Clinical Practice Guideline: **Ankle Foot Orthoses**

Date of Implementation: **February 18, 2016**

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GUIDELINES

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- For ambulatory beneficiaries who require stabilization for medical reasons and have the potential to benefit functionally.

Knee-ankle-foot orthoses (KAFO) described by **HCPCS codes L2000, L2005, L2010, L2020, L2030, L2034, L2035, L2036, L2037, L2038, L2126, L2128, L2132, L2134, L2136, and L4370** are considered medically necessary for ambulatory beneficiaries for whom an ankle-foot orthosis is covered and for whom additional knee stability is required.

Ankle-foot orthoses (AFOs) and knee-ankle-foot orthoses (KAFOs) that are custom-fabricated are covered for ambulatory beneficiaries when the basic coverage criteria listed above and **one** of the following criteria are met:

1. The beneficiary could not be fit with a prefabricated AFO; or
2. The condition necessitating the orthosis is expected to be permanent or of longstanding duration (more than 6 months); or

3. There is a need to control the knee, ankle, or foot in more than one plane; or
4. The beneficiary has a documented neurological, circulatory, or orthopedic status that requires custom fabricating to prevent tissue injury; or
5. The beneficiary has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.

If a custom fabricated orthosis is provided but basic coverage criteria above and the additional criteria 1-5 for a custom fabricated orthosis are not met, the custom fabricated orthosis will be denied as not medically necessary.

B. **HCPCS codes L2180, L2182, L2184, L2186, L2188, L2190, L2192, L2200, L2210, L2220, L2230, L2232, L2240, L2250, L2260, L2265, L2270, L2275, L2280, L2300, L2310, L2320, L2330, L2335, L2340, L2350, L2360, L2370, L2375, L2380, L2385, L2387, L2390, L2395, L2397, L2405, L2415, L2425, L2430, L2492, L2500, L2510, L2520, L2525, L2526, L2530, L2540, L2550, L2750, L2755, L2760, L2768, L2780, L2785, L2795, L2800, L2810, L2820, L2830** (additions to AFOs and KAFOs) will be denied as not medically necessary for ambulatory beneficiaries if either the base orthosis is not medically necessary, or the specific addition is not medically necessary.

II. For AFOs Not Used During Ambulation

A. ASH considers ankle-foot orthoses described by **HCPCS Code L4396 or L4397** to be medically necessary for the treatment of foot and ankle weakness or deformity **IF either all of criteria 1 - 4 *or* criterion 5 is met**:
1. Plantar flexion contracture of the ankle (see ICD-10 Diagnosis Code table below) with dorsiflexion on passive range of motion testing of at least 10 degrees (i.e., a nonfixed contracture); and
2. Reasonable expectation of the ability to correct the contracture; and
3. Contracture is interfering or expected to interfere significantly with the beneficiary's functional abilities; and
4. Used as a component of a therapy program which includes active stretching of the involved muscles and/or tendons; and
5. The beneficiary has plantar fasciitis (see ICD-10 Diagnosis Code table below).

If an L4396 or L4397 is used for the treatment of a plantar flexion contracture, the pre-treatment passive range of motion must be measured with a goniometer and documented in the medical record. There must be documentation of an appropriate stretching program carried out by professional staff (in a nursing facility) or caregiver (at home).

An L4396 or L4397 and replacement interface (L4392) will be denied as not medically necessary if the contracture is fixed. Code L4396, L4397, or L4392 will be denied as not medically necessary for a beneficiary with a foot drop but without an ankle flexion contracture. A component of a static/dynamic AFO that is used to address positioning of the knee or hip will be denied as not medically necessary because the effectiveness of this type of component is not established.

If code L4396 or L4397 is covered, a replacement interface (L4392) is covered as long as the beneficiary continues to meet indications and other coverage rules for the splint. Coverage of a replacement interface is limited to a maximum of one per 6 months. Additional interfaces will be denied as not medically necessary.

ICD-10 Codes and Descriptions Applicable When Medically Necessary

ICD- 10 Code	ICD-10 Code Description
M24.571	Contracture right ankle
M24.572	Contracture left ankle
M24.573	Contracture unspecified ankle
M24.574	Contracture right foot
M24.575	Contracture left foot
M24.576	Contracture unspecified foot
M72.2	Plantar fascial fibromatosis

ASH policy for HCPCS codes are based primarily on Centers for Medicare and Medicaid Services (CMS) coverage policy on Ankle-Foot/Knee-Ankle-Foot Orthoses.

