

MedStar Health, Inc. POLICY AND PROCEDURE MANUAL

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SUBJECT: Lower Limb Orthotics and Shoes
INDEX TITLE: Medical Management
ORIGINAL DATE: September 2014

This policy applies to the following lines of business: (Check those that apply.)

COMMERCIAL	<input type="checkbox"/> HMO	<input type="checkbox"/> PPO	<input type="checkbox"/> Fully Insured	<input type="checkbox"/> Individual Product	<input type="checkbox"/> Marketplace (Exchange)	<input checked="" type="checkbox"/> All
GOVERNMENT PROGRAMS	<input type="checkbox"/> MA HMO	<input type="checkbox"/> MA PPO	<input type="checkbox"/> MA C-SNP	<input type="checkbox"/> MA D-SNP	<input checked="" type="checkbox"/> MA All	
OTHER	<input checked="" type="checkbox"/> Self-funded/ASO					

I. POLICY

It is the policy of MedStar Health Insurance Services Division to cover lower limb foot orthotics and specialty shoes when it is medically necessary (Refer to CRM.015.MH – Medical Necessity policy) as detailed in this policy and covered under the member’s specific benefit plan.

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the indications for **Lower Limb Orthotics and Shoes**.

IV. SCOPE

The policy applies to various MedStar Health Insurance Services Division departments as indicated by the Benefit and Reimbursement Committee. These include, but are not limited to, Medical Management, Benefit Configuration, and Claims Departments.

V. PROCEDURE

A. Medical Description and Background

Musculoskeletal conditions of the foot and ankle are an important public health challenge due to their increasing incidence combined with their substantial negative impacts on patient’s quality of life. Non-surgical treatments serve as the

first line of treatment and are frequently used for patients with musculoskeletal conditions of the foot and ankle.

Orthotics are devices that are worn to correct foot and ankle problems non-surgically. They include foot pads, heel lifts, shoe inserts, and ankle braces. Foot pads are placed on the sole of the shoe. Shoe inserts are placed in the shoe. These devices are used to treat a wide variety of problems that include foot arthritis and flat feet. Ankle/foot braces and knee/ankle/foot braces are devices that treat a variety of diseases like ankle arthritis, foot drop, and tendinitis.

Proper footwear is an important part of the comprehensive treatment program for members with diabetes. The footwear should relieve areas of excessive pressure, reduce shock and shear, accommodate, stabilize, and support deformities, and limit motion of joints. Wearing the right footwear is crucial for the diabetic, especially if there is any evidence of neuropathy, lack of sensation, or deformity noted. Many serious complications may be prevented with the use of proper footwear.

B. Indications

Shoes

Prosthetic shoes (L3250) are covered if the following criteria are met:

- The shoe is an integral part of a prosthesis for a member with a partial foot amputation

Orthopedic shoes (L3224, L3225, or L3649) are covered when all of the following criteria are met:

- The shoe is an integral part of a covered leg brace (L1900, L1920, L1980-L2030, L2050, L2060, L2080, or L2090)
- The shoe is medically necessary and needed for the proper functioning of the brace

Diabetic shoes (A5500, A5501) are covered when all of the following criteria are met:

- Member has a diagnosis of diabetes mellitus; and
- The certifying physician has documented one or more of the following:
 - Previous amputation of the other foot, or part of either foot, or
 - History of previous foot ulceration of either foot, or
 - History of pre-ulcerative calluses of either foot; or
 - Peripheral neuropathy with evidence of callus formation of either foot; or
 - Foot deformity of either foot; or
 - Poor circulation in either foot; and
- The certifying physician has certified that the member is under a comprehensive plan of care for his/her diabetes.



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Shoe Modifications (Refer to Variations Section for Medicare Advantage)

Heel replacements (L3455, L3460), sole replacements (L3530, L3540), shoe transfers (L3600-L3640), inserts, lifts, and other shoe modifications (L3000-L3170, L3300-L3450, L3465-L3520, L3550-L3595) are covered when any of the following criteria are met:

