

# Ankle-Foot Orthoses (AFOs), Knee-Ankle-Foot Orthoses (KAFOs), and Hip-Knee-Ankle-Foot Orthoses (HKAFOs)

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## Introduction

Lower extremity orthoses (braces) covered in this guideline include: ankle-foot orthoses (AFOs), knee-ankle-foot orthoses (KAFOs), and hip-knee-ankle-foot orthoses (HKAFOs).

## Criteria

### Non-ambulatory or Minimally Ambulatory Individuals:

A **static or dynamic positioning ankle-foot orthosis (AFO)** (HCPCS L4396, L4397, L4392) is medically necessary for a non-ambulatory or minimally ambulatory individual if **either** of the following apply:

- There is documentation of **all** of the following:
  - The individual has a plantar flexion contracture, which causes the foot to point either forward or downward due to tight muscles and tendons. The individual has at least 10 degrees of upward movement at the ankle, which indicates it is possible to correct the non-fixed contracture.
  - The contracture is causing or is projected to cause disruption to the individual's function or the condition of their skin.
  - The static or dynamic positioning brace is used along with active stretching of the affected muscles and/or tendons.
- The individual has plantar fasciitis, which is an inflammatory condition of the thick band of tissue that runs from the heel bone to the toes.

### Ambulatory Individuals

A **pre-fabricated ankle-foot orthosis (AFO)** HCPCS L1902, L1906, L1910, L1930, L1932, L1933, L1951, L1952, L1971, L2112, L2114, L2116, L4350, L4360, L4361, L4386, L4387) is medically necessary in an ambulatory individual when **all** of the following apply:

- The individual can walk, but they encounter muscular weakness or structural abnormalities in the lower extremities, specifically the foot or ankle.
- Stabilizing the individual's foot or ankle is necessary for medical reasons.
- The individual's function will be improved by using the brace.

An **ankle-foot orthosis (AFO)** (HCPCS L1900, L1902, L1904, L1906, L1907, L1910, L1920, L1930, L1932, L1940, L1945, L1950, L1951, L1960, L1970, L1971, L1980, L1990, L2106, L2108, L2112, L2114, L2116, L4350, L4360, L4361, L4386, L4387, L4631) is medically necessary in an ambulatory **individual (≤18 years of age)** when **both** of the following apply:

- The individual can walk, but they have muscular weakness or structural abnormalities in the lower extremities, specifically the foot or ankle.
- The individual's function will be improved by using the brace.

A **prefabricated knee-ankle-foot orthosis (KAFO)** (HCPCS L2035, L2132, L2134, L2136, L4370) is medically necessary in an ambulatory individual when **all** of the following apply:

- The individual can walk, but they have muscular weakness or structural abnormalities in the lower extremities, specifically the foot or ankle.
- Stabilizing the individual's knee in addition to the foot or ankle is necessary for medical reasons.
- The individual's function will be improved by using the brace.

A **hip-knee-ankle-foot orthosis (HKAFO)** (HCPCS L2040, L2050, L2060, L2070, L2080, L2090) is medically necessary for an ambulatory individual when the individual meets criteria for a custom-fabricated orthosis and **all** of the following apply:

- The individual has hip weakness or deformity.
- Stabilizing the individual's hip in addition to the knee, foot or ankle is necessary for medical reasons.
- The individual's function will be improved by using the brace.

A **custom-fabricated AFO, KAFO or HKAFO** (HCPCS L1900, L1904, L1907, L1920, L1940, L1945, L1950, L1960, L1970, L1980, L1990, L2000, L2005, L2010, L2020, L2030, L2034, L2036, L2037, L2038, L2040, L2050, L2060, L2070, L2080, L2090, L2106, L2108, L2126, L2128, L4631) is medically necessary in an ambulatory individual when the basic criteria listed above for the AFO, KAFO, or HKAFO is met including **any** of the following criteria:

- The individual is unable to be fitted with a pre-made brace.
- The condition requiring the brace is anticipated to be permanent or of long-standing duration beyond six months.

- It is necessary to manage the movement of the knee, ankle, or foot in several directions.
- The individual has a medical condition that necessitates the creation of a custom-made brace to avoid damage to the tissues.
- The individual has a fractured bone that is mending, but the shape of the bone is not typical, and the brace will help stabilize the bone.

## Replacement Criteria

- Same or Similar Durable Medical Equipment
  - Duplication of the same or similar orthoses within the same case is not medically necessary.
- A replacement orthosis is medically necessary when **all** of the following apply:
  - The individual has been seen recently by their provider and has a documented care plan that includes the use of the brace.
  - There is clinical documentation of **any** of the following:
    - The individual is no longer able to wear the brace because of growth or a change in physical condition.
    - The brace has been lost or stolen.
    - The brace is broken, unable to be repaired, and no longer under warranty.

