Anthem

Clinical UM Guideline

Subject: Ankle-Foot & Knee-Ankle-Foot Orthoses
Guideline #: CG-DME-22
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Description

This document addresses orthoses for the ankle-foot or the knee-ankle-foot. The purpose of an orthosis (rigid or semi-rigid brace) is to support a weak or deformed body part, or to restrict or eliminate motion in a diseased or injured part of the body.

Note: Please see the following related documents for additional information:

- CG-DME-19 Therapeutic Shoes, Inserts or Modifications for Individuals with Diabetes
- CG-DME-20 Orthopedic Footwear
- CG-OR-PR-02 Prefabricated and Prophylactic Knee Braces
- CG-OR-PR-03 Custom-made Knee Braces
- CG-OR-PR-09 Microprocessor Controlled Knee-Ankle-Foot Orthosis
- SURG.00104 Extraosseous Subtalar Joint Implantation and Subtalar Arthroereisis

Clinical Indications

Medically Necessary:

An ankle-foot orthosis (AFO) is considered **medically necessary** for ambulatory (i.e., able to walk, independently or with assistance) individuals with weakness or deformity of the foot and ankle who require stabilization for medical reasons and have the potential to benefit functionally.

Knee-ankle-foot orthoses (KAFOs) are considered **medically necessary** for ambulatory individuals for whom an ankle-foot orthosis is appropriate and additional knee stability is required.

AFOs and KAFOs that are custom-fabricated are considered **medically necessary** for ambulatory individuals when medically necessary criteria are otherwise met and ***one or more*** of the following criteria are met:

1. The individual 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 individual has a documented neurological, circulatory, or orthopedic status that requires custom fabricating over a model to prevent tissue injury; **or**
5. The individual has a healing fracture which lacks normal anatomical integrity or anthropometric proportions.

Walking boots used to provide immobilization as treatment for an orthopedic condition or after orthopedic surgery are considered **medically necessary.**

A static AFO is considered **medically necessary** for non-ambulatory individuals if ***all*** of the following criteria are met:

1. Plantar flexion contracture of the ankle with dorsiflexion on passive range of motion testing of at least 10 degrees (that is, a non-fixed contracture); **and**
2. Reasonable expectation of the ability to correct or prevent a fixed contracture in those who may become ambulatory; **and**
3. Contracture is interfering or expected to interfere significantly with the individual's functional abilities; **and**
4. Used as a component of a therapy program that includes passive stretching of the involved muscles or tendons.

If a static AFO 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).

Not Medically Necessary:

AFOs and KAFOs are considered **not medically necessary** if the above criteria are not met and for all other indications, including but not limited to the following:

1. Used solely for the treatment of edema; **or**
2. Used for the prevention or treatment of a heel pressure ulcer; **or**
3. Used for a fixed contracture; **or**
4. Used for foot drop but without an ankle flexion contracture.

Walking boots used primarily to relieve pressure, especially on the sole of the foot, or used for individuals with foot ulcers are considered **not medically necessary**.

A component of a static AFO that is used to address positioning of the knee or hip in a non-ambulatory individual is considered **not medically necessary.**

A foot drop splint/recumbent positioning device and replacement interface is considered **not medically necessary** when it is used solely for the prevention or treatment of a heel pressure ulcer because this does not meet the definition of a brace.

A foot drop splint/recumbent positioning device and replacement interface is considered **not medically necessary** in an individual with foot drop who is non-ambulatory.

Repairs and/or Replacement

Medically Necessary:

Repairs to medically necessary AFOs and KAFOs, due to wear or damage, are considered**medically necessary** when they are necessary to make the AFO or KAFO functional.

Replacement of an AFO or KAFO or component of an AFO or KAFO due to loss, significant change in the individual's condition*, or irreparable damage is considered **medically necessary** if the device is still medically necessary.

* This may include significant growth in a child or adolescent, major weight loss or gain, or other body changes that result in poor prosthetic fit or function.

Not Medically Necessary:

Replacement components (for example, soft interfaces) that are provided on a routine basis without regard to whether the original item is worn out are considered **not medically necessary.**