HCPCS Codes and Descriptions

HCPCS Code	HCPC Code Description
L1900	Ankle-foot orthosis (AFO), spring wire, dorsiflexion assist calf band, custom fabricated
L1902	Ankle orthosis (AO), ankle gauntlet or similar, with or without joints, prefabricated, off-the-shelf
L1904	Ankle orthosis (AO), ankle gauntlet or similar, with or without joints, custom fabricated
L1906	Ankle foot orthosis (AFO), multiligamentous ankle support, prefabricated, off-the-shelf
L1907	Ankle orthosis (AO), supramalleolar with straps, with or without interface/pads, custom fabricated
L1910	Ankle-foot orthosis (AFO), posterior, single bar, clasp attachment to shoe counter, prefabricated, includes fitting and adjustment
L1920	Ankle-foot orthosis (AFO), single upright with static or adjustable stop (Phelps or Perlstein type), custom fabricated

HCPCS Code	HCPC Code Description
L1930	Ankle-foot orthosis (AFO), plastic or other material, prefabricated, includes fitting and adjustment
L1932	Ankle-foot orthosis (AFO), rigid anterior tibial section, total carbon fiber or equal material, prefabricated, includes fitting and adjustment
L1933	Ankle foot orthosis, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, off-the-shelf
L1940	Ankle-foot orthosis (AFO), plastic or other material, custom fabricated
L1945	Ankle-foot orthosis (AFO), plastic, rigid anterior tibial section (floor reaction), custom fabricated
L1950	Ankle-foot orthosis (AFO), spiral, (Institute of Rehabilitative Medicine type), plastic, custom fabricated
L1951	Ankle-foot orthosis (AFO), spiral, (Institute of Rehabilitative Medicine type), plastic or other material, prefabricated, includes fitting and adjustment
L1952	Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated, off-the-shelf
L1960	Ankle-foot orthosis (AFO), posterior solid ankle, plastic, custom fabricated
L1970	Ankle-foot orthosis (AFO), plastic with ankle joint, custom fabricated
L1971	Ankle-foot orthosis (AFO), plastic or other material with ankle joint, prefabricated, includes fitting and adjustment
L1980	Ankle-foot orthosis (AFO), single upright free plantar dorsiflexion, solid stirrup, calf band/cuff (single bar 'BK' orthosis), custom fabricated
L1990	Ankle-foot orthosis (AFO), double upright free plantar dorsiflexion, solid stirrup, calf band/cuff (double bar 'BK' orthosis), custom fabricated
L2000	Knee ankle foot orthosis, single upright, free knee, free ankle, solid stirrup, thigh and calf bands/cuffs (single bar 'ak' orthosis), custom fabricated
L2005	Knee ankle foot orthosis, any material, single or double upright, stance control, automatic lock and swing phase release, any type activation, includes ankle joint, any type, custom fabricated
L2010	Knee ankle foot orthosis, single upright, free ankle, solid stirrup, thigh and calf bands/cuffs (single bar 'ak' orthosis), without knee joint, custom fabricated

HCPCS Code	HCPC Code Description
L2020	Knee ankle foot orthosis, double upright, free ankle, solid stirrup, thigh and calf bands/cuffs (double bar 'ak' orthosis), custom fabricated
L2030	Knee ankle foot orthosis, double upright, free ankle, solid stirrup, thigh and calf bands/cuffs, (double bar 'ak' orthosis), without knee joint, custom fabricated
L2034	Knee ankle foot orthosis, full plastic, single upright, with or without free motion knee, medial lateral rotation control, with or without free motion ankle, custom fabricated
L2035	Knee ankle foot orthosis, full plastic, static (pediatric size), without free motion ankle, prefabricated, includes fitting and adjustment
L2036	Knee ankle foot orthosis, full plastic, double upright, with or without free motion knee, with or without free motion ankle, custom fabricated
L2037	Knee ankle foot orthosis, full plastic, single upright, with or without free motion knee, with or without free motion ankle, custom fabricated
L2038	Knee ankle foot orthosis, full plastic, with or without free motion knee, multi-axis ankle, custom fabricated
L2106	Ankle foot orthosis, fracture orthosis, tibial fracture cast orthosis, thermoplastic type casting material, custom fabricated
L2108	Ankle-foot orthosis (AFO), fracture orthosis, tibial fracture cast orthosis, custom fabricated
L2112	Ankle-foot orthosis (AFO), fracture orthosis, tibial fracture orthosis, soft, prefabricated, includes fitting and adjustment
L2114	Ankle-foot orthosis (AFO), fracture orthosis, tibial fracture orthosis, semi-rigid, prefabricated, includes fitting and adjustment
L2116	Ankle-foot orthosis (AFO), fracture orthosis, tibial fracture orthosis, rigid, prefabricated, includes fitting and adjustment
L2126	Knee ankle foot orthosis, fracture orthosis, femoral fracture cast orthosis, thermoplastic type casting material, custom fabricated
L2128	Knee ankle foot orthosis, fracture orthosis, femoral fracture cast orthosis, custom fabricated
L2132	KAFO, fracture orthosis, femoral fracture cast orthosis, soft, prefabricated, includes fitting and adjustment
L2134	KAFO, fracture orthosis, femoral fracture cast orthosis, semi-rigid, prefabricated, includes fitting and adjustment

