

1 **Clinical Practice Guideline: Ankle Foot Orthoses**

2
3 **Date of Implementation: February 18, 2016**

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5 **Product: Specialty**

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7
8 **GUIDELINES**

9 **I. For ankle-foot orthoses (AFOs) Used During Ambulation**

10
11 A. American Specialty Health – Specialty (ASH) considers ankle-foot orthoses
12 described by **HCPCS Codes L1900 – L1971, L1990, L2108 – L2116, L4350,**
13 **L4360, L4361, and L4386** to be medically necessary for the treatment of foot and
14 ankle weakness or deformity according to the following criteria:

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

17
18 Ankle-foot orthoses (AFOs) and knee-ankle-foot orthoses (KAFOs) that are
19 custom-fabricated are covered for ambulatory beneficiaries when the basic
20 coverage criteria listed above and **one** of the following criteria are met:

- 21 1. The beneficiary could not be fit with a prefabricated AFO; or
- 22 2. The condition necessitating the orthosis is expected to be permanent or of
23 longstanding duration (more than 6 months); or
- 24 3. There is a need to control the knee, ankle, or foot in more than one plane;
25 or
- 26 4. The beneficiary has a documented neurological, circulatory, or orthopedic
27 status that requires custom fabricating to prevent tissue injury; or
- 28 5. The beneficiary has a healing fracture which lacks normal anatomical
29 integrity or anthropometric proportions.

30
31 If a custom fabricated orthosis is provided but basic coverage criteria above and the
32 additional criteria 1-5 for a custom fabricated orthosis are not met, the custom
33 fabricated orthosis will be denied as not medically necessary.

34
35 **B. HCPCS codes L2210, L2220, L2230, L2232, L2250, L2270, L2275, L2280,**
36 **L2320, L2330, L2340, L2360, L2755, L2760, L2275, L2820, and L2840**
37 (additions to AFOs and KAFOs) will be denied as not medically necessary for
38 ambulatory beneficiaries if either the base orthosis is not medically necessary, or
39 the specific addition is not medically necessary.

1 II. For AFOs Not Used During Ambulation

2
3 A. ASH considers ankle-foot orthoses described by **HCPCS Code L4396** to be
4 medically necessary for the treatment of foot and ankle weakness or deformity **IF**
5 **either all of criteria 1 - 4 or criterion 5 is met:**

- 6 1. Plantar flexion contracture of the ankle (see ICD-10 Diagnosis Code table
7 below) with dorsiflexion on passive range of motion testing of at least 10
8 degrees (i.e., a nonfixed contracture); and
9 2. Reasonable expectation of the ability to correct the contracture; and
10 3. Contracture is interfering or expected to interfere significantly with the
11 beneficiary's functional abilities; and
12 4. Used as a component of a therapy program which includes active stretching of
13 the involved muscles and/or tendons; and
14 5. The beneficiary has plantar fasciitis (see ICD-10 Diagnosis Code table below).
15

16 If an L4396 is used for the treatment of a plantar flexion contracture, the pre-
17 treatment passive range of motion must be measured with a goniometer and
18 documented in the medical record. There must be documentation of an appropriate
19 stretching program carried out by professional staff (in a nursing facility) or
20 caregiver (at home).
21

22 An L4396 and replacement interface (L4392/L4394) will be denied as not
23 medically necessary if the contracture is fixed. Code L4396 will be denied as not
24 medically necessary for a beneficiary with a foot drop but without an ankle flexion
25 contracture. A component of a static/dynamic AFO that is used to address
26 positioning of the knee or hip will be denied as not medically necessary because
27 the effectiveness of this type of component is not established.
28

29 If code L4396 is covered, a replacement interface (L4392/L4394) is covered as long
30 as the beneficiary continues to meet indications and other coverage rules for the
31 splint. Coverage of a replacement interface is limited to a maximum of one per 6
32 months. Additional interfaces will be denied as not medically necessary.
33

34 **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

1 ASH policy for ankle-foot orthoses codes L1900-L1971, L1990, L2108 – L2116, L2210,
 2 L2220, L2230, L2232, L2250, L2270, L2275, L2280, L2320, L2330, L2340, L2360,
 3 L2755, L2760, L2820, L4350, L4360, L4361, L4386, L4392 and L4396 are based
 4 primarily on Centers for Medicare and Medicaid Services (CMS) coverage policy on ankle-
 5 foot orthoses.

