Clinical Policy Title: Foot orthoses, foot care services

Clinical Policy Number: CCP.1328

Effective Date:	**October 1, 2017**
Initial Review Date:	August 17, 2017
Most Recent Review Date:	August 30, 2018
Next Review Date:	September 2019

Policy contains:

- Diabetes care.
- Foot care.
- Foot orthoses.

Related policies:

None.

ABOUT THIS POLICY: *AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.*

Coverage policy

AmeriHealth Caritas considers routine foot care to be clinically proven, and therefore medically necessary, under any of the following conditions:

1. As a necessary and integral part of otherwise covered services.

2. Treatment of warts on foot.

3. Presence of systemic conditions, such as metabolic, neurologic, or peripheral vascular disease. These diseases can include diabetes mellitus, arteriosclerosis obliterans, Buerger's disease, or chronic thrombophlebitis.

4. Peripheral neuropathies involving the feet, associated with malnutrition and vitamin deficiency (malnutrition, alcoholism, malabsorption, pernicious anemia), associated with traumatic injury, associated with leprosy or neurosyphilis, or associated with hereditary disorders.

5. Mycotic nails, either in the presence of systemic conditions, in ambulatory patients with marked limitation of ambulation, pain, or secondary infection resulting from the thickening and dystrophy of infected toenail plate, or in nonambulatory patients suffering from pain or secondary infection resulting from the thickening and dystrophy of infected toenail plate (Local Coverage Determination L36404).

Limitations:

Foot care and orthoses for all other purposes are considered investigational or experimental, and therefore not medically necessary.

Alternative covered services:

None.

Background

Many conditions of the foot are routine and often non-pathogenic, including flat feet, subluxation (partial dislocation or displacement of joint surfaces, tendons, ligaments, and muscles), corns, and calluses. Routine treatments such as trimming or cutting toenails, paring or trimming of corns and calluses, soaking and skin creams, are often optional or cosmetic, and do not require the services of medical professionals. They are not to be confused with conditions of the foot that hamper body functions and impair activities such as ambulation, thus requiring medical interventions.

Aside from diseases affecting only the foot, some foot conditions may be part of systemic diseases such as diabetes, peripheral vascular disease, and peripheral neuropathy, and require care for the feet. Diabetes is a particular problem, due to its high and rising prevalence. In 2015, 30.3 million Americans (9.4 percent) had the disease, with one-quarter of them not diagnosed, while another 84.1 million (33.9 percent of adults over 18) had pre-diabetes. Rates for Hispanics and non-Hispanic blacks are substantially higher than for other racial and ethnic groups (American Diabetes Association, 2017). From 1958 to 2015, the proportion of diagnosed diabetics soared from 0.93 percent to 7.40 percent, or from 1.6 million to 23.4 million Americans (Centers for Disease Control and Prevention, 2017).

About 60 to 70 percent of diabetics have peripheral neuropathy, which affects the legs, feet, arms, and hands. Neuropathy makes blister and sore healing difficult, and can cause numbness in the extremities, making it more likely for infections and ulcers to spread. A small proportion of diabetics lose their feet to amputation (American Orthopaedic Foot and Ankle Society, 2017), with one estimate ranging from 0.25 to 1.80 percent each year (Hunt, 2011). Early management to evaluate risk, and ongoing care, are needed to prevent and limit the adverse effects of neuropathy.

Foot orthoses, also known as foot pads or shoe inserts, are devices custom-made of rubber, metal, leather, or plastic material. After insertion into a shoe, orthoses can provide better balance, reduce pressure, and reduce pain in the foot. Many Americans who use foot orthoses do so for routine purposes, but some require these devices when physical impairment occurs. A related device is ankle foot orthoses, a supportive plastic brace that covers portions of both the foot and ankle. Foot prostheses are artificial devices used after amputation.

The Medicare program specifies coverage for various services related to foot care and orthoses (Centers for Medicare & Medicaid Services, 2017). Other professional guidelines make recommendations for various aspects of foot care; the majority of these pertain to diabetics. Foot care was part of a global consensus guideline on preventing and managing diabetes in the foot (Bakker, 2012).