HCPCS Code	HCPC Code Description
L2136	KAFO, fracture orthosis, femoral fracture cast orthosis, rigid, prefabricated, includes fitting and adjustment
L2180	Addition to lower extremity fracture orthosis, plastic shoe insert with ankle joints
L2182	Addition to lower extremity fracture orthosis, drop lock knee joint
L2184	Addition to lower extremity fracture orthosis, limited motion knee joint
L2186	Addition to lower extremity fracture orthosis, adjustable motion knee joint, Lerman type
L2188	Addition to lower extremity fracture orthosis, quadrilateral brim
L2190	Addition to lower extremity fracture orthosis, waist belt
L2192	Addition to lower extremity fracture orthosis, hip joint, pelvic band, thigh flange, and pelvic belt
L2200	Addition to lower extremity, limited ankle motion, each joint
L2210	Addition to lower extremity, dorsiflexion assist (plantar flexion resist), each joint
L2220	Addition to lower extremity, dorsiflexion and plantar flexion assist/resist, each joint
L2230	Addition to lower extremity, split flat caliper stirrups and plate attachment
L2232	Addition to lower extremity orthosis, rocker bottom for total contact ankle-foot orthosis (AFO), for custom fabricated orthosis only
L2240	Addition to lower extremity, round caliper and plate attachment
L2250	Addition to lower extremity, foot plate, molded to patient model, stirrup attachment
L2260	Addition to lower extremity, reinforced solid stirrup (scott-craig type)
L2265	Addition to lower extremity, long tongue stirrup
L2270	Addition to lower extremity, varus/valgus correction (T) strap, padded/lined or malleolus pad
L2275	Addition to lower extremity, varus/valgus correction, plastic modification, padded/lined
L2280	Addition to lower extremity, molded inner boot

HCPCS Code	HCPC Code Description
L2300	Addition to lower extremity, abduction bar (bilateral hip involvement), jointed, adjustable
L2310	Addition to lower extremity, abduction bar-straight
L2320	Addition to lower extremity, nonmolded lacer, for custom fabricated orthosis only
L2330	Addition to lower extremity, lacer molded to patient model, for custom fabricated orthosis only
L2335	Addition to lower extremity, anterior swing band
L2340	Addition to lower extremity, pretibial shell, molded to patient model
L2350	Addition to lower extremity, prosthetic type, (bk) socket, molded to patient model, (used for 'PTB' 'AFO' orthoses)
L2360	Addition to lower extremity, extended steel shank
L2370	Addition to lower extremity, patten bottom
L2375	Addition to lower extremity, torsion control, ankle joint and half solid stirrup
L2380	Addition to lower extremity, torsion control, straight knee joint, each joint
L2385	Addition to lower extremity, straight knee joint, heavy duty, each joint
L2387	Addition to lower extremity, polycentric knee joint, for custom fabricated knee ankle foot orthosis, each joint
L2390	Addition to lower extremity, offset knee joint, each joint
L2395	Addition to lower extremity, offset knee joint, heavy duty, each joint
L2397	Addition to lower extremity orthosis, suspension sleeve
L2405	Addition to knee joint, drop lock, each
L2415	Addition to knee lock with integrated release mechanism (bail, cable, or equal), any material, each joint
L2425	Addition to knee joint, disc or dial lock for adjustable knee flexion, each joint
L2430	Addition to knee joint, ratchet lock for active and progressive knee extension, each joint

HCPCS Code	HCPC Code Description
L2492	Addition to knee joint, lift loop for drop lock ring
L2500	Addition to lower extremity, thigh/weight bearing, gluteal/ ischial weight bearing, ring
L2510	Addition to lower extremity, thigh/weight bearing, quadri-lateral brim, molded to patient model
L2520	Addition to lower extremity, thigh/weight bearing, quadri-lateral brim, custom fitted
L2525	Addition to lower extremity, thigh/weight bearing, ischial containment/narrow m-l brim molded to patient model
L2526	Addition to lower extremity, thigh/weight bearing, ischial containment/narrow m-l brim, custom fitted
L2530	Addition to lower extremity, thigh-weight bearing, lacer, non-molded
L2540	Addition to lower extremity, thigh/weight bearing, lacer, molded to patient model
L2550	Addition to lower extremity, thigh/weight bearing, high roll cuff
L2750	Addition to lower extremity orthosis, plating chrome or nickel, per bar
L2755	Addition to lower extremity orthosis, high strength, lightweight material, all hybrid lamination/prepreg composite, per segment, for custom fabricated orthosis only
L2760	Addition to lower extremity orthosis, extension, per extension, per bar (for lineal adjustment for growth)
L2768	Orthotic side bar disconnect device, per bar
L2780	Addition to lower extremity orthosis, non-corrosive finish, per bar
L2785	Addition to lower extremity orthosis, drop lock retainer, each
L2795	Addition to lower extremity orthosis, knee control, full kneecap
L2800	Addition to lower extremity orthosis, knee control, knee cap, medial or lateral pull, for use with custom fabricated orthosis only
L2810	Addition to lower extremity orthosis, knee control, condylar pad
L2820	Addition to lower extremity orthosis, soft interface for molded plastic, below knee section