6
 7

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
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
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
L1960	Ankle-foot orthosis (AFO), posterior solid ankle, plastic, custom fabricated
L1970	Ankle-foot orthosis (AFO), plastic with ankle joint, custom fabricated

HCPCS Code	HCPC Code Description
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
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
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
L2250	Addition to lower extremity, foot plate, molded to patient model, stirrup attachment
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
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

HCPCS Code	HCPC Code Description
L2340	Addition to lower extremity, pretibial shell, molded to patient model
L2360	Addition to lower extremity, extended steel shank
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)
L2820	Addition to lower extremity orthosis, soft interface for molded plastic, below knee section
L2840	Addition to lower extremity orthosis, tibial length sock, fracture or equal, each
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
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
L4392	Replacement, soft interface material, static AFO
L4394	Replace soft interface material, foot drop splint
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
L4398	Foot drop splint, recumbent positioning device, prefabricated, off-the-shelf

1 BACKGROUND

2 Ankle-Foot Orthotics (AFOs)

3 An AFO extends well above the ankle to the top of the calf. It requires fastening at the
4 lower leg, just above the ankle. This device may be used for ambulatory patients with
5 weakness or deformity of the foot and ankle, which also require stabilization for medical
6 reasons and when the patient has the potential to benefit functionally from use of the device.
7 Commonly, AFOs are used to treat disorders including but not limited to ankle
8 dorsiflexion, plantar flexion, inversion, and eversion, spastic diplegia due to cerebral palsy,
9 lower motor neuron weakness due to poliomyelitis and spastic hemiplegia in cerebral
10 infarction. Certain neurologic and muscle control conditions such as stroke, neoplasms,
11 hemiplegia, cerebral palsy, myelomeningocele and atrophic or dystrophic conditions may
12 produce lower extremity spasticity or hyperactivity of muscles, hypotonicity of certain
13 muscles and neuromuscular imbalances. Gait functioning, balance and foot/ankle
14 positioning may be impacted. Custom-fitted and custom-molded AFOs are used in
15 ambulatory patients to control or correct foot joints, counteract internal deforming forces,
16 compensate for weakness, correct, or eliminate pathologic positioning, improve balance,
17 improve gait functioning and reduce excessive plantar flexion.

18
19 The use of AFOs is one of the most common treatment approaches for ankle-foot weakness
20 or deformity. An orthosis or “orthotic” is an orthopedic appliance or apparatus used to
21 support, align, prevent, or correct deformities or to improve the function of movable parts
22 of the body. Orthoses can either be an over-the-counter orthotic (prefabricated) or a custom
23 device derived from a three-dimensional representation of the member’s ankle and foot.

24
25 A *custom* fabricated orthosis is one which is individually made for a specific patient
26 starting with basic materials including, but not limited to, plastic, metal, leather, or cloth in
27 the form of sheets, bars, etc. It involves substantial work such as cutting bending, molding,
28 sewing, etc. It may involve the incorporation of some prefabricated components. It involves
29 more than trimming, bending, or making other modifications to a substantially
30 prefabricated item. A molded-to-patient-model orthosis is a particular type of custom
31 fabricated orthosis in which an impression of the specific body part is made by means of
32 impression casting material and this impression is then used to make a positive model (of
33 plaster or other material) of the body part. The orthosis is then molded on this positive
34 model.

35
36 A *prefabricated* orthosis is one that is manufactured in quantity without a specific patient
37 in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or
38 otherwise modified for use by a specific patient (i.e., custom-fitted). An orthosis that is
39 assembled from prefabricated components is considered prefabricated. Any orthosis that
40 does not meet the definition of a custom-fabricated (custom-made) orthosis is considered
41 prefabricated.

1 AFOs extend well above the ankle (usually to near the top of the calf) and are fastened
2 around the lower leg above the ankle. In general, there are three types of ankle foot orthotic
3 devices: passive devices, semiactive devices, and active devices. Passive AFO devices are
4 not comprised of any electrical or electronic elements or any power sources. It may be
5 comprised of mechanical elements like dampers or springs to control the motion of the
6 ankle-foot complex. Semiactive AFO devices are capable of varying flexibility of the ankle
7 joint by using computer control. Active AFOs contain an onboard power source, a control
8 system, sensors, and actuators. Among these devices, a passive AFO is the most popular
9 daily-wear device due to its compactness, durability, and simplicity of the design. Active
10 and semiactive AFOs have the limited usage only for rehabilitation purpose due to the need
11 of improvement of actuator weight, portable power supply, and general control strategy
12 (Alam et al., 2014). AFOs can be constructed from metal, plastic, leather, synthetic fabrics,
13 or any combination of these materials.

