

09-L0000-03

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Subject: Orthotics

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Description	Position Statement	Billing/Coding	Reimbursement	Program Exceptions
Definitions	Related Guidelines	Other	References	Updates

DESCRIPTION:

For the purposes of this guideline, an orthotic is a rigid or semi-rigid device used to support, restore, or protect body function. Orthotics may also redirect or restrict motion of an impaired body part.

POSITION STATEMENT:

NOTE: Orthotic devices are covered services, according to the member's individual contract benefit. Refer to the applicable benefit plan document to determine specific benefit availability and the terms, conditions and limitations of coverage:

If an orthotics benefit is available, the following orthotic devices and orthotic-related services **meet the definition of medical necessity:**

- Appliances essential to effective use of artificial limbs **OR** corrective braces
- Braces for leg, arm, neck, back, shoulder
- Corsets for back or for use after special surgical procedures
- Harnesses essential to use of artificial limbs
- Hernia devices
- Orthopedic shoes, when one or both are an integral part of a leg brace and are necessary for proper functioning fo the brace; a matching shoe for the unaffected leg is covered
- Space shoes
- [Splints](#) for extremities
- Therapeutic shoes or sandals following surgical foot procedures

- [Therapeutic shoes](#) (depth or custom-molded) including [inserts](#) **OR** [modifications for the treatment of](#) impaired peripheral circulation and/or loss of protective sensation in the lower extremities from a systemic condition such as diabetes mellitus, peripheral vascular disease, peripheral neuropathy, arteriosclerosis obliterans, Buerger's disease (i.e., thromboangiitis obliterans), or chronic thrombophlebitis (not an all-inclusive list),

Trusses

- Additions **OR** modifications to an orthotic device when it is ordered by a physician
- Replacement of an orthotic device when the need for replacement is documented by the attending physician and is due to change in members condition, loss, or irreparable damage or wear
- Custom fabricated and designed foot orthosis.

NOTE: Custom fabricated and designed foot orthosis (shoe inserts or supportive devices for the feet) **meet the definition of medical necessity** when:

1. The contract has a benefit and does not exclude foot orthotics, and
2. The orthotics are prescribed by a physician to treat a medical problem or deformity such as but not limited to the following in adults with skeletally mature feet with:
 - Chronic or acute plantar fasciitis
 - Calcaneal spurs
 - Strained or injured soft tissues
 - Bony prominences
 - Deformed bones and joints that impairs walking with a normal shoe. The member may have significant pain that interferes with activities of daily living, or the member has impaired gait, balance or mobility.(e.g. bunions, hallux valgus, talipes deformities, pes deformities, anomalies fo the toes)
 - Rheumatoid nodules
 - Inflammatory conditions of the foot (i.e., sesamoiditis, submetatarsal bursitis, synovitis, tenosynovitis, synovial cyst, osteomyelitis, and plantar fascial fibromatosis, inflamed or chronic bursae
 - Dermatologic lesions secondary to deforming arthritis or biomechanical abnormality.

Or in pediatrics with skeletally immature feet:

- Hallux valgus deformities
- In-toe or out-toe gait
- Musculoskeletal weakness (e.g., pronation, pes planus)
- Structural deformities (e.g., tarsal coalitions)
- Torsional conditions (e.g., metatarsus adductus, tibial torsion, femoral torsion), **OR**

3. Therapeutic shoes, inserts **OR** modifications **meet the definition of medical necessity** when certification from the physician managing the medical condition indicates that **ALL** of the following are met:
- a. The member has impaired peripheral circulation and/or loss of protective sensation in the lower extremities from a systemic condition such as diabetes mellitus, peripheral vascular disease, peripheral neuropathy, arteriosclerosis obliterans, Buerger's disease (i.e., thromboangiitis obliterans), or chronic thrombophlebitis (not an all-inclusive list);
AND
 - b. The member is under a comprehensive plan of care for the medical condition; **AND**
 - c. The member has one **OR** more of the following conditions in one or both feet:
 - Previous amputation of the foot or part of the foot
 - Foot deformity with a potential for ulceration
 - Callus formation **OR** a history of callus formation with peripheral neuropathy
 - A history of previous foot ulceration
 - Poor pedal **OR** lower extremity circulation.
 - Following certification by the physician managing the member's medical condition, any physician knowledgeable in the fitting of the therapeutic shoes and inserts may prescribe the particular type of footwear necessary.