The Internal Clinical Guidelines team declared that variations in efficacy of preventing and managing diabetic foot problems persist due to geography, individual trusts, organization and access of diabetic foot care services, and availability of professionals with expertise in diabetic foot problems (Internal Clinical Guidelines team, 2015). The International Working Group on the Diabetic Foot issued guidelines on prevention of diabetes in the foot, including footwear and offloading, peripheral artery disease, infections, and wound healing (Bakker, 2016).

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality's National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on July 10, 2018. Search terms were: "foot care," "foot orthoses," and "diabetes."

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

Starting in 2003, Belgian and German groups began collecting data at baseline and after six months on the treatment of diabetic feet, a project that had reached 24,000 subjects by 2016, as a basis for assessing means of improving care and outcomes (Morbach, 2016).

Numerous systematic reviews on foot care and orthoses appear in the professional literature, many of them addressing diabetes. Antibiotics are often the initial choice to treat diabetic foot infections, although a Cochrane review could not find any outcomes differences in types of antibiotics (Selva Olid, 2015).

Offloading of non-infected ulcers was shown to heal in six – eight weeks, while wearing custom-made footwear relieves pressure (Bus, 2016a); use of total contact casting was found to be the most effective type of offloading device, in a review of 15 studies (de Oliveira, 2015). A Cochrane review of seven studies (n = 366) compared non-removable casts with removable pressure-relieving devices to relieve diabetes-related plantar foot ulcers, and concluded casts were more effective (Lewis, 2013).

Prevention was the focus of other foot care and orthosis systematic reviews. An analysis of 30 studies, including nine randomized controlled trials, showed that preventing complications, understanding risk factors, and managing complications outside the clinical encounter are critical to effective diabetes foot self-care management, but further research documenting complications is needed (Bonner, 2016). A review of 23 studies on preventing foot ulcers estimated a reduction of over 60 percent when home monitoring of foot temperature, pressure-relieving therapeutic footwear, and certain surgical interventions are used (Bus, 2016b). A 2014 Cochrane review of 12 randomized controlled trials failed to reach an agreement that education of patients with a high risk of foot ulceration resulted in a significant reduction of amputations one year later (Dorresteijn, 2014).

A meta-analysis of diabetic foot care included two studies of 514 patients, 213 on telemedicine, and 301 on usual care. Telemedicine patients and controls had similar average healing time (43 versus 45 days, $P = .83$), healing time ratio adjusted for age (1.0 versus 1.4, $P = .10$), unhealed ulcers or loss to follow up (3 of 20 versus 7 of 120; $P = .13$), amputations (12 of 193 versus 14 of 182, $P = .59$), and odds of complete ulcer healing ($P = .53$). Subjects higher mortality rate (8/193 versus 1/181, $P = .0001$) due to unexplained factors. No adverse events were attributed to telemedicine (Tchero, 2017).

Conditions other than diabetes are topics of reviews for foot care and orthoses. A review of 1,862 stroke patients in hospitals who were prescribed ankle-foot orthoses (compared to those who were not) had significantly higher propensity scores, functional independence measures scores, and functional independence efficiency, and performed more independent exercise (Momosaki, 2015). A review of 20 trials (n = 314) of stroke survivors showed ankle-foot orthosis had a positive effect on ankle kinematics ($P < .00001$), knee kinematics in stance phase ($P < .0001$), kinetics ($P = .0001$), and energy cost ($P = .004$), but not on knee kinematics in swing phase ($P = .084$), hip kinematics ($P < .018$), or energy expenditure ($P = .043$). All of these measures represented immediate improvements (Tyson, 2013).

A systematic review of 27 studies of stroke patients who used ankle foot orthoses found all types of orthoses had positive effects on ankle kinematic in the first rocker and swing phases, but not on knee kinematics in the swing phase, hip kinematics, or the third rocker function. In addition, 25 of 27 studies only assessed immediate or short-term effects. Articulated passive orthoses compared with the non-articulated passive ankle foot orthoses had better effects on some aspects of the gait of patients with hemiplegia following stroke than did nonarticulated passive orthoses (Daryabor, 2018).