HCPCS Code	HCPC Code Description
L2830	Addition to lower extremity orthosis, soft interface for molded plastic, above knee section
L2999	Lower extremity orthoses, not otherwise specified
L4350	Ankle control orthosis, stirrup style, rigid, includes any type of interface (e.g., pneumatic, gel), prefabricated, off-the-shelf
L4360	Walking boot, pneumatic and/or vacuum, with or without joints, with or without interface material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L4361	Walking boot, pneumatic and/or vacuum, with or without joints, with or without interface material, prefabricated, off-the-shelf
L4370	Pneumatic full leg splint, prefabricated, off-the-shelf
L4386	Walking boot, non-pneumatic, with or without joints, with or without interface material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L4387	Walking boot, non-pneumatic, with or without joints, with or without interface material, prefabricated, off-the-shelf
L4392	Replacement, soft interface material, static AFO
L4396	Static or dynamic ankle-foot orthosis, including soft interface material, adjustable for fit, for positioning, may be used for minimal ambulation, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L4397	Static or dynamic ankle foot orthosis, including soft interface material, adjustable for fit, for positioning, may be used for minimal ambulation, prefabricated, off-the-shelf
L4631	Ankle foot orthosis, walking boot type, varus/valgus correction, rocker bottom, anterior tibial shell, soft interface, custom arch support, plastic or other material, includes straps and closures, custom fabricated

BACKGROUND

Ankle-Foot Orthotics (AFOs)

An AFO extends well above the ankle to the top of the calf. It requires fastening at the lower leg, just above the ankle. This device may be used for ambulatory patients with weakness or deformity of the foot and ankle, which also require stabilization for medical

reasons and when the patient has the potential to benefit functionally from use of the device. Commonly, AFOs are used to treat disorders including but not limited to ankle dorsiflexion, plantar flexion, inversion, and eversion, spastic diplegia due to cerebral palsy, lower motor neuron weakness due to poliomyelitis and spastic hemiplegia in cerebral infarction. Certain neurologic and muscle control conditions such as stroke, neoplasms, hemiplegia, cerebral palsy, myelomeningocele and atrophic or dystrophic conditions may produce lower extremity spasticity or hyperactivity of muscles, hypotonicity of certain muscles and neuromuscular imbalances. Gait functioning, balance and foot/ankle positioning may be impacted. Custom-fitted and custom-molded AFOs are used in ambulatory patients to control or correct foot joints, counteract internal deforming forces, compensate for weakness, correct, or eliminate pathologic positioning, improve balance, improve gait functioning and reduce excessive plantar flexion.

The use of AFOs is one of the most common treatment approaches for ankle-foot weakness or deformity. An orthosis or "orthotic" is an orthopedic appliance or apparatus used to support, align, prevent, or correct deformities or to improve the function of movable parts of the body. Orthoses can either be an over-the-counter orthotic (prefabricated) or a custom device derived from a three-dimensional representation of the member's ankle and foot.

A *custom* fabricated orthosis is one which is individually made for a specific patient starting with basic materials including, but not limited to, plastic, metal, leather, or cloth in the form of sheets, bars, etc. It involves substantial work such as cutting bending, molding, sewing, etc. It may involve the incorporation of some prefabricated components. It involves more than trimming, bending, or making other modifications to a substantially prefabricated item. A molded-to-patient-model orthosis is a particular type of custom fabricated orthosis in which an impression of the specific body part is made by means of impression casting material and this impression is then used to make a positive model (of plaster or other material) of the body part. The orthosis is then molded on this positive model.

A *prefabricated* orthosis is one that is manufactured in quantity without a specific patient in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is assembled from prefabricated components is considered prefabricated. Any orthosis that does not meet the definition of a custom-fabricated (custom-made) orthosis is considered prefabricated.

AFOs extend well above the ankle (usually to near the top of the calf) and are fastened around the lower leg above the ankle. In general, there are three types of ankle foot orthotic devices: passive devices, semiactive devices, and active devices. Passive AFO devices are not comprised of any electrical or electronic elements or any power sources. It may be comprised of mechanical elements like dampers or springs to control the motion of the

ankle-foot complex. Semiactive AFO devices are capable of varying flexibility of the ankle joint by using computer control. Active AFOs contain an onboard power source, a control system, sensors, and actuators. Among these devices, a passive AFO is the most popular daily-wear device due to its compactness, durability, and simplicity of the design. Active and semiactive AFOs have the limited usage only for rehabilitation purpose due to the need of improvement of actuator weight, portable power supply, and general control strategy (Alam et al., 2014). AFOs can be constructed from metal, plastic, leather, synthetic fabrics, or any combination of these materials.