14 **Stroke and Ankle-Foot Orthoses (AFO)**

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

27
28
29 The traditional treatment for persistent drop foot is an AFO that holds the foot in a neutral
30 position. The most common type of AFO is a solid plastic brace, although it may be made
31 of metal or composite materials, with any number of modifications, including an articulated
32 or hinged ankle joint. In general, AFOs have been found to support ankle dorsiflexion
33 during swing phase and improve knee stability in early stance phase in individuals with
34 drop foot (Kluding et al., 2013). Furthermore, AFOs have been shown to reduce the energy
35 cost of ambulation in a wide variety of conditions (Brehm et al., 2008; Chen et al., 2008).

36
37 Van Swigchem et al. (2012) looked at use of an AFO compared to peroneal muscle
38 stimulation during gait with and without an orthotic device. During activities of daily
39 living, often individuals encounter obstacles during walking. For someone with foot drop,
40 these can be dangerous experiences that can lead to falls. This study aimed to identify
41 which intervention is more beneficial with respect to the ability to negotiate a sudden
42 obstacle. Twenty-four community dwelling individuals with hemiplegia post stroke

1 participated in the study. These subjects used AFO bracing consistently. All 24 were fitted
2 with a functional electrical stimulation (FES) device. Obstacle avoidance ability was tested
3 after 2 and 8 weeks. Thirty obstacles needed to be avoided during a treadmill walk. These
4 objects were dropped in front of the affected foot while walking on the treadmill with the
5 AFO and then repeated with the FES. Obstacle avoidance rates were calculated for each
6 device. Success rates for avoidance were significantly higher among the 24 participants
7 when they used FES compared to when they were wearing the AFO; this was emphasized
8 further when normalized for muscle strength of the lower extremity.

9
10 Another study looked at the effects of dynamic AFOs in chronic stroke patients. Erel et al.
11 (2011) completed an RCT with 3 month follow up looking at the long- and short-term
12 effects of AFO use on function of patients with hemiparesis. Twenty-eight patients with
13 chronic hemiparesis were randomly assigned to a study or control group. The control group
14 wore tennis shoes, and the study group wore the dynamic AFO after an initial assessment
15 with tennis shoes. For the initial assessment both groups had no differences between
16 outcome measures. After 3 months of AFO use, the subjects were retested. Timed Up
17 Stairs, gait velocity and physiologic cost index (measure of effort), showed significant
18 differences in favor of the study group. Functional reach and Timed Up and Go and Timed
19 Down Stairs did not show differences. Thus, patients with chronic hemiparesis may benefit
20 from using a dynamic AFO.

21
22 Tyson and Kent (2013) sought to determine the effectiveness of an AFO on mobility,
23 walking and balance in people with stroke. Randomized controlled trials of AFOs in people
24 with stroke, which measured balance, walking impairments, or mobility and were reported
25 in English, were selected. Thirteen trials with 334 participants were selected. The effect of
26 an AFO on walking activity ($P=.000-.001$), walking impairment ($P=.02$), and balance
27 (weight distribution) ($P=.003$) was significant and beneficial. The effect on postural sway
28 ($P=.10$) and timed mobility tests ($P=.07-.09$) was non-significant, and the effect on
29 functional balance was mixed. The selected trials were all crossover trials of the immediate
30 effects; long-term effects are unexplored. Authors concluded that an AFO can improve
31 walking and balance after stroke, but only the immediate effects have been examined. The
32 effects and acceptability of long-term usage need to be evaluated. Tyson et al. (2013)
33 systematically reviewed the evidence on the effects of an AFO on gait biomechanics after
34 stroke. Controlled trials of an ankle-foot orthosis on gait biomechanics in stroke survivors
35 were identified. Twenty trials involving 314 participants were selected. An ankle-foot
36 orthosis had a positive effect on ankle kinematics ($P < 0.00001-0.0002$); knee kinematics
37 in stance phase ($P < 0.0001-0.01$); kinetics ($P = 0.0001$) and energy cost ($P = 0.004$), but
38 not on knee kinematics in swing phase ($P = 0.84$), hip kinematics ($P < 0.18-0.89$) or energy
39 expenditure ($P = 0.43$). There were insufficient data for pooled analysis of individual joint
40 moments, muscle activity or spasticity. All trials, except one, evaluated immediate effects
41 only. Authors concluded that an ankle-foot orthosis can improve the ankle and knee
42 kinematics, kinetics, and energy cost of walking in stroke survivors.