## Not Covered

- Additions to AFOs, KAFOs, or HKAFOs are considered not medically necessary if either the base orthosis is not medically necessary, or the specific addition is not medically necessary.
- AFOs, KAFOs, or HKAFOs and any related addition are considered not medically necessary when used solely for the treatment of edema and/or for the prevention or treatment of a heel pressure ulcer in ambulatory individuals.
- A foot drop splint/recumbent positioning device (HCPCS L4398) or replacement interface (HCPCS L4394) will be denied as not reasonable and necessary in an individual with foot drop who is nonambulatory because there are other more appropriate treatment modalities. The treatment plan is based on the etiology of the foot drop and the localization of the lesion. Potential treatment options may include but are not limited to: splinting and braces used in conjunction with physical therapy to maintain the foot in a neutral position during ambulation, functional electrical stimulation, botulinum toxin, or surgical intervention for preservation of nerve function.
- Tape and wrapping do not meet the durability requirement for covered durable medical equipment (DME), in that they are not reusable and are not made to withstand prolonged use.

- AFOs and KAFOs are not considered medically necessary treatment of disease when used to prevent injury. In these cases, the use is deemed solely preventive, and therefore is considered not medically necessary treatment of a disease or injury.
- Ankle foot orthoses (AFOs) are considered experimental, investigational, or unproven for treatment of osteoarthritis of the knee because their effectiveness for this indication has not been established.
- Elastic or other fabric support garments (HCPCS A4467) with or without stays or panels do not meet the definition of a brace because they are not rigid or semi-rigid devices.

## Definitions

- An **orthosis** (brace) is a rigid or semi-rigid device used for the purpose of supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body. An orthosis can be classified as either prefabricated (off-the-shelf), custom-fitted, or custom-fabricated.
- A **pre-fabricated orthosis** can be used for individuals requiring only minimal self-adjustment. A pre-fabricated orthosis can also be custom-fitted by a certified orthotist or individual with specialized training. Prefabricated orthoses are available in multiple sizes and can be adjusted to accommodate an individual's functional and anatomical needs.
- An **off-the-shelf (OTS) orthosis** is a prefabricated item that may or may not be supplied as a kit that requires some assembly. OTS items require minimal self-adjustment for fitting at the time of delivery for appropriate use and do not require expertise in trimming, bending, and molding, assembling, or customizing to fit an individual. This fitting does not require expertise of a certified orthotist or an individual who has specialized training in the provision of orthoses to fit the item to the individual.
- A **custom fitted orthosis** is prefabricated and may or may not be supplied as a kit that requires some assembly. Custom fitting can include trimming, bending, or molding of the prefabricated orthoses beyond minimal self-adjustment. This fitting at delivery requires the expertise of a certified orthotist or an individual who has specialized training in the provision of the orthosis to fit the item to the individual.
- A **custom-fabricated orthosis** is made for a specific individual based on clinically-derived castings, tracings, molds, or images of the body part. Custom fabrication may be appropriate when specific fit issues are unable to be addressed by adjusting a prefabricated brace or orthosis (e.g., cutting, bending, adding extra straps). Custom-fabricated additions are appropriate only for custom-fabricated orthoses and should not be billed with prefabricated orthoses.

- A **molded-to-patient-model** is a particular type of custom-fabricated device in which either: an impression (usually by means of a plaster or fiberglass cast) of the specific body part is made directly on the individual, and this impression is then used to make a positive model of the body part from which the final product is crafted; or a digital image of the individual's body part is made using computer-aided design/ computer-aided manufacturing (CAD/CAM) systems software. This technology includes specialized probes/digitizers and scanners that create a computerized positive model, and then direct milling equipment to carve a positive model. The device is then individually fabricated and molded over the positive model.
- A **positive model** is an exact replica of the actual body part for which the custom-fabricated orthosis is being constructed. Fabrication of an orthosis using molding, CAD/CAM, or similar technology without the creation of a positive model is considered to be a prefabricated orthosis.
- **Plantar fasciitis** is a clinical diagnosis characterized by pain in the plantar heel and local point tenderness near the origin of the plantar fascia at the medial tuberosity of the calcaneum.
- A **pressure injury** occurs when pressure from a bony prominence or a medical device causes localized damage to the skin and underlying soft tissue. Heel pressure injuries are common in diabetic individuals who experience peripheral neuropathy, as well as in individuals who require bracing or casting of the feet or ankles due to injury or surgery.
- **Foot drop** is defined as a weakness of the dorsiflexors of the foot, and manifests in an inability to lift the forefoot. This often leads to an unsafe antalgic gait, and can result in falls. The etiology of foot drop may stem from neurologic disorders, compressive disorders, or traumatic injuries. AFOs can be used to prevent plantarflexion and improve gait for safe ambulation.

