

PROVIDER POLICIES & PROCEDURES

MICROPROCESSOR-CONTROLLED KNEE-ANKLE-FOOT ORTHOSIS

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for a microprocessor-controlled knee-ankle-foot orthosis. By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

This policy applies to the use of a microprocessor-controlled knee-ankle-foot orthosis (e.g., the C-Brace® Ottobock HealthCare LP, Austin, TX) that provides support for individuals with lower extremity weakness. This device is a stance and swing phase control orthosis intended to augment the function of the quadriceps and/or other knee extensor muscles in individuals experiencing weakness. The device consists of individually fabricated thigh, calf, and foot components. A spring element connects the foot and calf components, and a sensor system continuously measures flexion of the knee joint and angular acceleration. This allows the device to detect the individual's walking phase and regulate the resistance as well as control flexion and extension of the knee joint.

CLINICAL GUIDELINE

Coverage guidelines for a microprocessor-controlled knee-ankle-foot orthosis are made in accordance with the DSS definition of Medical Necessity. The following criteria are guidelines *only*. Coverage determinations are based on an assessment of the individual and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

A microprocessor-controlled knee-ankle-foot orthosis may be considered medically necessary when the following criteria are met:

- A. The individual is ambulatory; and
- B. The individual has adequate cardiac and pulmonary reserve and the cognitive ability to fully utilize and maintain the device (e.g., charging the battery, using the app etc.); and
- C. There is a documented, completed trial/simulation with the device demonstrating improvement with the individual's movement and stability; and
- D. There is documentation from the ordering physician with expertise in the individual's condition (e.g., a neurologist, an orthopedist, or physiatrist) that there is a reasonable likelihood of improved mobility or stability when using the device; and
- E. There is documentation describing why a traditional knee-ankle-foot orthosis will not meet the individual's needs; and
- F. There is a documented need for ambulation in situations where the device can provide benefit (i.e., routine need to ascend or descend stairs, traverse on uneven surfaces, or ambulate for long distances); and
- G. A medical evaluation has been completed by the ordering physician with expertise in the

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- individual's condition (e.g., a neurologist, an orthopedist, or physiatrist) that documents lower extremity weakness or deformity, and knee instability; and
- H. There is documentation from a physical or occupational therapist describing the level of assistance needed for transfers/ambulation with and without use of requested device; the need for the assistive device; and individual/caregiver training on donning/doffing, and operating the device; and
- A multidisciplinary assessment including an evaluation by a certified orthotist has been completed that documents that the above criteria have been met and that the individual possesses no known contraindications (as described by the manufacturer) for use of the device; and
- J. The device will be fitted and programmed by an orthotist trained in the use of the device; and
- K. The individual will work with a physical or occupational therapist to ensure optimal use of the device; and
- L. If the orthotist allows the individual to modify the controls, the individual will be <u>fully responsible</u> for obtaining/maintaining the needed requirements i.e., a tablet or smartphone, and internet service.

NOTE: EPSDT Special Provision

Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

PROCEDURE

Prior authorization of a microprocessor-controlled knee-ankle-foot orthosis is required. Requests for coverage are reviewed in accordance with procedures in place for reviewing requests for durable medical equipment. Coverage determinations are based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for a microprocessor-controlled knee-ankle-foot orthosis:

- 1. Fully completed authorization request via on-line web portal;
- 2. Signed prescription by the ordering physician; and
- 3. Clinical documentation supporting medical necessity as outlined in the *Clinical Guideline* section of this policy; and
- 4. Medical evaluation by the ordering physician documenting lower extremity weakness or deformity, and knee instability within the last 12 months of the request; and
- 5. PT/OT evaluation including the individual's strength, tone, range of motion, balance, and level of assistance needed for ADLs; and
- 6. For repairs only (note: the initial purchase of a C-brace, HCPCS code L2006, has a maximum allowed fee effective 1/1/2024): a detailed product description including manufacturer, model/part number, HCPC code, unit(s), the manufacturer's suggested retail purchase price (MSRP) and actual acquisition cost (AAC) which includes all manufacturer and volume discounts.