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

HCPCS	
L1900-L1990	Ankle-foot orthoses (AFO) [includes prefabricated orthoses codes L1902, L1906, L1910, L1930, L1932, L1951, L1971; custom fabricated orthoses codes L1900, L1904, L1907, L1920, L1940, L1945, L1950, L1960, L1970, L1980, L1990]
L2000-L2038	Knee-ankle-foot orthoses (KAFO) [includes prefabricated orthoses code L2035; custom fabricated orthoses codes L2000, L2005, L2010, L2020, L2030, L2034, L2036, L2037, L2038]
L2106-L2116	AFO, fracture orthoses [includes prefabricated orthoses codes L2112, L2114, L2116; custom fabricated orthoses codes L2106, L2108]
L2126-L2136	KAFO, fracture orthoses [includes prefabricated orthoses codes L2132, L2134, L2136; custom fabricated orthoses codes L2126. L2128]
L2180-L2192	Additions to lower extremity fracture orthoses [includes codes L2180, L2182, L2184, L2186, L2188, L2190, L2192]
L2200-L2397	Additions to lower extremity orthoses (shoe-ankle-shin-knee) [includes codes 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-L2492	Additions to knee joint [includes codes L2405, L2415, L2425, L2430, L2492]
L2500-L2550	Additions to lower extremity, thigh/weight bearing [includes codes L2500, L2510, L2520, L2525, L2526, L2530, L2540, L2550]
L2570-L2830	Addition to lower extremity orthoses (general) [includes codes L2570, L2580, L2600, L2610, L2620, L2622, L2624, L2627, L2628, L2630, L2640, L2650, L2660, L2670, L2680, L2750, L2755, L2760, L2768, L2780, L2785, L2795, L2800, L2810, L2820, L2830]
L2861	Addition to lower extremity joint, knee or ankle, concentric adjustable torsion style mechanism for custom fabricated orthotics only, each
L2999	Lower extremity orthosis, not otherwise specified
L4002-L4130	Replacements (specific repairs) [includes codes L4002, L4010, L4020, L4030, L4040, L4045, L4050, L4055, L4060, L4070, L4080, L4090, L4100, L4110, L4130]
L4350	Ankle control orthosis, stirrup style, rigid, includes any type interface (eg, pneumatic gel), prefabricated, includes fitting and adjustment
L4360	Walking boot, pneumatic and/or vacuum, with or without joints, with or without interface material, prefabricated, includes fitting and adjustment
L4386	Walking boot, non-pneumatic, with or without joints, with or without interface material, prefabricated, includes fitting and adjustment
L4392-L4394	Replacement, soft interface material [includes codes L4392, L4394]
L4396	Static or dynamic ankle foot orthosis, including soft interface material, adjustable for fit, for positioning, may be used for minimal ambulation, prefabricated, includes fitting and adjustment
L4398	Foot drop splint, recumbent positioning device, prefabricated, includes fitting and adjustment
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

ICD-10 Diagnosis	
	All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

A non-ambulatory ankle-foot orthosis may be either an ankle contracture splint or a foot drop splint.

A **static AFO** is a prefabricated ankle-foot orthosis that has all of the following characteristics:

1. Designed to accommodate an ankle with a plantar flexion contracture up to 45°; and
2. Applies a dorsiflexion force to the ankle; and
3. Allows pressure reduction; and
4. Has a soft interface.

A **foot drop splint/recumbent positioning device** is a prefabricated ankle-foot orthosis that has all of the following characteristics:

1. Designed to maintain the foot at a fixed position of zero degrees (that is, perpendicular to the lower leg); and

2. Not designed to accommodate an ankle with a plantar flexion contracture; and
3. Used by an individual who is non-ambulatory; and
4. Has a soft interface.

A clinical practice guideline published in 2021 from the American Physical Therapy Association (APTA) and the Academy of Neurologic Physical Therapy (ANPT), addressed AFO and functional electrical stimulation (FES) post-stroke. Based on a review of published literature, the guideline had the following conclusions:

> 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 plantarflexor 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.

Meta-analyses of published literature have found that AFOs significantly improve walking-related outcome measures (e.g. walking speed, stride length and timed walking distance) in ambulatory children with cerebral palsy (Betancourt, 2019; Lintanf, 2018). Meta-analyses have had mixed findings regarding the impact of AFOs in individuals who have had strokes. Several meta-analyses (Choo, 2021, Nascimento, 2020; Prenton, 2020) found positive impacts of AFOs on walking outcomes in individuals after stroke. However, Shahabi (2020) did not find a significant positive impact of AFOs on walking speed in individuals after stroke, and Daryabor (2021) did not find that AFO use significantly improved results of the 6-minute walking or Time up-Stairs tests.

Definitions

Ankle flexion contracture: A condition in which there is shortening of the muscles or tendons that plantar-flex the ankle with the resulting inability to bring the ankle to zero degrees by passive range of motion (zero degrees ankle position is when the foot is perpendicular to the lower leg).

Ankle-foot orthoses (AFOs): These extend well above the ankle (usually to near the top of the calf) and are fastened around the lower leg above the ankle. These features distinguish them from foot orthoses which are shoe inserts that do not extend above the ankle.

Custom-fabricated orthosis: An orthosis that is individually made for a specific individual starting with basic materials including, but not limited to, plastic, metal, leather, or cloth in the form of sheets, bars, etc. The process involves substantial work such as cutting, bending, molding, sewing, etc. It may involve the incorporation of some prefabricated components and it involves more than trimming, bending, or making other modifications to a substantially prefabricated item.

Foot drop: A condition in which there is weakness or lack of use of the muscles that dorsiflex the ankle, but there is the ability to bring the ankle to zero degrees by passive range of motion.

Knee-ankle-foot-orthoses (KAFOs): An orthosis designed to control knee and ankle motion that extends from the upper portion of the thigh, crossing the knee and ankle and ending at the toes.