EVIDENCE REVIEW

Stroke and Ankle-Foot Orthoses (AFO)

The main cause of musculoskeletal impairment is the weakness of plantar flexor and dorsiflexor muscles. Plantar flexor muscle weakness would result in reduction of push-off power and elevation in energy cost of patient as most of the power in walking is generated during ankle push-off. Plantar flexor muscles are not frequently affected; therefore, most of the ankle foot orthotic devices are designed for drop-foot prevention. Individuals with dorsal muscle weakness are not capable of lifting the foot adequately in mid-swing due to insufficient dorsiflexion; it results in toe-dragging, lowering walking speed, shortening of step length, elevation in walking metabolism, and high risk of tripping. “Foot-slap” and toe-dragging are the major complications of the patients having dorsiflexor muscle weakness. “Foot-slap” is the uncontrolled and rapid strike of foot on the ground producing distinctive sound at heel strike and “toe-drag” refers to dragging of forefoot during walking due to inadequate ground clearance during swing phase of the gait cycle (Alam et al., 2014).

The traditional treatment for persistent drop foot is an AFO that holds the foot in a neutral position. The most common type of AFO is a solid plastic brace, although it may be made of metal or composite materials, with any number of modifications, including an articulated or hinged ankle joint. In general, AFOs have been found to support ankle dorsiflexion during swing phase and improve knee stability in early stance phase in individuals with drop foot (Kluding et al., 2013). Furthermore, AFOs have been shown to reduce the energy cost of ambulation in a wide variety of conditions (Brehm et al., 2008; Chen et al., 2008).

Van Swigchem et al. (2012) looked at use of an AFO compared to peroneal muscle stimulation during gait with and without an orthotic device. During activities of daily living, often individuals encounter obstacles during walking. For someone with foot drop, these can be dangerous experiences that can lead to falls. This study aimed to identify which intervention is more beneficial with respect to the ability to negotiate a sudden obstacle. Twenty-four community dwelling individuals with hemiplegia post stroke participated in the study. These subjects used AFO bracing consistently. All 24 were fitted with a functional electrical stimulation (FES) device. Obstacle avoidance ability was tested after 2 and 8 weeks. Thirty obstacles needed to be avoided during a treadmill walk. These objects were dropped in front of the affected foot while walking on the treadmill with the

AFO and then repeated with the FES. Obstacle avoidance rates were calculated for each device. Success rates for avoidance were significantly higher among the 24 participants when they used FES compared to when they were wearing the AFO; this was emphasized further when normalized for muscle strength of the lower extremity.

Another study looked at the effects of dynamic AFOs in chronic stroke patients. Erel et al. (2011) completed an RCT with 3 month follow up looking at the long- and short-term effects of AFO use on function of patients with hemiparesis. Twenty-eight patients with chronic hemiparesis were randomly assigned to a study or control group. The control group wore tennis shoes, and the study group wore the dynamic AFO after an initial assessment with tennis shoes. For the initial assessment both groups had no differences between outcome measures. After 3 months of AFO use, the subjects were retested. Timed going up stairs, gait velocity and physiologic cost index (measure of effort), showed significant differences in favor of the study group. Functional reach, timed going up and go, and timed going downstairs did not show differences. Thus, patients with chronic hemiparesis may benefit from using a dynamic AFO.

Tyson and Kent (2013) sought to determine the effectiveness of an AFO on mobility, walking and balance in people with stroke. Randomized controlled trials of AFOs in people with stroke, which measured balance, walking impairments, or mobility and were reported in English, were selected. Thirteen trials with 334 participants were selected. The effect of an AFO on walking activity (P=.000-.001), walking impairment (P=.02), and balance (weight distribution) (P=.003) was significant and beneficial. The effect on postural sway (P=.10) and timed mobility tests (P=.07-.09) was non-significant, and the effect on functional balance was mixed. The selected trials were all crossover trials of the immediate effects; long-term effects are unexplored. Authors concluded that an AFO can improve walking and balance after stroke, but only the immediate effects have been examined. The effects and acceptability of long-term usage need to be evaluated. Tyson et al. (2013) systematically reviewed the evidence on the effects of an AFO on gait biomechanics after stroke. Controlled trials of an ankle-foot orthosis on gait biomechanics in stroke survivors were identified. Twenty trials involving 314 participants were selected. An ankle-foot orthosis had a positive effect on ankle kinematics ($P < 0.00001$-0.0002); knee kinematics in stance phase ($P < 0.0001$-0.01); kinetics ($P = 0.0001$) and energy cost ($P = 0.004$), but not on knee kinematics in swing phase ($P = 0.84$), hip kinematics ($P < 0.18$-0.89) or energy expenditure ($P = 0.43$). There were insufficient data for pooled analysis of individual joint moments, muscle activity or spasticity. All trials, except one, evaluated immediate effects only. Authors concluded that an ankle-foot orthosis can improve the ankle and knee kinematics, kinetics, and energy cost of walking in stroke survivors.