## Evidence Discussion

### Medical Background

The United States Food and Drug Administration (FDA) considers AFOs, KAFOs, and HKAFOs to be Class I devices. As such, they are considered to be low to moderate risk, and manufacturers are not required to complete pre-market notification or seek pre-market approval for these items (FDA, 2024).

### Literature Review

- Tyson and Kent (2013) performed a systematic review and meta-analysis to determine the effectiveness of an AFO on mobility, walking, and balance in post-stroke individuals. Thirteen randomized trials with 334 participants were selected. The authors reported a significant and beneficial effect of AFO use on walking and

balance. The effect on postural sway and timed mobility tests was not significant, and the effect on functional balance was mixed. Thus, the investigators concluded that an AFO can improve walking and balance after stroke. However, the authors noted that further research is needed regarding long-term usage.

- A 2021 systematic review and meta-analysis reported by Choo and Chang examined the effectiveness of AFO use in improving gait biomechanical parameters such as walking speed, mobility, and kinematics in post-stroke individuals with gait disturbance. A total of 19 studies, including 434 subjects, which reported on the immediate or short-term effectiveness of AFO use were included in the analysis. The data indicated that AFO use improved walking speed, cadence, step length, and stride length, most notably in post-stroke individuals. Thus, the authors concluded that an AFO is considered beneficial in enhancing gait stability and ambulatory ability in post-stroke individuals.
- Cooke et al. (2009) performed a randomized controlled trial to evaluate the effectiveness of a below knee cast, Aircast®, Bledsoe® boot, or double layer tubular compression for the treatment of severe ankle sprains. Five hundred eighty-four participants ages 16 years and older with an ankle sprain and an inability to bear weight were randomized to one of four treatment arms: tubular bandage, below knee cast, Aircast® ankle brace, or Bledsoe® boot, all applied two to three days after presentation to allow swelling to resolve. Although the results indicated a small statistically significant benefit at four weeks with the below knee cast, and at 12 weeks for the below knee cast and Aircast® in comparison to the compression bandage, no significant differences were noted between the casting or braces and tubular compression for any outcome measures at nine months. Thus, the authors concluded no differences in long-term outcomes were identified between the treatments.
- A 2021 study performed by Barkocy et al. examined the effectiveness of serial casting and AFOs in five children with autism spectrum disorder who toe walk. Five participants increased passive range of motion with serial casting. In addition, following serial casting two of four participants regained near typical ankle dorsiflexion. Following six months of AFO use, all five participants improved ankle dorsiflexion during walking. Thus, the authors recommended serial casting followed by AFO use as a potential intervention for children with autism spectrum disorder who toe walk.
- Aboutorabi et al. (2017) conducted a systematic review to determine the effectiveness of treatment with various types of AFOs on gait pattern in cerebral palsy (CP). Seventeen studies (four randomized controlled trials) investigating a total of 1,139 children with CP wearing the following AFOs: hinged (HAFO), solid (SAFO), floor reaction, posterior leaf spring, and dynamic. The authors reported that the HAFO improved stride length, speed of walking, single limb support and gait symmetry, and decreased energy expenditure with hemiplegic CP as compared with the barefoot condition. Moreover, in participants with diplegic CP,

the HAFO and SAFO improved gross motor function. Thus, the authors concluded that the available evidence demonstrated that use of an HAFO or SAFO improved motor function in children with CP.

#### Professional organizations/societies:

- A 2021 clinical practice guideline (CPG) reported by Johnston et al. provided evidence to guide clinical decision-making for the use of either 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 and decreased lower extremity motor control. A total of 122 meta-analyses, systematic reviews, randomized controlled trials, and cohort studies were included. The guideline reported strong evidence indicating that AFO and FES increased gait speed, mobility, and dynamic balance. In addition, the guideline reported moderate evidence that AFO and FES increased quality of life, walking endurance, and muscle activation. In summary, the authors concluded that AFO and FES both resulted in functional improvements post-stroke.

