Ankle-Foot (AFO)/Knee-Ankle-Foot (KAFO)/Hip-Knee-Ankle-Foot (HKAFO) Orthoses
(Custom fabricated)

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Developed By: Medical Necessity Criteria Committee

I. Description

An orthosis is an externally applied device intended to modify the structural and functional characteristics of the neuromuscular and skeletal systems. The prevention of persistently abnormal postures reduces the risk of musculoskeletal adaptations that lead to fixed structural deformities.

Ankle-Foot Orthoses (AFOs)
An ankle-foot orthosis extends above the ankle to the top of the calf. It requires fastening at the lower leg, just above the ankle. The device maybe considered medically necessary for patients with weakness or deformity of the foot and ankle, which also requires stabilization, and when the patient has the potential to benefit functionally from its use. AFOs are used to treat disorders including but not limited to ankle dorsiflexion (upward motion), plantar flexion (downward motion), inversion and eversion (turning inward or outward), spastic diplegia due to cerebral palsy, lower motor neuron weakness due to poliomyelitis and spastic hemiplegia with cerebral infarction.

Knee-Ankle-Foot Orthoses (KAFOs)
A KAFO is an AFO with metal uprights, a mechanical knee joint and two thigh bands. KAFOs provide stability to the knee and foot when needed during the stance phase of ambulation and knee hyperextension control from midstance to the terminal stance phase in the gait cycle. Clinical indications include instability of the knee and ankle, quadriceps weakness or absence, hyperextension of the knee, varus or valgus deformity correction in children, and paralysis of one or both legs.

Hip-Knee-Ankle-Foot Orthoses (HKAFOs)
HKAFOs are typically used in the pediatric and adult spinal cord injury population to allow for stabilization of the hips and pelvis during standing and walking with assistive devices. HKAFOs are KAFOs (usually bilateral) that are attached to a hip device (pelvic band, lumbar sacral orthoses (LSO), or thoracic lumbar sacral orthoses (TLSO) for medical conditions warranting hip control. Paralysis of hip abductor muscles is one of the most common reasons for prescribing HKAFOs. HKAFOs are usually

fabricated using mechanical hip joints, most commonly made of metal. They can incorporate flexion-extension and abduction-adduction control and have free or locking joints. Hip-knee-ankle-foot orthoses consist of the same components as standard AFOs and KAFOs, with the addition of a lockable hip joint and a pelvic band to control movements at the anatomic hip joint. Indications for HKAFO include traumatic paraplegia, spina bifida, muscular dystrophy and rotational control.

Definitions:

Prefabricated orthosis – An orthosis that is generally premade without a specific patient in mind. A prefabricated orthosis may require a fitting or adjustment to fit the individual.

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. An impression of the body part may also be made to form a model which the orthotic is molded.

II. Criteria:

A. Custom-made AFOs and KAFOs (custom-fabricated, custom-molded)

a. Custom-fabricated AFOs and KAFOs are considered medically necessary when ALL of the following criteria are met

i. Functional deficit of the knee, as indicated by **1 or more** of the following;

1. Knee joint contracture in the patient receiving physical therapy to promote ambulation
2. Knee joint instability not corrected by ankle-orthotic alone, and assistance with functional or therapeutic ambulation needed

ii. No balance, trunk control, or upper body strength deficits that prevent safe ambulation with or without assistive devices (e. g. Lofstrand forearm orthoses, walker)

iii. No cardiopulmonary disease that limits energy expenditure

iv. No cognitive impairment that prevents gait training or problem-solving during the knee-ankle-foot orthosis use

v. Functional deficit of ankle, as indicated by **1 or more** of the following;

1. Ankle joint contracture prevention or reduction needed
2. Ankle joint instability (mediolateral), and assistance with ambulation needed
3. Dorsiflexors or plantar flexors that are paralyzed or weak, and assistance with ambulation needed
4. Plantar flexor muscles that are hypertonic or spastic, and assistance with ambulation needed

vi. **AND ONE of the following**:

1. The member could **not** be fitted with a prefabricated AFO
2. The condition necessitating the orthosis is expected to be permanent or lasting greater than 6 months

3. There is a need (not prophylactic) to control the knee, ankle, or foot in more than 1 plane
4. The patient has a documented neurological, circulatory, or orthopedic status that necessitates custom fabrication to prevent tissue injury
5. The patient has a healing fracture that lacks normal anatomical integrity or anthropometric proportions

B. Hip-knee-ankle-foot orthotics (HKAFO) will be reviewed on a case-by-case basis

Custom-made AFOs and KAFOs that do not meet the criteria above are considered not medically necessary

C. General notes
   a. Repairs to medically necessary AFOs or KAFOs due to wear and tear are considered medically necessary when they are needed to make the orthosis functional
   b. Replacement of a complete AFO or KAFO or component of these orthoses due to a significant change in the members condition or irreparable wear is considered for coverage if the device is still medically necessary

D. The following orthoses are considered **not** medically necessary
   a. AFOs and KAFOs that are only to be used during participation in sports, since participation in sports is an elective activity
   b. Orthoses used on uninjured body parts or to prevent injury
   c. Orthoses used to treat pressure ulcers
   d. Orthoses used to treat edema
   e. Deluxe equipment when basic (standard) equipment is available and meets the member's functional needs

E. The following orthoses are considered experimental and investigational
   a. Electronic/electromagnetic activated stance control KAFO devices (e. g. E-Mag Active, Sensor Walk)

III. Information Submitted with the Prior Authorization Request:

1. An order/prescription from the physician/healthcare provider responsible for the patient's care that states the purpose of the orthosis
2. Documentation of the member's physical functional impairment related to the completion of activities of daily living (ADLs) without the prescribed device and the member's medical condition that requires long-term use of the orthotic
3. Other devices that have been trialed and found to be inadequate or unsafe or contraindicated to meet the member's functional needs
4. Documentation needs to clearly address the need of a CUSTOM orthotic or it will be denied

IV. CPT or HCPC codes covered:

Codes	Description
	AFO Custom-fabricated
L1900	Ankle-foot orthotic (AFO), spring wire, dorsiflexion assist calf band, custom fabricated
L1904	Ankle orthosis, ankle gauntlet or similar, with or without joints, custom fabricated
L1907	Ankle orthosis, supramalleolar with straps, with or without interface/pads, custom fabricated
L1920	Ankle-foot orthotic (AFO), single upright with static or adjustable stop (Phelps or Perlstein type), custom fabricated
L1940	Ankle-foot orthotic (AFO), plastic or other material, custom fabricated
L1945	Ankle-foot orthotic (AFO), plastic, rigid anterior tibial section (floor reaction), custom fabricated
L1950	Ankle-foot orthotic (AFO), spiral, (Institute of rehabilitative Medicine type), plastic, custom fabricated
L1960	Ankle-foot orthotic (AFO), posterior solid ankle, plastic, custom fabricated
L1970	Ankle-foot orthotic (AFO), plastic with ankle joint, custom fabricated
L1980	Ankle-foot orthotic (AFO), single upright free plantar dorsiflexion, solid stirrup, calf band/cuff (single bar 'BK' orthotic), custom fabricated
L1990	Ankle-foot orthotic (AFO), double upright free plantar dorsiflexion, solid stirrup, calf band/cuff (single bar 'BK' orthotic), custom fabricated
L2106	Ankle-foot orthotic (AFO), fracture orthotic, tibial fracture cast orthotic, thermoplastic type casting material, custom fabricated
L2108	Ankle-foot orthotic (AFO), fracture orthotic, tibial fracture cast orthotic, custom fabricated
	KAFO Custom-fabricated
L2000	Knee-ankle-foot orthotics (KAFO), single upright, free knee, free ankle, solid stirrup, thigh and calf bands/cuffs (single bar 'AK' orthotic), custom fabricated
L2005	Knee-ankle-foot orthotic (KAFO), 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-orthotic (KAFO), single upright, free ankle, solid stirrup, thigh and calf bands/cuffs (single bar 'AK' orthotic), without knee joint, custom fabricated
L2020	Knee-ankle-foot orthotic (KAFO), double upright, free ankle solid stirrup, thigh and calf bands/cuffs (double bar 'AK' orthotic), custom fabricated
L2030	Knee-ankle-foot orthotic (KAFO), double upright, free ankle, solid stirrup, thigh and calf bands/cuffs (double bar 'AK' orthotic), without knee joint, custom fabricated
L2034	Knee-ankle-foot orthotic (KAFO), full plastic, single upright, with or without free motion knee, medial lateral rotation control, with or without free motion ankle, custom fabricated
L2036	Knee-ankle-foot orthotic (KAFO), full plastic, double upright, with or without free motion knee, with or without free motion ankle, custom fabricated