- Member has any of the following conditions:
 1. Adults (skeletally mature feet):
 1. Acute or chronic plantar fasciitis
 2. Acute sport-related injuries (including: diagnoses related to inflammatory problems; e.g., bursitis, tendonitis)
 3. Calcaneal bursitis (acute or chronic)
 4. Calcaneal spurs (heel spurs)
 5. Inflammatory conditions (i.e., sesamoiditis; submetatarsal bursitis; synovitis; tenosynovitis; synovial cyst; osteomyelitis; and plantar fascial fibromatosis)
 6. Medial osteoarthritis of the knee (lateral wedge insoles)
 7. Musculoskeletal/arthropathic deformities (including: deformities of the joint or skeleton that impairs walking in a normal shoe; e.g., bunions, hallux valgus, talipes deformities, pes deformities, anomalies of toes)
 8. Neurologically impaired feet (including: neuroma; tarsal tunnel syndrome; ganglion cyst; and neuropathies involving the feet, including those associated with peripheral vascular disease, diabetes, carcinoma, drugs, toxins, and chronic renal disease)
 9. Vascular conditions (including: ulceration, poor circulation, peripheral vascular disease, Buerger's disease (thromboangiitis obliterans), chronic thrombophlebitis).
 2. Children (skeletally immature feet):
 1. Hallux valgus deformities
 2. In-toe or out-toe gait
 3. Musculoskeletal weakness (e.g., pronation, pes planus)
 4. Structural deformities (e.g., tarsal coalitions)
 5. Torsional conditions (e.g., metatarsus adductus, tibial torsion, femoral torsion)

Ankle/Foot Orthoses (AFO's)

General Criteria:

AFO's Not Used During Ambulation

Static or dynamic ankle/foot orthoses which are not used during ambulation are covered when all of the criteria 1-4 or criterion 5 is met:

1. Member has a plantar flexion contracture of the ankle with dorsiflexion on passive range of motion (PROM) testing of at least ten degrees (i.e. a non-fixed contracture); and,
 2. There is reasonable expectation of the ability to correct the contracture; and,
 3. The contracture is interfering or expected to interfere significantly with the member's functional abilities; and,
 4. The AFO is used as a component of a therapy program which includes active stretching of the involved muscles and/or tendons
- OR
5. Member has a diagnosis of plantar fasciitis

AFO's Used During Ambulation

AFO's (L1900, L1902-L1990, L2106-L2116, L4350, L4360, L4386, L4387, and L4631) are covered when all of the following criteria are met:

- Member is ambulatory with weakness or deformity of the foot or ankle; and
- Requires stabilization for medical reasons; and
- Member has the potential to benefit functionally.

Knee/Ankle/Foot Orthoses (KAFO's)

General Criteria:

KAFO'S (L2000-L2038, L2126-L2136, and L4370) are covered when all of the following criteria are met:

- Member is ambulatory; and
- Member requires additional knee stability.

Custom Fabricated AFO'S and KAFO'S

Custom-fabricated AFO'S and KAFO's (L1910, L1930, L1932, L1951, L1971, L2035, L2112-L2116, L2132-L2136, L4360, L4386, and L4396) will be covered when the member is ambulatory and meets the general criteria for AFO or KAFO above and any of the following criteria are met:

- The member could not be fit with a pre-fabricated AFO; or,
- The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than six months); or,
- There is a need to control the knee, ankle, or foot in more than one plane; or,
- The member has a documented neurological, circulatory, or orthopedic status that requires custom fabricating over a model to prevent tissue injury; or,
- The member has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.



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Repairs and Replacements

- Repairs to a covered orthosis due to wear or accidental damage are covered when necessary to make the orthosis functional.
- Replacement of a complete orthosis or component of an orthosis due to loss, significant change in the member's condition, or irreparable accidental damage is covered if the device is still medically necessary.

C. Limitations

Shoes and Modifications

- Claims for prosthetic shoes for other diagnoses besides a partial foot amputation will be denied as not medically necessary.
- Coverage is limited to one of the following within one calendar year (January – December)
 - One pair of custom molded shoes (A5501) (which includes inserts provided with these shoes) and two additional pairs of inserts (A5512 or A5513); or
 - One pair of depth shoes (A5500) and three pairs of inserts (A5512 or A5513) (not including the non-customized removable inserts provided with such shoes)
 - A modification of a custom molded or depth shoe may be covered as a substitute for an insert.
- Quantities of shoes, inserts, and/or modifications greater than those listed will be denied as non-covered.
- Diabetic shoe inserts used in non-covered shoes will be denied as non-covered.
- There is no separate payment for the fitting of shoes, inserts, or modifications, or for the certification of the need or prescription of the footwear.
- Deluxe features of diabetic shoes (A5508) will be denied as non-covered.
- Shoes, orthoses, and modifications for members with diabetes are limited to those coded A5500-A5511.

AFO'S/KAFO's

- If a custom fabricated AFO/KAFO is provided but general criteria above and the additional criteria for a custom fabricated orthosis are not met, the custom fabricated orthosis will be denied as non-covered.
- L coded additions to AFO's/KAFO's (L2180-L2550, L2750-L2768, L2780-L2830) will be denied as non-covered if either the base orthosis or the specific addition is not medically necessary.