#### Codes included

The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

| HCPCS Description |                                                                                                 |
|-------------------|-------------------------------------------------------------------------------------------------|
| A4467             | Belt, strap, sleeve, garment, or covering, any type                                             |
| E1815             | Dynamic adjustable ankle extension/flexion device, includes soft interface material             |
| L1900             | Ankle foot orthosis, spring wire, dorsiflexion assist calf band, custom fabricated              |
| L1902             | Ankle orthosis, ankle gauntlet or similar, with or without joints, prefabricated, off-the-shelf |
| L1904             | Ankle orthosis, ankle gauntlet or similar, with or without joints, custom fabricated            |

| HCP   | CS | Description                                                                                                                                                                                                                                               |
|-------|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| L1906 |    | Ankle foot orthosis, multiligamentous ankle support, prefabricated, off-the-shelf                                                                                                                                                                         |
| L1907 |    | Ankle orthosis, supramalleolar with straps, with or without interface/pads, custom fabricated                                                                                                                                                             |
| L1910 |    | Ankle foot orthosis, posterior, single bar, clasp attachment to shoe counter, prefabricated, includes fitting and adjustment                                                                                                                              |
| L1920 |    | Ankle foot orthosis, single upright with static or adjustable stop (Phelps or Perlstein type), custom fabricated                                                                                                                                          |
| L1930 |    | Ankle foot orthosis, plastic or other material, prefabricated, includes fitting and adjustment                                                                                                                                                            |
| L1932 |    | Ankle foot orthosis, rigid anterior tibial section, total carbon fiber or equal material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise            |
| L1933 |    | Ankle foot orthosis, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, off-the-shelf                                                                                                                                    |
| L1940 |    | Ankle foot orthosis, plastic or other material, custom fabricated                                                                                                                                                                                         |
| L1945 |    | Ankle foot orthosis, plastic, rigid anterior tibial section (floor reaction), custom fabricated                                                                                                                                                           |
| L1950 |    | Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic, custom fabricated                                                                                                                                                      |
| L1951 |    | Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise |
| L1952 |    | Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated, off-the-shelf                                                                                                                         |
| L1960 |    | Ankle foot orthosis, posterior solid ankle, plastic, custom fabricated                                                                                                                                                                                    |
| L1970 |    | Ankle foot orthosis, plastic with ankle joint, custom fabricated                                                                                                                                                                                          |

| HCP   | CS | Description                                                                                                                                                                                      |
|-------|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| L1971 |    | Ankle foot orthosis, plastic or other material with ankle joint, with or without dorsiflexion assist, prefabricated, includes fitting and adjustment                                             |
| L1980 |    | Ankle foot orthosis, single upright free plantar dorsiflexion, solid stirrup, calf band/cuff (single bar 'bk' orthosis), custom fabricated                                                       |
| L1990 |    | Ankle foot orthosis, 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                                |
| 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                                                   |

| HCP   | CS | Description                                                                                                                           |
|-------|----|---------------------------------------------------------------------------------------------------------------------------------------|
| L2038 |    | Knee ankle foot orthosis, full plastic, with or without free motion knee, multi-axis ankle, custom fabricated                         |
| L2040 |    | Hip knee ankle foot orthosis, torsion control, bilateral rotation straps, pelvic band/belt, custom fabricated                         |
| L2050 |    | Hip knee ankle foot orthosis, torsion control, bilateral torsion cables, hip joint, pelvic band/belt, custom fabricated               |
| L2060 |    | Hip knee ankle foot orthosis, torsion control, bilateral torsion cables, ball bearing hip joint, pelvic band/ belt, custom fabricated |
| L2070 |    | Hip knee ankle foot orthosis, torsion control, unilateral rotation straps, pelvic band/belt, custom fabricated                        |
| L2080 |    | Hip knee ankle foot orthosis, torsion control, unilateral torsion cable, hip joint, pelvic band/belt, custom fabricated               |
| L2090 |    | Hip knee ankle foot orthosis, torsion control, unilateral torsion cable, ball bearing hip joint, pelvic band/ belt, custom fabricated |
| L2106 |    | Ankle foot orthosis, fracture orthosis, tibial fracture cast orthosis, thermoplastic type casting material, custom fabricated         |
| L2108 |    | Ankle foot orthosis, fracture orthosis, tibial fracture cast orthosis, custom fabricated                                              |
| L2112 |    | Ankle foot orthosis, fracture orthosis, tibial fracture orthosis, soft, prefabricated, includes fitting and adjustment                |
| L2114 |    | Ankle foot orthosis, fracture orthosis, tibial fracture orthosis, semi-rigid, prefabricated, includes fitting and adjustment          |
| L2116 |    | Ankle foot orthosis, 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   |

| HCP   | CS | Description                                                                                                                                                                                                                                                                                             |
|-------|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                                                                                                                                                     |
| L2136 |    | KAFO, fracture orthosis, femoral fracture cast orthosis, rigid, prefabricated, includes fitting and adjustment                                                                                                                                                                                          |
| L2999 |    | Lower extremity orthoses, not otherwise specified                                                                                                                                                                                                                                                       |
| L4350 |    | Ankle control orthosis, stirrup style, rigid, includes any type 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                                                                                                                                                                                                                                                        |
| 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 |

| HCP   | Description                                                                                                                                                                                                            |
|-------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                        |
| L4398 | Foot drop splint, recumbent positioning device, 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 |

## References

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