1 Daryabor et al. (2018) aimed at evaluating the efficacy of different designs of AFOs and
2 comparison between them on the gait parameters of individuals with hemiplegic stroke. A
3 total of 27 articles were found for the final evaluation. All types of AFOs had positive
4 effects on ankle kinematic in the first rocker and swing phases, but not on knee kinematics
5 in the swing phase, hip kinematics or the third rocker function. The articulated passive
6 AFO compared with the non-articulated passive AFO had better effects on some aspects
7 of the gait of patients with hemiplegia following stroke, more investigations are needed in
8 this regard though. Authors conclude that an ankle-foot orthosis can immediately improve
9 the dropped foot in the stance and swing phases. The effects of long-term usage and
10 comparison among the different types of AFOs need to be evaluated.

11
12 Daryabor et al. (2021) compared the effect of ankle-foot orthosis (AFOs) types on
13 functional outcome measurements in individuals with (sub)acute or chronic stroke
14 impairments. Overall pooled results indicated improvements in favor of AFOs versus
15 without for the Berg Balance Scale, timed-up and go test, Functional Ambulatory
16 Categories, 6-Minute Walking Test, Timed Up-Stairs, and Motricity Index. Heterogeneity
17 was non-significant for all outcomes except the Berg Balance Scale and Functional
18 Ambulatory Categories. Additionally, there was not sufficient evidence to determine the
19 effectiveness of specific orthotic designs over others. Authors concluded that an AFO can
20 improve ambulatory function in stroke survivors. Wearing an AFO in rehabilitation care
21 during the subacute phase post stroke may have beneficial effects on functional outcomes
22 measured.

23
24 Choo et al. (2021) conducted a meta-analysis to investigate the effectiveness of ankle-foot
25 orthosis (AFO) use in improving gait biomechanical parameters such as walking speed,
26 mobility, and kinematics in patients with stroke with gait disturbance. Experimental and
27 prospective studies were included that evaluated biomechanics or kinematic parameters
28 with or without AFO in patients with stroke. Gait biomechanical parameters, including
29 walking speed, mobility, balance, and kinematic variables, in studies involving patients
30 with and without AFO use were analyzed. A total of 19 studies including 434 participants
31 that reported on the immediate or short-term effectiveness of AFO use were included in
32 the analysis. Significant improvements in walking speed, cadence, step length, stride
33 length, Timed up-and-go test, functional ambulation category (FAC) score, ankle sagittal
34 plane angle at initial contact, and knee sagittal plane angle at toe-off were observed when
35 the patients wore AFOs. Stride time, body sway, and hip sagittal plane angle at toe-off
36 were not significantly improved. Among these results, the FAC score showed the most
37 significant improvement, and stride time showed the lowest improvement. Authors
38 concluded that an AFO improves walking speed, cadence, step length, and stride length,
39 particularly in patients with stroke. AFO is considered beneficial in enhancing gait stability
40 and ambulatory ability.