Daryabor et al. (2018) aimed at evaluating the efficacy of different designs of AFOs and comparison between them on the gait parameters of individuals with hemiplegic stroke. A total of 27 articles were found for the final evaluation. All types of AFOs 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. The articulated passive AFO compared with the non-articulated passive AFO had better effects on some aspects of the gait of patients with hemiplegia following stroke, more investigations are needed in this regard though. Authors conclude that an ankle-foot orthosis can immediately improve the dropped foot in the stance and swing phases. The effects of long-term usage and comparison among the different types of AFOs need to be evaluated.

Daryabor et al. (2021) compared the effect of ankle-foot orthosis (AFOs) types on functional outcome measurements in individuals with (sub)acute or chronic stroke impairments. Overall pooled results indicated improvements in favor of AFOs versus without for the Berg Balance Scale, timed-up and go test, Functional Ambulatory Categories, 6-Minute Walking Test, Timed Up-Stairs, and Motricity Index. Heterogeneity was non-significant for all outcomes except the Berg Balance Scale and Functional Ambulatory Categories. Additionally, there was not sufficient evidence to determine the effectiveness of specific orthotic designs over others. Authors concluded that an AFO can improve ambulatory function in stroke survivors. Wearing an AFO in rehabilitation care during the subacute phase post stroke may have beneficial effects on functional outcomes measured.

Choo et al. (2021) conducted a meta-analysis to investigate the effectiveness of ankle-foot orthosis (AFO) use in improving gait biomechanical parameters such as walking speed, mobility, and kinematics in patients with stroke with gait disturbance. Experimental and prospective studies were included that evaluated biomechanics or kinematic parameters with or without AFO in patients with stroke. Gait biomechanical parameters, including walking speed, mobility, balance, and kinematic variables, in studies involving patients with and without AFO use were analyzed. A total of 19 studies including 434 participants that reported on the immediate or short-term effectiveness of AFO use were included in the analysis. Significant improvements in walking speed, cadence, step length, stride length, timed up-and-go test, functional ambulation category (FAC) score, ankle sagittal plane angle at initial contact, and knee sagittal plane angle at toe-off were observed when the patients wore AFOs. Stride time, body sway, and hip sagittal plane angle at toe-off were not significantly improved. Among these results, the FAC score showed the most significant improvement, and stride time showed the lowest improvement. Authors concluded that an AFO improves walking speed, cadence, step length, and stride length, particularly in patients with stroke. AFO is considered beneficial in enhancing gait stability and ambulatory ability.

Johnston et al. (2021) authored a clinical practice guideline (CPG) to provide evidence to guide clinical decision-making for the use of either ankle-foot orthosis (AFO) or functional electrical stimulation (FES) as an intervention to improve body function and structure, activity, and participation as defined by the International Classification of Functioning,

Disability and Health (ICF) for individuals with post stroke hemiplegia with decreased lower extremity motor control. One-hundred twenty-two meta-analyses, systematic reviews, randomized controlled trials, and cohort studies were included. Strong evidence exists that AFO and FES can each increase gait speed, mobility, and dynamic balance. Moderate evidence exists that AFO and FES increase quality of life, walking endurance, and muscle activation, and weak evidence exists for improving gait kinematics. AFO or FES should not be used to decrease plantar flexor spasticity. Studies that directly compare AFO and FES do not indicate overall superiority of one over the other. But evidence suggests that AFO may lead to more compensatory effects while FES may lead to more therapeutic effects. Due to the potential for gains at any phase post stroke, the most appropriate device for an individual may change, and reassessments should be completed to ensure the device is meeting the individual's needs. This CPG cannot address the effects of one type of AFO over another for the majority of outcomes, as studies used a variety of AFO types and rarely differentiated effects. The recommendations also do not address the severity of hemiparesis, and most studies included participants with varied baseline ambulation ability. According to authors, this CPG suggests that AFO and FES both lead to improvements post stroke.

Daryabor et al. (2022) evaluated the efficacy of AFO types and comparison between them on the energy expenditure metrics of walking in individuals who had suffered a stroke with (sub)acute or chronic evolution. A total of 15 trials involving 195 participants were selected for the final evaluation. All trials, except one, examined individuals in chronic phase. Although the evidence from the selected studies was generally weak, the consensus was that an AFO may have a positive immediate effect on the energy expenditure metrics including energy cost, physiological cost index, mechanical work, and vertical center of mass trajectory on the affected leg, in both overground walking and treadmill walking in adults with chronic stroke. There were insufficient studies to evaluate the medium term efficacy of wearing an AFO combined with gait training on metabolic cost parameters during ambulation. There were also insufficient studies for comparison among different designs of AFOs. Authors concluded that an AFO can immediately improve energy expenditure metrics of walking in stroke survivors. There is a need for further well-designed randomized trials to evaluate long-term effect of gait training using AFOs and comparison among the different types of orthoses.