Clinical documentation should include information that support why commercially available off-the-shelf shoes in retail stores in various styles, widths, depths, with inner sole removed, will not address the person's orthopedic needs, (e.g., copy of the foot exam, biomechanical exam or gait analysis performed by the Doctor of Podiatric Medicine (D.P.M.), Doctor of Osteopathic Medicine (D.O.), or Medical Doctor (M.D.)

Modifications of depth or custom-molded shoes include, but are not limited to:

- Rigid rocker bottoms
- Roller bottoms
- Wedges
- Metatarsal bars
- Offset heels
- Flared heels.

The following items **do not meet the definition** of an orthotic device or are excluded per contract language unless covered per specific plan document:

- Arch supports or shoe inserts designed to effect conformational changes in the foot (i.e., change in the shape of the foot) or foot alignment (define conformational changes)
- [Orthopedic shoes](#), unless one or both shoes are an integral part of a leg brace

- Self-purchased splints and trusses
- Over-the-counter, custom-made or built-up shoes
- Cast shoes
- Sneakers labeled as footwear for a medical condition through retail or internet purchase
- Ready-made compression hose (stockings with less than 18mm HG gradient pressure)
- Support hose.

BILLING/CODING INFORMATION:

HCPCS Coding:

A5500 – A5510	Diabetic shoes, fitting, and modifications
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 (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
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
K0672	Addition to lower extremity orthosis, removable soft interface, all components, replacement only, each
L3201 – L3265	Orthopedic Shoes and Boots
L0112 – L5020	Orthotic devices, procedures

NOTE: Some orthotics may be addressed in separate policies.

Repairs of orthotic devices are to be coded by adding modifier –RP to the applicable procedure code for the device.

REIMBURSEMENT INFORMATION:

Reimbursement for an orthotic device is based on established allowance or actual cost if invoice is submitted, whichever is less.

Reimbursement for custom molded and designed shoe inserts or supportive devices for the feet (L3000 – L3090) is limited to one (1) pair of any type orthotic for orthopedic shoes a 12-month period. Items in excess of these limitations are subject to medical review of documentation supporting medical necessity. The following information may be required documentation to support medical necessity:

medical records, attending physician initial assessment, physician visit notes, physician history and physical.

LOINC Codes:

DOCUMENTATION TABLE	LOINC CODES	LOINC TIME FRAME MODIFIER CODE	LOINC TIME FRAME MODIFIER CODES NARRATIVE
Physician Initial Assessment	18736-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

Reimbursement for therapeutic shoes and inserts **OR** modifications (A5500 – A5507, A5512 – A5513, & A5514) is limited to the following:

- One (1) pair of extra-depth shoes (A5500) **OR** one (1) pair of custom molded shoes (A5501) in 12 months **AND**
- Six (6) inserts (A5512 or A5513 or A5514) in 12 months.

A “modification” of a custom molded shoe or depth shoe (e.g., A5503, A5504, A5505, A5506, and A5507) may be covered as a substitute for an insert.

Deluxe features (A5508) are not eligible for reimbursement as deluxe items are generally contract exclusions.

Direct formed compression molded to the patient’s foot without external heat source, multiple-density insert(s) (A5510) is not eligible for reimbursement since these types of inserts are not considered total contact at the time of dispensing. These inserts reflect compression molding to the patient’s foot over time through the heat and pressure generated by wearing a shoe with the insert in place.

Reimbursement is limited to inserts for therapeutic shoes; inserts alone (i.e., inserts used with standard shoes) are not eligible for reimbursement.

Reimbursement for travel time and for professional services for preparation and fitting is included in the basic allowance for the orthotic device.

Reimbursement for the repair is not to exceed the allowance for the cost of a new device.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following Durable Medical Equipment Regional Carrier (DMERC) Local Coverage Determinations (LCDs) were reviewed on the last guideline reviewed date: Orthopedic Footwear (L33641), Spinal Orthoses: TLSO and LSO (L33790), Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686), and Therapeutic Shoes for Persons with Diabetes (L33369) located at cgsmedicare.com.

DEFINITIONS:

Custom Fabricated Orthosis: Orthosis, which is individually made for a specific patient. Created using an impression generally by means of plaster or fiber cast, a digital image using computer-aided design-computer aided manufacture (CAD-CAM) systems software, or direct form to patient.