Orthosis (brace): A rigid or semi-rigid device that is used for the purpose of supporting a weak or deformed body part, or for restricting or eliminating motion in a diseased or injured part of the body. An orthosis can be either prefabricated or custom-fabricated.

Prefabricated orthosis: An orthosis that is manufactured in quantity without a specific individual in mind. A prefabricated orthosis may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific individual (that is, 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 orthosis is considered prefabricated.

References

Peer Reviewed Publications:

1. Betancourt JP, Eleeh P, Stark S et al. Impact of Ankle-foot orthosis on gait efficiency in ambulatory children with cerebral palsy: a systematic review and meta-analysis. Am J Phys Med Rehabil. 2019; 98(9):759-770.
2. Choo YJ, Chang MC. Effectiveness of an ankle-foot orthosis on walking in patients with stroke: a systematic review and meta-analysis. Sci Rep. 2021; 11(1):15879.
3. Daryabor A, Kobayashi T, Yamamoto S et al. Effect of ankle-foot orthoses on functional outcome measurements in individuals with stroke: a systematic review and meta-analysis. Disabil Rehabil. 2021; 1-16.
4. Lintanf M, Bourseul JS, Houx L et al. Effect of ankle-foot orthoses on gait, balance and gross motor function in children with cerebral palsy: a systematic review and meta-analysis. Clin Rehabil. 2018; 32(9):1175-1188.
5. Nascimento LR, da Silva LA, Araújo Barcellos JVM et al. Ankle-foot orthoses and continuous functional electrical stimulation improve walking speed after stroke: a systematic review and meta-analyses of randomized controlled trials. Physiotherapy. 2020; 109:43-53.
6. Prenton S, Hollands KL, Kenney LP. Functional electrical stimulation versus ankle foot orthoses for foot-drop: a meta-analysis of orthotic effects. J Rehabil Med. 2016; 48(8):646-656.
7. Shahabi S, Shabaninejad H, Kamali M et al. The effects of ankle-foot orthoses on walking speed in patients with stroke: a systematic review and meta-analysis of randomized controlled trials. Clin Rehabil. 2020; 34(2):145-159.

Government Agency, Medical Society, and Other Authoritative Publications:

1. CGS Administrators, LLC and Noridian Healthcare Solutions, LLC. Local Coverage Determination for Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686). Effective 1/1/2020. Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33686. Accessed on June 30, 2023.
2. Johnston TE, Keller S, Denzer-Weiler C et al. A clinical practice guideline for the use of ankle-foot orthoses and functional electrical stimulation post-stroke. J Neurol Phys Ther. 2021; 45(2):112-196.

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History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References section.
	10/27/2022	Added note to MN statement on Repairs and/or Replacement.
Revised	08/11/2022	MPTAC review. Reformatted clinical criteria to combine ambulatory and non-ambulatory statements. Removed 'not medically necessary' statement on socks. Changed "accidental damage" to "damage" in MN statements on repair/replacement. Updated Discussion/General Information and References sections. Updated Coding section; removed codes L2840, L2850 no longer addressed.
Reviewed	08/12/2021	MPTAC review. Updated Discussion/General Information and References sections. Updated Coding section to remove L2006 now addressed elsewhere.
Reviewed	08/13/2020	MPTAC review. Updated Discussion/General Information and References sections. Reformatted Coding section.
	12/31/2019	Updated Coding section with 01/01/2020 HCPCS changes; added L2006.
Reviewed	08/22/2019	MPTAC review. Updated Discussion/General Information and References sections.
Reviewed	09/13/2018	MPTAC review. Updated Discussion/General Information and References sections.
Revised	11/02/2017	MPTAC review. Updated References section. Title change. The document header wording updated from "Current Effective Date" to "Publish Date."
Reviewed	11/03/2016	MPTAC review. Updated Reference section.
Revised	11/05/2015	MPTAC review. Clarifications to Clinical Indications. Updated References. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Updated References.
Reviewed	11/14/2013	MPTAC review. No change to Clinical Indications.
Reviewed	11/08/2012	MPTAC review. Updated References.
Reviewed	11/17/2011	MPTAC review. Updated References.
Reviewed	11/18/2010	MPTAC review. Updated References. Updated Coding section with 01/01/2011 HCPCS changes.
Reviewed	11/19/2009	MPTAC review. Removed Place of Service section. Updated References. Updated Coding section with 01/01/2010 HCPCS changes; removed L1901, L2770 deleted 12/31/2009.
Reviewed	11/20/2008	MPTAC review. Updated references, Discussion/General Information section and Definitions. Coding section updated with 01/01/2009 HCPCS changes; removed L2860 deleted 12/31/2008.
Reviewed	11/29/2007	MPTAC review. References and coding updated. Clarification of wording.
Reviewed	12/07/2006	MPTAC review. References and coding updated; removed HCPCS L2039 deleted 12/31/2005.
New	12/01/2005	MPTAC initial document development.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.			No Document
Anthem CO/NV	10/29/2004	DME.708	Ankle-Foot/Knee-Ankle-Foot Orthotics
WellPoint Health Networks, Inc.			No Document