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- Concentric adjustable torsion style mechanisms used to assist ankle joint plantarflexion or dorsiflexion codes as L2999 are covered for members who require knee extension assist in the absence of any co-existing joint contracture.
- A static/dynamic AFO (L4396, L4397) and replacement interface will be denied as non-covered when they are used solely for the prevention or treatment of a heel pressure ulcer.
- A foot pressure off-loading/supportive device (A9283) will be denied as non-covered because it does not support a weak or deformed body member or eliminate motion in a diseased or injured part of the body.
- Socks (L2840, L2850) used in conjunction with orthosis will be denied as non-covered.

D. Codes

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPSC Codes for diabetic shoes and inserts

A5500	For diabetics only, fitting (including follow-up), custom preparation and supply of off-the-shelf depth-inlay shoe manufactured to accommodate multi- density insert(s), per shoe
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
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



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- A5507 For diabetics only, not otherwise specified modification (including fitting) of off-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
- 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 1/4 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 material of shore a 35 durometer or higher), includes arch filler and other shaping material, custom fabricated, each

ICD-9 codes for diabetic shoes and inserts

- 249.00-249.91 Secondary diabetes mellitus
250.00-250.93 Diabetes mellitus

ICD-10 codes for diabetic shoes and inserts

- E10-E10.9 Type 1 diabetes mellitus
E11-E11.9 Type 2 diabetes mellitus
E13-E13.9 Other specified diabetes mellitus

ICD-9 codes for Prosthetic Shoes (L3250)

- 755.31 Transverse deficiency of lower limb
755.38 Longitudinal deficiency, tarsals or metatarsals, complete or partial (with or without incomplete phalangeal deficiency)
755.39 Longitudinal deficiency, phalanges, complete or partial
895.0-896.3 Traumatic amputation of toes and/or foot

ICD-10 codes for Prosthetic Shoes (L3250)

- Q72.00 Congenital complete absence of unspecified lower limb
Q72.30 Congenital absence of unspecified foot and toe(s)
S98.0-S98.92 Traumatic amputation of foot at ankle level



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E. Variations

For Medicare Advantage Products:

Shoe Modifications (Refer to Variations Section)

Heel replacements (L3455, L3460), sole replacements (L3530, L3540), and shoe transfers (L3600-L3640), inserts, lifts, and other shoe modifications (L3000-L3170, L3300-L3450, L3465-L3520, L3550-L3595) are covered when all of the following criteria are met:

- The shoe is an integral part of a covered leg brace (L1900, L1920, L1980-L2030, L2050, L2060, L2080, or L2090)
- The shoe is medically necessary and needed for the proper functioning of the brace

F. Quality Audit

Quality Audit monitors policy compliance and/or billing accuracy at the request of the MedStar Health Insurance Services Division's Technology Assessment Committee or the Benefits Reimbursement Committee.

G. Records Retention

Records Retention for documents, regardless of medium, are provided within the MedStar Health System Policy HS-LE0009 Records Retention, Management and Retirement, and as indicated in the MedStar Health Insurance Services Division Policy and Procedure CORP.028.MH Records Retention.

Unless otherwise mandated by Federal or State law, or unless required to be maintained for litigation purposes, any communications recorded pursuant to this Policy are maintained for a minimum of ten (10) years from the date of recording.

H. References

Medical Literature/Clinical Information

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2. Rao S, Riskowski JL, Hannan MT. Musculoskeletal conditions of the foot and ankle: assessments and treatment options. Best Pract ResClin Rheumatol. 2012 Jun;26(3):345-68. doi: 10.1016/j.berh.2012.05.009.



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Regulatory/Government Source

1. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) No. L11467 - Orthopedic Footwear. (Contractor: NHIC, Corp.) Revision Effective Date: 01/01/2014. <http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11467&ContrlId=137&ver=28&ContrVer=1&DocType=Active%7cFuture&bc=AgIAAAAAAAAAAAAA%3d%3d&>
2. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) No. L11535 – Therapeutic Shoes for Persons with Diabetes. (Contractor: NHIC, Corp.) Revision Effective Date: 02/04/2011. <http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11535&ContrlId=137&ver=39&ContrVer=1&DocType=All&bc=AgIAAAAAAAAAAAAA%3d%3d&>
3. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) No. L11527 – Ankle-Foot/Knee-Ankle-Foot Orthosis. (Contractor: NHIC, Corp.) Revision Effective Date: 01/01/2014. <http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11527&ContrlId=137&ver=64&ContrVer=1&DocType=All&bc=AgIAAAAAAAAAAAAA%3d%3d&>
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<http://www.guideline.gov/content.aspx?id=15625&search=orthotics>

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