1 Johnston et al. (2021) authored a clinical practice guideline (CPG) to provide evidence to
2 guide clinical decision-making for the use of either ankle-foot orthosis (AFO) or functional
3 electrical stimulation (FES) as an intervention to improve body function and structure,
4 activity, and participation as defined by the International Classification of Functioning,
5 Disability and Health (ICF) for individuals with post stroke hemiplegia with decreased
6 lower extremity motor control. One-hundred twenty-two meta-analyses, systematic
7 reviews, randomized controlled trials, and cohort studies were included. Strong evidence
8 exists that AFO and FES can each increase gait speed, mobility, and dynamic balance.
9 Moderate evidence exists that AFO and FES increase quality of life, walking endurance,
10 and muscle activation, and weak evidence exists for improving gait kinematics. AFO or
11 FES should not be used to decrease plantar flexor spasticity. Studies that directly compare
12 AFO and FES do not indicate overall superiority of one over the other. But evidence
13 suggests that AFO may lead to more compensatory effects while FES may lead to more
14 therapeutic effects. Due to the potential for gains at any phase post stroke, the most
15 appropriate device for an individual may change, and reassessments should be completed
16 to ensure the device is meeting the individual's needs. This CPG cannot address the effects
17 of one type of AFO over another for the majority of outcomes, as studies used a variety of
18 AFO types and rarely differentiated effects. The recommendations also do not address the
19 severity of hemiparesis, and most studies included participants with varied baseline
20 ambulation ability. According to authors, this CPG suggests that AFO and FES both lead
21 to improvements post stroke.

22
23 Daryabor et al. (2022) evaluated the efficacy of AFO types and comparison between them
24 on the energy expenditure metrics of walking in individuals who had suffered a stroke with
25 (sub)acute or chronic evolution. A total of 15 trials involving 195 participants were selected
26 for the final evaluation. All trials, except one, examined individuals in chronic phase.
27 Although the evidence from the selected studies was generally weak, the consensus was
28 that an AFO may have a positive immediate effect on the energy expenditure metrics
29 including energy cost, physiological cost index, mechanical work, and vertical center of
30 mass trajectory on the affected leg, in both overground walking and treadmill walking in
31 adults with chronic stroke. There were insufficient studies to evaluate the medium term
32 efficacy of wearing an AFO combined with gait training on metabolic cost parameters
33 during ambulation. There were also insufficient studies for comparison among different
34 designs of AFOs. Authors concluded that an AFO can immediately improve energy
35 expenditure metrics of walking in stroke survivors. There is a need for further well-
36 designed randomized trials to evaluate long-term effect of gait training using AFOs and
37 comparison among the different types of orthoses.

38
39 Wada et al. (2022) evaluated whether ankle-foot orthosis (AFO) has a beneficial effect on
40 dorsiflexion angle increase during the swing phase among individuals with stroke and
41 patient-important outcomes in individuals with stroke. Studies reporting on AFO use to
42 improve walking, functional mobility, quality of life, and activity limitations and reports

1 of adverse events in individuals with stroke were included. Fourteen trials that enrolled 282
2 individuals with stroke and compared AFO with no AFO were included. Compared with
3 no AFO, AFO could increase the dorsiflexion angle of ankle joints during walking; (low
4 certainty of evidence). Furthermore, AFO could improve walking ability (walking speed);
5 (low certainty of evidence). No study had reported the effects of AFO on quality of life,
6 adverse events, fall frequency, and activities of daily life. Authors concluded that findings
7 suggest that AFO improved ankle kinematics and walking ability in the short term;
8 nonetheless, the evidence was characterized by a low degree of certainty.

9 10 **Orthotic Management in Cerebral Palsy (CP)**

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

23
24 Morris et al. (2011) published a result from an international consensus conference with
25 regards to orthotic management of cerebral palsy. Participants reviewed the evidence and
26 considered how these patients are treated on a day-to-day basis. They determined that many
27 of the papers were of low quality. Of interest is that substantial evidence suggests AFOs
28 which control the ankle and foot within the gait pattern allow for a more efficient gait in
29 those children who are ambulatory. Minimal evidence exists for the use of hip, spine, or
30 upper limb orthoses. Overall, the extent to which orthoses may prevent further deformity
31 was not established. Sees and Miller (2013) reviewed foot deformities and in children with
32 CP and treatments. Authors state that treatment for the young children should be primarily
33 with orthotics and manual therapy. Equinus is the most common deformity, with orthotics
34 augmented with botulinum toxin being the primary management in young children. Varus
35 deformity of the feet is often associated with equinus and can almost always be managed
36 with orthotics until 8 or 10 years of age. Planovalgus is the most common deformity in
37 children with bilateral lower extremity spasticity. The primary management is orthotics
38 until the child no longer tolerates the orthotic; then surgical management needs to consider
39 all the deformities, and all should be corrected.