Direct formed (molded): the insert has been conformed by molding directly to match the plantar surface of the individual patient's foot.

Foot Deformities: Foot deformities such as flatfoot (pes planus) and bunions (hallux valgus) may cause malalignment of the feet and/or ankles and pathologic foot positioning, thereby causing impaired gait, balance and pain. Flatfoot deformity may occur in both pediatric and adult populations.

Foot Orthotics: Shoe inserts that are intended to correct foot function and minimize stress forces that could ultimately cause foot deformity and pain by altering slightly the angles at which foot strikes a walking or running surface (The American College of Foot and Ankle Surgeons (ACFAS) Clinical Practice Guidelines (Lee et al., 2004; Harris et al., 2004; Vanore et al., 2003)

Orthopedic shoes correct functional or bio-mechanical abnormalities such as "flat feet" or other skeletal problems. Therapeutic shoes, inserts or modifications serve a different purpose and are not considered orthopedic shoes.

Prefabricated Orthosis: Orthosis, which is manufactured in quantity without a specific patient in mind, which may be trimmed, bent, molded, or otherwise modified for use by a specific patient (i.e., custom fitted). A preformed orthosis is considered prefabricated even if it requires the attachment of straps and/or the addition of a lining and/or other finishing work or is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom fabricated orthosis is considered prefabricated. Also referred to as custom-fitted.

Rigid rocker bottoms: Exterior elevations with apex position for 51% to 75% 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 taper 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): The same as rocker bottoms except the heel is tapered from the apex to the front tip of the sole.

Splint: a rigid or flexible appliance used to maintain in position a displaced or movable part or to keep in place and protect an injured part.

Therapeutic shoes, inserts or modifications are designed to provide protection for insensate feet and promote altered support for feet that are changing in shape and for which normal shoes provide inadequate support.

Total contact: the insert makes and retains actual and continuous physical contact with the weight-bearing portions of the foot, including the arch throughout the standing and walking phases of gait.

Trusse: an elastic, canvas, or metallic device for retaining a hernia reduced within the cavity.

RELATED GUIDELINES:

[Cranial Orthosis as a Treatment for Plagiocephaly, 09-L0000-02](#)

[Durable Medical Equipment \(DME\), 09-E0000-01](#)

[Home Health Care, 01-99500-01](#)

[Knee Braces, 09-L0000-01](#)

OTHER:

Florida Statute 641.31 (26) (a, b, c):

(26)(a) Each health maintenance organization and prepaid health plan shall provide coverage for all medically appropriate and necessary equipment, supplies, and services used to treat diabetes, including outpatient self-management training and educational services, if the patient's primary care physician, or the physician to whom the patient has been referred who specializes in treating diabetes, certifies that the equipment, supplies, or services are necessary.

(b) The contract may require that diabetes outpatient self-management training and educational services be provided under the direct supervision of a certified diabetes educator or a board-certified endocrinologist under contract with or designated by the health maintenance organization or prepaid health plan.

(c) The Agency for Health Care Administration shall adopt standards for outpatient self-management training and educational services, taking into consideration standards approved by the American Diabetes Association.

REFERENCES:

1. Academy of Minimally Invasive Foot & Ankle Surgery (formerly known as The Academy of Ambulatory Foot & Ankle Surgery); accessed at aafas.org. The American College of Foot & Ankle Orthopedics & Medicine. Prescription Custom Foot Orthoses Practice Guidelines. December, 2006; acfaom.org.
2. American College of Foot and Ankle Surgeons. Clinical Practice Guideline. (The American College of Foot and Ankle Surgeons (ACFAS) Clinical Practice Guidelines (Lee et al., 2004; Harris et al., 2004; Vanore et al., 2003); acfas.org).