Wada et al. (2022) evaluated whether ankle-foot orthosis (AFO) has a beneficial effect on dorsiflexion angle increase during the swing phase among individuals with stroke and patient-important outcomes in individuals with stroke. Studies reporting on AFO use to improve walking, functional mobility, quality of life, and activity limitations and reports of adverse events in individuals with stroke were included. Fourteen trials that enrolled 282 individuals with stroke and compared AFO with no AFO were included. Compared with no AFO, AFO could increase the dorsiflexion angle of ankle joints during walking; (low certainty of evidence). Furthermore, AFO could improve walking ability (walking speed);

(low certainty of evidence). No study had reported the effects of AFO on quality of life, adverse events, fall frequency, and activities of daily life. Authors concluded that findings suggest that AFO improved ankle kinematics and walking ability in the short term; nonetheless, the evidence was characterized by a low degree of certainty.

Orthotic Management in Cerebral Palsy (CP)

AFOs have long been used for children with spastic CP to assist with gait and function. Taking this a step further, Bahramizadeh et al. (2012) studied whether a specific floor reaction type AFO (FRATO) would actually assist postural control in children with spastic CP. A quasi-experimental design was used to test eight children with spastic CP against eight matched control subjects. Posture control was assessed with and without the brace in a standing position. Centers of pressure (CoP) were measured; standard deviations (SDs) were included as an indication of excursion from center. The greater the lack of postural control, the higher the standard deviation. Velocities of these SDs were also analyzed. It appeared from the data that postural control was not significantly different between groups and therefore the FRATOs did not affect postural control. The authors did note that maximum knee extension was affected by the brace and could potentially positively affect alignment of the knee.

Morris et al. (2011) published a result from an international consensus conference with regards to orthotic management of cerebral palsy. Participants reviewed the evidence and considered how these patients are treated on a day-to-day basis. They determined that many of the papers were of low quality. Of interest is that substantial evidence suggests AFOs which control the ankle and foot within the gait pattern allow for a more efficient gait in those children who are ambulatory. Minimal evidence exists for the use of hip, spine, or upper limb orthoses. Overall, the extent to which orthoses may prevent further deformity was not established. Sees and Miller (2013) reviewed foot deformities and in children with CP and treatments. Authors state that treatment for the young children should be primarily with orthotics and manual therapy. Equinus is the most common deformity, with orthotics augmented with botulinum toxin being the primary management in young children. Varus deformity of the feet is often associated with equinus and can almost always be managed with orthotics until 8 or 10 years of age. Planovalgus is the most common deformity in children with bilateral lower extremity spasticity. The primary management is orthotics until the child no longer tolerates the orthotic; then surgical management needs to consider all the deformities, and all should be corrected.

Aboutorabi et al. (2017) conducted a systematic review of the literature and establish the effect of treatment with various types of AFOs on gait patterns of children with CP. Authors included 17 studies investigating a total of 1,139 children with CP. In general, the use of AFOs improved speed and stride length. The hinged AFO (HAFO) was effective for improving gait parameters and decreasing energy expenditure with hemiplegic CP as compared with the barefoot condition. It also improved stride length, speed of walking,

single limb support and gait symmetry with hemiplegic CP. The plastic solid AFO (SAFO) and floor reaction orthoses (FRO) were effective in reducing energy expenditure with diplegic CP. With diplegic CP, the HAFO and SAFO improved gross motor function. Authors concluded that for children with CP, use of specific types of AFOs improved gait parameters, including ankle and knee range of motion, walking speed and stride length. AFOs reduced energy expenditure in children with spastic CP. However, further studies with better quality are required for more conclusive evidence regarding the effectiveness of AFOs in children with CP.

Lintanf et al. (2018) determined the effects of AFOs on gait, balance, gross motor function and activities of daily living in children with cerebral palsy. Studies of the effect of AFOs on gait, balance, gross motor function and activities of daily living in children with cerebral palsy were included. Articles with a modified PEDro score ≥ 5/9 were selected. Data regarding population, AFO, interventions and outcomes were extracted. When possible, standardized mean differences (SMDs) were calculated from the outcomes. Thirty-two articles, corresponding to 56 studies (884 children) were included. Fifty-one studies included children with spastic cerebral palsy. AFOs increased stride length and gait speed, and decreased cadence. Gross motor function scores improved [Gross Motor Function Measure (GMFM) and Pediatric Evaluation of Disability Inventory (PEDI)]. Data relating to balance and activities of daily living were insufficient to make conclusions. Posterior AFOs (solid, hinged, supra-malleolar, dynamic) increased ankle dorsiflexion at initial contact and during swing, and decreased ankle power generation in stance in children with equinus gait. Authors concluded that for children with spastic cerebral palsy, there is strong evidence that AFOs induce small improvements in gait speed and moderate evidence that AFOs have a small to moderate effect on gross motor function. In children with equinus gait, there is strong evidence that posterior AFOs induce large changes in distal kinematics.