1 Aboutorabi et al. (2017) conducted a systematic review of the literature and establish the
2 effect of treatment with various types of AFOs on gait patterns of children with CP. Authors
3 included 17 studies investigating a total of 1,139 children with CP. In general, the use of
4 AFOs improved speed and stride length. The hinged AFO (HAFO) was effective for
5 improving gait parameters and decreasing energy expenditure with hemiplegic CP as
6 compared with the barefoot condition. It also improved stride length, speed of walking,
7 single limb support and gait symmetry with hemiplegic CP. The plastic solid AFO (SAFO)
8 and floor reaction orthoses (FRO) were effective in reducing energy expenditure with
9 diplegic CP. With diplegic CP, the HAFO and SAFO improved gross motor function.
10 Authors concluded that for children with CP, use of specific types of AFOs improved gait
11 parameters, including ankle and knee range of motion, walking speed and stride length.
12 AFOs reduced energy expenditure in children with spastic CP. However, further studies
13 with better quality are required for more conclusive evidence regarding the effectiveness
14 of AFOs in children with CP.

15
16 Lintanf et al. (2018) determined the effects of AFOs on gait, balance, gross motor function
17 and activities of daily living in children with cerebral palsy. Studies of the effect of AFOs
18 on gait, balance, gross motor function and activities of daily living in children with cerebral
19 palsy were included. Articles with a modified PEDro score $\geq 5/9$ were selected. Data
20 regarding population, AFO, interventions and outcomes were extracted. When possible,
21 standardized mean differences (SMDs) were calculated from the outcomes. Thirty-two
22 articles, corresponding to 56 studies (884 children) were included. Fifty-one studies
23 included children with spastic cerebral palsy. AFOs increased stride length and gait speed,
24 and decreased cadence. Gross motor function scores improved [Gross Motor Function
25 Measure (GMFM) and Pediatric Evaluation of Disability Inventory (PEDI)]. Data relating
26 to balance and activities of daily living were insufficient to make conclusions. Posterior
27 AFOs (solid, hinged, supra-malleolar, dynamic) increased ankle dorsiflexion at initial
28 contact and during swing, and decreased ankle power generation in stance in children with
29 equinus gait. Authors concluded that for children with spastic cerebral palsy, there is strong
30 evidence that AFOs induce small improvements in gait speed and moderate evidence that
31 AFOs have a small to moderate effect on gross motor function. In children with equinus
32 gait, there is strong evidence that posterior AFOs induce large changes in distal kinematics.

33
34 Firouzeh et al. (2019) described research on outcomes associated with early Ankle Foot
35 Orthosis (AFO) use, AFO use patterns, and parent and clinician perspectives on AFO use
36 among young children with cerebral palsy. Nineteen articles were included in the review;
37 14 focused on body functions and structures, seven on activity level outcomes and no
38 studies addressed participation outcomes. Evaluations of the effects of AFOs on gross
39 motor skills other than gait were limited. Overall, the body of evidence is comprised of
40 methodologically weak studies with common threats to validity including inadequate
41 descriptions of study protocols, AFO construction, and comparison interventions. Authors
42 concluded that research evaluating the effects of AFOs on age-appropriate, functional

1 outcomes including transitional movements, floor mobility and participation in early
2 childhood settings is needed to inform practice regarding early orthotic prescription.
3 Implications for rehabilitation. Lack of rigorous evidence about the effects of AFOs in
4 young children limits the ability of research to guide practice in pediatric rehabilitation.

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

24 **PRACTITIONER SCOPE AND TRAINING**

25
26 Practitioners should practice only in the areas in which they are competent based on their
27 education, training, and experience. Levels of education, experience, and proficiency may
28 vary among individual practitioners. It is ethically and legally incumbent on a practitioner
29 to determine where they have the knowledge and skills necessary to perform such services
30 and whether the services are within their scope of practice.

31
32 It is best practice for the practitioner to appropriately render services to a member only if
33 they are trained, equally skilled, and adequately competent to deliver a service compared
34 to others trained to perform the same procedure. If the service would be most competently
35 delivered by another health care practitioner who has more skill and training, it would be
36 best practice to refer the member to the more expert practitioner.

37
38 Best practice can be defined as a clinical, scientific, or professional technique, method, or
39 process that is typically evidence-based and consensus driven and is recognized by a
40 majority of professionals in a particular field as more effective at delivering a particular
41 outcome than any other practice (Joint Commission International Accreditation Standards
42 for Hospitals, 2020).

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

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