3. Babatunde O, Legha A, et al. Comparative effectiveness of treatment options for plantar heel pain: a systematic review with network meta-analysis. *Br J Sports Med.* 2019 Feb;53(3):182-194. doi: 10.1136/bjsports-2017-098998. Epub 2018 Jun 28. PMID: 29954828.
4. Bonanno DR, Landorf KB, et al. Effectiveness of foot orthoses and shock-absorbing insoles for the prevention of injury: a systematic review and meta-analysis. *Br J Sports Med.* 2017 Jan;51(2):86-96. doi: 10.1136/bjsports-2016-096671. Epub 2016 Dec 5. PMID: 27919918.
5. CGS Administrators, LLC. Local Coverage Determination (LCD): Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686); located at cgsmedicare.com.
6. CGS Administrators, LLC. Local Coverage Determination (LCD): Orthopedic Footwear (L33641); located at cgsmedicare.com.
7. CGS Administrators, LLC. Local Coverage Determination (LCD): Spinal Orthoses: TLSO and LSO (L33790); located at cgsmedicare.com.
8. CGS Administrators, LLC. Local Coverage Determination (LCD): Therapeutic Shoes for Persons with Diabetes (L33369); located at cgsmedicare.com.
9. Florida Statute 641.31 Health Maintenance Contracts; accessed at leg.state.fl.us/statutes.
10. Kent Stuber , et al. Conservative therapy for plantar fasciitis: a narrative review of randomized controlled trials. *J Can Chiropr Assoc.* Jun 2006; 50(2): 118–133.
11. McDermott P, Wolfe E, et al. Evaluating the immediate effects of wearing foot orthotics in children with Joint Hypermobility Syndrome (JHS) by analysis of temperospatial parameters of gait and dynamic balance: A preliminary study. *Gait Posture.* 2018 Feb;60:61-64. doi: 10.1016/j.gaitpost.2017.11.005. Epub 2017 Nov 15. PMID: 29156379.
12. U.S. Food & Drug Administration (FDA); accessed at fda.gov.
13. Whittaker GA, Munteanu SE, et al. Foot orthoses for plantar heel pain: a systematic review and meta-analysis. *Br J Sports Med.* 2018 Mar;52(5):322-328. doi: 10.1136/bjsports-2016-097355. Epub 2017 Sep 21. PMID: 28935689.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 07/28/22.

GUIDELINE UPDATE INFORMATION:

07/15/99	Medical Coverage Guideline reformatted.
01/01/01	Coding changes.
09/15/01	Reviewed.
01/01/02	Coding changes.
07/01/03	HCPCS coding changes.
09/15/03	Reviewed; no changes.
04/01/04	2 nd Quarter 2004 HCPCS coding update.
05/15/04	Revision to reimbursement limitation.
06/15/04	Revision to limitations for shoes, shoe inserts, and modifications.
04/01/05	2 nd Quarter HCPCS coding update; added S8434.
05/15/05	Revision to add clarification regarding covered and non-covered items.
09/15/05	Scheduled review; no changes in coverage statement.

01/01/06	Annual HCPCS coding update (delete A5511, K0628, and K0629; add A5512 and A5513).
04/01/06	2 nd Quarter HCPCS coding update; revised A5513 descriptor.
01/01/07	Annual HCPCS coding update (deleted L0100, L0110, L3902, and L3914).
06/15/07	Revisions consisting of reformatting guideline; the addition of the Florida State mandate language regarding diabetic supplies; removal of HOI Program Exception information.
08/15/07	Scheduled review; reformatted guideline; updated references.
02/15/08	Revision consisting of changes to reimbursement of therapeutic shoes, inserts, modifications.
04/01/08	2 nd Quarter HCPCS coding update (added K0672).
09/15/09	Scheduled review; no change in position statement; updated references.
05/15/10	Revision consisting of removal of code range E1800 – E1840.
10/15/10	Revisions consisting of adding reimbursement information regarding A5508 and A5510; formatting changes.
07/15/11	Revision; formatting changes.
05/11/14	Revision: Program Exceptions section updated.
07/01/14	Revision: Reimbursement section updated to reflect individual diabetic shoe inserts rather than pairs of inserts.
07/15/14	Revision of Reimbursement section regarding diabetic shoes and inserts.
02/15/15	Revisions: Position Statement revised; Definitions added; references updated; formatting changes.
11/01/15	Revision: ICD-9 Codes deleted.
12/15/16	Revision; position statements maintained, program exception and references updated; formatting changes.
04/01/18	Quarterly HCPCS/CPT update. Added code K0903.
01/01/19	Annual CPT/HCPCS coding update. Added code A5514; revised code A5513; deleted code K0903; reimbursement section updated.
08/15/19	Review; Position statements maintained and references updated.
10/15/20	Review; position statements maintained and references updated.
01/01/23	Review: Position statements updated; references updated.