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EFFECTIVE DATE

This policy for the prior authorization for a microprocessor-controlled knee-ankle-foot orthosis for individuals covered under the HUSKY Health Program is effective May, 01, 2024.

LIMITATIONS

Not Applicable

CODES:

Code	Description
L2006	Knee ankle foot device, any material, single or double upright, swing and stance phase
	microprocessor control with adjustability, includes all components (e.g., sensors, batteries,
	charger), any type activation, with or without ankle joint(s), custom fabricated

DEFINITIONS

- 1. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
- 2. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
- 3. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
- 4. **HUSKY D**: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
- 5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
- 6. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
- 7. **HUSKY Plus Physical Program (or HUSKY Plus Program):** A supplemental physical health program pursuant to Conn. Gen. Stat. § 17b-294, for medically eligible members of HUSKY B in Income Bands 1 and 2, whose intensive physical health needs cannot be accommodated within the HUSKY Plan, Part B.
- 8. **Medically Necessary or Medical Necessity**: (as defined in Connecticut General Statutes § 17b-259b) Those health services required to prevent, identify, diagnose, treat, rehabilitate or ameliorate an individual's medical condition, including mental illness, or its effects, in order to attain or maintain the individual's achievable health and independent functioning provided such services are: (1) Consistent with generally-accepted standards of medical practice that are defined as standards that are based on (A) credible scientific evidence published in peer-reviewed medical literature that is generally recognized by the relevant medical community, (B) recommendations of a physician-specialty society, (C) the views of physicians practicing in relevant clinical areas, and (D) any other relevant factors; (2) clinically appropriate in terms of type, frequency, timing, site, extent and duration

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and considered effective for the individual's illness, injury or disease; (3) not primarily for the convenience of the individual, the individual's health care provider or other health care providers; (4) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the individual's illness, injury or disease; and (5) based on an assessment of the individual and his or her medical condition.

9. **Prior Authorization**: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

REFERENCES

- Centers for Medicare & Medicaid Services (CMS). Policy Article: Ankle-Foot/Knee-Ankle-Foot
 Orthoses (A52457). Revision effective date 2/1/2021. Available at:
 https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleld=52457 Accessed
 on December 15, 2023.
- Deems-Dluhy S, Hoppe-Ludwig S, Mummidisetty CK, Semik P, Heinemann AW, Jayaraman A. Microprocessor Controlled Knee Ankle Foot Orthosis (KAFO) vs Stance Control vs Locked KAFO: A Randomized Controlled Trial. Arch Phys Med Rehabil. 2021;102(2):233-244. doi:10.1016/j.apmr.2020.08.013
- Ottobock. C-Brace Practitioner Brochure. Available at: https://shop.ottobock.us/Orthotics/Custom-Orthotics/KAFO-KO---Knee-Ankle-Foot-Orthosis-Knee-Orthosis/C-Brace/c/4036 February, 2021. Accessed on January 3, 2024.
- Pröbsting E, Kannenberg A, Zacharias B. Safety and walking ability of KAFO users with the C-Brace® Orthotronic Mobility System, a new microprocessor stance and swing control orthosis.
 Prosthet Orthot Int. 2017;41(1):65-77. doi:10.1177/0309364616637954
- Schmalz T, Pröbsting E, Auberger R, Siewert G. A functional comparison of conventional knee-ankle-foot orthoses and a microprocessor-controlled leg orthosis system based on biomechanical parameters. Prosthet Orthot Int. 2016;40(2):277-286. doi:10.1177/0309364614546524

PUBLICATION HISTORY

Status	Date	Action Taken
Original Publication	January 2024	Approved at the January 10, 2024 Medical Reviewer meeting.
		Approved at the CHNCT Clinical Quality Subcommittee on
		March 18, 2024. Approved by DSS on March 28, 2024.

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