A Cochrane review of eight studies found that phototherapy may increase the proportion of foot wounds completely healed during follow-up and may reduce wound size, but showed no evidence that quality of life improved (Wang, 2017).

Arthritis is another aspect of foot care and orthoses addressed in the literature. A review of 17 studies of rheumatoid feet and ankles provided weak evidence for custom orthoses reducing pain and forefoot plantar pressures, and inconclusive evidence for foot function, walking speed, gait parameters, and reducing hallux abductovalgus angle progression (Hennessy, 2012). Another review of 25 studies of knee osteoarthritis found that knee braces and foot orthoses are effective in decreasing pain, joint stiffness, drug dosage, and improve proprioception, balance, Kellgren/Lawrence grading, and physical function scores (Raja, 2011).

A systematic review and meta-analysis of five studies (n=301) with rheumatoid arthritis and foot pain were given orthoses or not treated. After being followed from four to 36 months, orthosis use appeared to alleviate pain, but without any significant differences between control and intervention groups regarding long- and short-term pain relief or reduced disability (Gijon-Noqueron, 2018).

Gait and balance improvements from foot care and orthoses have also been the topic of systematic reviews. Even healthy older adults have been advised to wear thin, hard-soled footwear with high collars to reduce risk of falling (Aboutorabi, 2016), although more reviews are needed to better understand any long-term effects (Hatton, 2013). A review of nine trials (none are randomized controlled trials) found limited evidence to suggest footwear and insole devices can alter postural stability, or affect static balance or gait (Paton, 2016). Ankle-foot orthoses in children with cerebral palsy improves motor function and gait performance, according to systematic reviews (Neto, 2012; Ridgewell, 2010).

Peripheral artery disease should always be treated with thorough foot care (Kiernan, 2010).

A meta-analysis of 11 trials showed foot orthoses were effective for preventing injuries (risk ratio 0.72) and stress fractures (0.59), but not soft tissue injuries (0.79); shock-absorbing insoles were not effective for preventing overall injuries in any of the three above categories (Bonnano, 2017).

A systematic review and meta-analysis of 20 studies addressed foot orthoses for plantar heel pain. Data showed no short-term difference between prefabricated and sham orthoses, as well as sham custom and sham orthoses for pain (Rasenberg, 2018; Whittaker, 2018). Another systematic

review/meta-analysis for plantar heel pain included 19 studies (n=1660). Orthoses did not improve function (versus controls) in the short, medium, or long term. Only in the medium term did evidence show pain reduction (Whittaker, 2018).

Foot orthoses are also used for children with various disorders. A systematic review of 17 studies (n=1,139), only four randomized, assessed efficacy of ankle foot orthoses in children with cerebral palsy. In general, the use of ankle foot orthoses improved speed and stride length (Aboutorabi, 2017).

Policy updates:

A total of six peer-reviewed references were added to this policy in July 2018.

Summary of clinical evidence:

Citation	Content, Methods, Recommendations
Bonnano (2017) Effectiveness of foot orthoses and shock-absorbing insoles for preventing injury	**Key points:** • Cochrane review of 11 trials of foot orthoses, seven trials of shock-absorbing insoles. • Foot orthoses were effective for preventing overall injuries (risk ratio [RR] 0.72) and stress fractures (0.59), but not significant for soft-tissue injuries (0.79). • Shock-absorbing insoles were not effective (RR short of statistical significance) for preventing the three above measures (0.92, 1.15, 0.92).
Bonner (2016) Foot care knowledge and practice interventions as part of diabetic foot care self-management	**Key points:** • Review of 30 studies, including nine randomized controlled trials and 13 survey designs. • Numerous types of foot care interventions were reviewed; outcomes varied greatly. • In randomized controlled trials, no studies reported improved outcomes in the control group compared to the intervention group, but consistency in types of intervention was lacking.
Bus (2016b) Foot care in preventing diabetic foot ulcers	**Key points:** • Systematic review of 23 studies on preventing diabetic foot ulcers. • Median effect of preventing recurrent foot ulcers is 60 %; effects can be 75 – 80% when attempts are made to ensure treatment adherence. • Home monitoring of foot temperature, pressure-relieving therapeutic footwear, and certain surgical interventions are effective.
Momosaki (2015) Effects of ankle-foot orthoses on recovery after stroke	**Key points:** • Study of 1,863 in-hospital stroke patients, 30.7% were prescribed ankle-foot orthoses. • Patients with orthoses had higher propensity scores ($P = .02$), functional independence measure scores ($P < .001$), and Functional Independence Measure efficiency ($P < .001$).
Lewis (2013) Pressure-relieving	**Key points:** • Cochrane review of 14 trials (n = 709).