L2037	Knee-ankle-foot orthotic (KAFO), full plastic, single upright, with or without free motion knee, with or without free motion ankle, custom fabricated
L2038	Knee-ankle-foot orthotic (KAFO), full plastic, single upright, with or without free motion knee, multi-axis ankle, custom fabricated
L2126	Knee-ankle-orthotic (KAFO), fracture orthotic, femoral fracture cast orthotic, thermoplastic type casting material, custom fabricated
L2128	Knee-ankle-orthotic (KAFO), fracture orthotic, femoral fracture cast orthotic, custom fabricated
HKAFO Custom-fabricated	
L2040	Hip-knee-ankle-foot orthotic (HKAFO), torsion control, bilateral rotation straps, pelvic band /belt, custom-fabricated
L2050	Hip-knee-ankle-foot orthotic (HKAFO), torsion control, bilateral torsion cables, hip joint, pelvic band/belt, custom-fabricated
L2060	Hip-knee-ankle-foot-orthotic (HKAFO), torsion control, bilateral torsion cables, ball bearing hip-joint, pelvic band/belt, custom-fabricated
L2070	Hip-knee-ankle-foot-orthotic (HKAFO), torsion control, unilateral rotation straps, pelvic band/belt, custom-fabricated
L2080	Hip-knee-ankle-foot-orthotic (HKAFO), torsion control, unilateral torsion cable, hip joint, pelvic band/belt, custom-fabricated
L2090	Hip-knee-ankle-foot-orthotic (HKAFO), torsion control, unilateral torsion cable, ball bearing hip joint, pelvic band/belt, custom-fabricated

V. CPT or HCPC codes NOT covered:

Codes	Description

VI. Annual Review History

Review Date	Revisions	Effective Date
8/28/2019	New criteria	11/04/2019
8/26/2020	Annual Review: Minor grammar changes	09/01/2020
8/25/2021	Annual Review: No changes	09/01/2021
7/27/2022	Annual Review: no changes	08/01/2022
7/23/2023	Annual Review: No changes	08/01/2023

VII. References

1. Spasticity in children and young people with non-progressive brain disorders: Management of spasticity and co-existing motor disorders and their early musculoskeletal complications. NICE Clinical Guidelines, N0. 145. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK116573/
2. The use of ambulatory Knee-Ankle-Foot Orthoses in pediatric patients. Journal of prosthetics and orthotics, June 2006, 192-198
3. Hip-Knee-Ankle-Foot Orthosis https://www.sciencedirect.com/topics/nursing-and-health-professions/hip-knee-ankle-foot-orthosis
4. Gonzalez-Fernandez, M., Taftian, D. &Hopkins, M. (2014). Upper and lower limb orthoses and therapeutic footwear. American Academy of Physical Medicine and Rehabilitation. https://now.aapmr.org/upper-and-lower-limb-orthoses-and-therapeutic-footwear/

Appendix 1 – Applicable Diagnosis Codes:

Codes	Description

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC