeutic	
	shoes for individuals with diabetes, statutory	
	coverage criteria for most of these items are	
	found in the related Policy Article (LCA). Thus,	
	the LCA is the primary Medicare Guidance source	
	for these items.	
IMPORTANT NOTICE: While so	ne services or items may appear medically indicated for an ind	lividual they may also be a
	the member's benefit plan. Such excluded services or items by	
	d to services or procedures considered to be cosmetic not m	

EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those

considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. (*Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021*)

## **POLICY CROSS REFERENCES**

Ankle-Foot and Knee-Ankle-Foot Orthotics, MP294

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

## **POLICY GUIDELINES**

#### **DOCUMENTATION REQUIREMENTS**

If needed for therapeutic shoes, the Noridian Durable Medical Equipment Medicare Administrative Contractor (DMEMAC) <u>Documentation Checklist For Therapeutic Shoes</u> can be used to determine if all applicable documentation to support medical necessity are available, in support of the relevant local coverage determination (LCD) and local coverage article (LCA) found below.

#### MEDICARE COVERAGE FOR SHOES/FOOTWEAR

Orthopedic shoes and other supportive devices for the feet generally are not covered benefits under Medicare.<sup>2</sup> However, Medicare has limited coverage provisions for shoes, inserts, or necessary shoe modifications. Specifically, in order to be eligible for coverage, the items must fall into one of the following benefit categories:<sup>1</sup>

- 1. The benefit category for therapeutic shoes used in the treatment of a diabetes-related condition(s) or
- 2. The benefit category for shoes and related items considered to be integral components of a covered leg brace.

There are no other categories of orthopedic footwear that are eligible for Medicare reimbursement, including shoes or footwear used for flat feet, subluxations of the foot, and routine foot care, as noted in SSA §1862(a)(13).<sup>1</sup>

#### MEMBERS WHO QUALIFY FOR BOTH DIABETIC SHOES AND A LEG BRACE

There may be situations where a single individual may qualify for **both** a diabetic shoe **and** a leg brace. In this unique situation, the items may be covered separately. This means the supplier of the shoes provided for the treatment of a diabetes-related condition may bill separately for such shoes, while a different supplier may bill for the associated brace.<sup>2</sup>

## **REGULATORY STATUS**

#### U.S. FOOD & DRUG ADMINISTRATION (FDA)

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While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

### BILLING GUIDELINES AND CODING

#### MULTIPLE DENSITY INSERTS FOR DIABETICS (HCPCS CODES A5512-A5514)

The only products that may be billed using HCPCS codes A5512 and A5514 are those specified in the Product Classification List (PCL) on the Pricing, Data Analysis, and Coding (PDAC) contractor <u>Product</u> <u>Classification List web site</u>. Items represented by HCPCS code A5513 may also require PDAC classification in some situations as well. (*LCA A52501*)

#### HCPCS CODING

Different sets of HCPCS codes are used to identify the types of shoes, modifications, or inserts that may be eligible for payment and the code set used is based on which benefit category the item or service falls under that qualify them for coverage. In other words:<sup>1</sup>

- HCPCS A-codes are used for shoes and related items used in the treatment of diabetes-related condition(s).
- L-codes are used for orthopedic footwear for non-diabetics.

Associated local coverage articles (LCAs) provide detailed information regarding billing and coding guidelines for these devices, as well as utilization and frequency limitations and requirements that much be met in order for a device to be reported with a specific HCPCS code:

- LCA: Orthopedic Footwear Policy Article (A52481)
- LCA: Therapeutic Shoes for Persons with Diabetes Policy Article (A52501)

For orthopedic footwear used with a leg brace, both the leg brace and the footwear must be billed by the same supplier.

HCPCS code L9900 is never allowed separate reimbursement because Medicare considers this code to be a bundled item or service, no matter what it is used to represent, and even if billed alone. While several LCAs and LCDs specifically call out this code as non-covered when used for specific types of devices, not all possible scenarios where this code may be used are addressed in LCDs or LCAs; however, the Noridian webpage for *Two New Codes Established for Miscellaneous Supplies* provides general non-coverage information, for any use not found in an LCD or LCA.

CODES*		
СРТ	None	
Prosthetic Shoes		

HCPCS	L3250	Orthopedic footwear, custom molded shoe, removable inner mold, prosthetic
neres	L3230	shoe, each
		Orthopedic Footwear (Shoes)
	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
	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
	L3251	Foot, shoe molded to patient model, silicone shoe, each
	L3254	Non-standard size or width
	L3255	Non-standard size or length
	L3257	Orthopedic footwear, additional charge for split size
	L3649	Orthopedic shoe, modification, addition or transfer, not otherwise specified
	23013	Therapeutic Shoes for Diabetics
	A5500	For diabetics only, fitting (including follow-up), custom preparation and supply of
	//3500	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
	//0001	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
	//3505	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
	A3304	or custom molded shoe with wedge(s), per shoe
	A5505	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe
	A3303	
	A5506	or custom molded shoe with metatarsal bar, per shoe
	AJJUD	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe
	AEE07	or custom molded shoe with off-set heel(s), per shoe
	A5507	For diabetics only, not otherwise specified modification (including fitting) of off-
	45500	the-shelf depth-inlay shoe or custom molded shoe, per shoe
	A5508	For diabetics only, deluxe feature of off-the-shelf depth-inlay shoe or custom
		molded shoe, per shoe

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A5510	For diabetics only, direct formed, compression molded to patient's foot without external heat source, multiple-density insert(s) prefabricated, 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
	Replacement Components, Shoe Inserts, and Shoe Modifications
 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
L3020	support, each
L3030	Foot, insert, removable, formed to patient foot, each
L3031	Foot, insert/plate, removable, addition to lower extremity orthosis, high strength,
13031	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 device
L3161	Foot, adductus positioning device, adjustable
L3170	Foot, plastic, silicone or equal, heel stabilizer, prefabricated, off-the-shelf,
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	Hell 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
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
	Shoe Transfers
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
	Miscellaneous
A9270	Non-covered item or service
 A9283	Foot pressure off loading/supportive device, any type, each
L3252	Foot, shoe molded to patient model, Plastazote (or similar), custom fabricated,
 	each
 L3253	Foot, molded shoe Plastazote (or similar) custom fitted, each
 L3260	Surgical boot/shoe, each
 L3265	Plastazote sandal, each
L9900	Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS "L" code

#### \*Coding Notes:

• The code list above 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. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT

or HCPCS code or the provision of a payment or fee amount by Medicare does <u>not</u> make a procedure medically reasonable or necessary or a covered benefit by Medicare. (*Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services*)

- 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 <u>Medical Policy, Reimbursement Policy, Pharmacy</u> <u>Policy and Provider Information website</u> 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

- Palmetto GBA PDAC web page for Medicare Coverage for Shoes Correct Coding Revised; Last Updated: 11/02/2021; Available at: <u>https://dmepdac.com/palmetto/PDACv2.nsf/DIDC/924YGYXQV~Articles%20and%20Publications</u> <u>~Advisory%20Articles</u>
- Medicare Benefit Policy Manual, Chapter 15 Covered Medical and Other Health Services, §140

   Therapeutic Shoes for Individuals with Diabetes, B. Coverage, 2. Coverage of Diabetic Shoes and Brace; Last Updated: 04/02/2018; Available at: <a href="https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf">https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/bp102c15.pdf</a>
- Medicare Benefit Policy Manual, Chapter 15 Covered Medical and Other Health Services, §290

   Foot Care, B. Exclusions from Coverage, 3. Supportive Devices for Feet; Last Updated: 10/01/2003; Available at: <u>https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf</u>

## **POLICY REVISION HISTORY**

## DATE REVISION SUMMARY

8/2022	Annual review, no changes (converted to new format 2/2023)
4/2023	Annual review, no changes to criteria, added L9900 to the policy
1/2024	Q1 2024 code updates
5/2024	Annual review, no changes
5/2025	Annual review, no changes