Citation	Content, Methods, Recommendations
interventions for treating diabetic foot ulcers	• Non-removable casts were more effective in healing diabetic foot ulcers than were removable pressure-relieving devices (RR = 1.17). • Achilles tendon lengthening combined with a non-removable cast resulted in more healed ulcers for non-removable casts (RR = 3.41).

References

Professional society guidelines/other:

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Centers for Medicare & Medicaid Services National Coverage Determinations:

70.2.1 Services Provided for the Diagnosis and Treatment of Diabetic Sensory Neuropathy with Loss of Protective Sensation (aka Diabetic Peripheral Neuropathy). Effective date July 1, 2002.

Local Coverage Determinations:

L33636 Routine Foot Care and Debridement of Nails. CT, IL, MA, ME, MN, NH, NY, RI, VT, WI. Effective date October 1, 2017. Accessed July 10, 2018.

L33941 Routine Foot Care. FL, PR, VI. Effective date February 8, 2018. Accessed July 10, 2018.

L34246 Routine Foot Care and Debridement of Nails. KY, OH. Effective date October 1, 2017. Accessed July 10, 2018.

L35138 Routine Foot Care. AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX. Effective date December 14, 2017. Accessed July 10, 2018.

L36404 Foot Care. 38 states. Effective date October 1, 2017. Accessed July 10, 2018.

L37643 Routine Foot Care. AL, GA, NC, SC, TN, VA, WV. Effective date February 26, 2018. Accessed July 10, 2018.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

CPT Code	Description	Comments
11055	Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus); single lesion	
11056	Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus); 2 to 4 lesions	
11057	Paring or cutting of benign hyperkeratotic lesion (eg, corn or callus); more than 4	

CPT Code	Description	Comments
	lesions	
11719	Trimming of nondystrophic nails, any number	
11720	Debridement of nail(s) by any method(s); 1 to 5	
11721	Debridement of nail(s) by any method(s); 6 or more	

ICD-10 Code	Description	Comments
C40.30 - C40.32	Malignant neoplasm of short bones of lower limb	
C47.20 -C47.22, C49.20 - C49.22	Malignant neoplasm of peripheral nerves and connective and soft tissue of lower limb, including hip	
C79.51 - C79.52	Secondary malignant neoplasm of bone and bone marrow	
D21.20 - D21.22, D36.13	Benign neoplasm of peripheral nerves and connective and other soft tissue, lower limb, including hip [neuroma]	
E08.00 -E08.9	Diabetes mellitus due to underlying condition	
E64.3	Sequelae of rickets	
G57.00 -G57.93	Mononeuropathies of lower limb	
G60.0	Hereditary motor and sensory neuropathy	
G60.1	Refsum's disease	
G60.3	Idiopathic progressive neuropathy	
G60.8	Other hereditary and idiopathic neuropathies	
G61.0 - G61.9	Inflammatory polyneuropathy	
G62.0 - G62.9	Other and unspecified polyneuropathies	
I70.201 - I70.299	Atherosclerosis of native arteries of the extremities	
I73.00 -I73.01	Raynaud's syndrome	
I73.1	Thromboangiitis obliterans [Buerger's disease]	
I73.81	Erythromelalgia	
I73.89	Other specified peripheral vascular diseases (e.g., acrocyanosis, acroparesthesia, erythrocyanosis)	
I73.9	Peripheral vascular diseases, unspecified	
I74.3	Embolism and thrombosis of arteries of the lower extremities	
I75.021 - I75.029	Atheroembolism of lower extremity	
I80.00 - I80.03	Phlebitis and thrombophlebitis of superficial vessels of lower extremities	
I80.10 - I80.13	Phlebitis and thrombophlebitis of femoral vein [deep and superficial]	
I80.201 - I80.299	Phlebitis and thrombophlebitis of other and unspecified deep vessels of lower extremities [e.g., femoropopliteal vein, popliteal vein, tibial vein]	
I80.3	Phlebitis and thrombophlebitis of lower extremities, unspecified	
I82.401 - I82.409	Acute embolism and thrombosis of unspecified deep veins of lower extremity	
I83.001 - I83.029	Varicose veins of lower extremities with ulcer	
I83.10 - I83.12	Varicose veins of lower extremities with inflammation	
I83.201 - I83.229	Varicose veins of lower extremities with both ulcer and inflammation	
I83.891 - I83.899	Varicose veins of lower extremities with other complications	
L97.101 - L97.929	Non-hyphenpressure chronic ulcer of lower limbs, not elsewhere classified	
M10.00 - M10.09	Idiopathic gout	
M12.271 - M12.279	Villonodular synovitis (pigmented), ankle and foot	
M12.571 -	Traumatic arthropathy, ankle and foot	