Firouzeh et al. (2019) described research on outcomes associated with early Ankle Foot Orthosis (AFO) use, AFO use patterns, and parent and clinician perspectives on AFO use among young children with cerebral palsy. Nineteen articles were included in the review; 14 focused on body functions and structures, seven on activity level outcomes and no studies addressed participation outcomes. Evaluations of the effects of AFOs on gross motor skills other than gait were limited. Overall, the body of evidence is comprised of methodologically weak studies with common threats to validity including inadequate descriptions of study protocols, AFO construction, and comparison interventions. Authors concluded that research evaluating the effects of AFOs on age-appropriate, functional outcomes including transitional movements, floor mobility and participation in early childhood settings is needed to inform practice regarding early orthotic prescription. Implications for rehabilitation. Lack of rigorous evidence about the effects of AFOs in young children limits the ability of research to guide practice in pediatric rehabilitation.

Skaaret et al. (2019) evaluated changes in gait and impacts of AFOs one-year postoperatively. In all, 33 children with spastic unilateral cerebral palsy (SUCP), 17 girls and 16 boys, mean age 9.2 years (5 to 16.5) were measured by 3D gait analysis walking barefoot preoperatively and walking barefoot and with AFOs one-year postoperatively. Changes in Gait Profile Scores (GPS), kinematic, kinetic, and temporal spatial variables were examined using linear mixed models, with gender, gross motor function and AFO type as fixed effects. The results confirm significant gait improvements in the GPS, kinematics and kinetics walking barefoot one year after surgery. Comparing AFOs with barefoot walking postoperatively, there was additionally reduced ankle plantarflexion by an average of 5.1° and knee flexion by 4.7° at initial contact, enhanced ankle moments during loading response, increased velocity, longer steps, and inhibited push-off power generation. Stance and swing phase dorsiflexion increased in children walking with hinged AFOs versus children walking with ground reaction AFOs. Changes in the non-affected limbs indicated less compensatory gait postoperatively. Authors concluded that major changes were found between pre- and postoperative barefoot conditions. The main impact of AFOs was correction of residual drop foot and improved prepositioning for initial contact, which could be considered as indications for continued use after the one-year follow-up.

Neuromuscular Disorders and Ankle-Foot Orthoses (AFO)

van Duijnhoven et al. (2025) reviewed the evidence for the effects of ankle-foot orthoses (AFOs) for improving walking in adults with calf muscle weakness due to slowly progressive neuromuscular disorders. Authors looked for randomized controlled trials (RCTs), including randomized cross-over studies and quasi-RCTs, and non-randomized studies (NRSs) that examined the effects of AFO interventions compared with shoes-only walking in adults with calf muscle weakness due to neuromuscular disorders. Authors included 4 randomized cross-over studies and 6 NRSs with 186 participants in total (the smallest study had 8 participants and the largest had 37). All studies were designed as self-controlled studies and examined the effects of custom-made and/or prefabricated AFOs. The AFOs were made of carbon (5 studies), polypropylene (5 studies), silicone (1 study), metal (1 study), elastic materials (2 studies), or leather combined with other materials (1 study). Outcome measures with AFOs were assessed during a single session (in some studies, people already used the study AFO in daily life), when the AFO was delivered, or at 3-week or 3-month follow-up. Authors found that carbon AFOs may reduce walking energy cost and may increase walking speed compared to shoes-only walking. They found that leather AFOs may increase walking speed. Little or no effect on walking speed was found with polypropylene AFOs and elastic AFOs. Carbon AFOs may also enhance satisfaction while walking (1 study, 16 participants; low-certainty evidence). They were unable to draw conclusions about perceived walking effort (1 study, 8 participants), balance (2 studies, 21 participants), and AFO use (2 studies, 51 participants), as the evidence is very uncertain. Finally, 2 studies (45 participants) reported on adverse events (low-certainty evidence). Authors concluded that available evidence for ankle-foot

orthoses (AFOs) to improve walking in adults with calf muscle weakness comes from a limited number of small studies with heterogeneity in intervention characteristics and outcome assessment and is of low to very low certainty. The evidence suggests that carbon AFOs may reduce walking energy cost (effort), increase walking speed, and enhance satisfaction, and leather AFOs may increase walking speed, while polypropylene and elastic AFOs may make little or no difference to walking speed. They were unable to draw conclusions about the effects of AFOs on perceived walking effort, balance, and use. Nor can they draw conclusions about adverse effects of using AFOs. The variety in the findings for AFOs made of different materials suggests further investigation is warranted to explore how different AFO materials impact walking improvement in people with calf muscle weakness due to slowly progressive neuromuscular disorders.

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education, training, and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner to determine where they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

It is best practice for the practitioner to appropriately render services to a member only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the member to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice guideline for information.

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