ICD-10 Code	Description	Comments
M12.579		
M12.871 - M12.879	Other specific arthropathies, not elsewhere classified, ankle and foot [contrature of joint]	
M17.0 - M17.12	Primary osteoarthritis of knee	
M17.2 - M17.5	Post-hyphentraumatic osteoarthritis of knee	
M17.9	Osteoarthritis of knee, unspecified	
M19.071 - M19.072	Primary osteoarthritis ankle and foot	
M19.271 - M19.279	Secondary osteoarthritis, ankle and foot	
M19.90 - M19.92	Osteoarthritis, unspecified site [ankle and foot]	
M20.10 - M20.12	Hallux valgus (acquired)	
M20.20 - M20.22	Hallux rigidus	
M20.30 - M20.32	Hallux varus (acquired)	
M20.40 - M20.42	Other hammer toe(s) (acquired)	
M20.5x1 M20.5x9	Other deformities of toe(s) (acquired)	
M20.60 - M20.62	Acquired deformity of toe(s), unspecified	
M21.251 - M21.279	Flexion deformity [hip, knee, ankle and toes]	
M21.40 - M21.42	Flat foot [pes planus] (acquired), [covered for children only]	
M21.611 - M21.629	Other acquired deformities of foot [pronation covered for children only]	
M21.751 - M21.769	Unequal leg length (acquired)	
M21.861 M21.869	Other specified acquired deformities of thigh and lower leg	
M24.571 - M24.576	Contracture, ankle and foot	
M25.371 - M25.373	Other instability, ankle and foot	
M25.771 - M25.776	Osteoophyte, ankle and foot	
M65.80	Other synovitis and tenosynovitis, unspecified site	
M65.871 - M65.879	Other synovitis and tenosynovitis, ankle and foot	
M65.9	Synovitis and tenosynovitis, unspecified	
N18.1 - N18.9	Chronic kidney disease (CKD)	
O22.20 - O22.23	Superficial thrombophlebitis in pregnancy	
O22.30 - O22.33	Deep phlebothrombosis in pregnancy	
O87.1	Deep phlebothrombosis in the puerperium [postpartum]	
Q66.3	Other congenital varus deformities of feet	
Q66.50 - Q66.52	Congenital pes planus	
Q66.6	Other congenital valgus deformities of feet	
Q66.80 - Q66.89	Other congenital deformities of feet	
Q69.2	Accessory toe(s)	

ICD-10 Code	Description	Comments
Q70.20 - Q70.23	Fused toes	
Q70.30 - Q70.33	Webbed toes	
Q74.2	Other congenital malformations of lower limb(s), including pelvic girdle	

HCPCS Level II Code	Description	Comments
G0127	Trimming of dystrophic nails, any number	