PROVIDER POLICIES & PROCEDURES

FUNCTIONAL ELECTRICAL STIMULATION DEVICES FOR THE FOOT AND ANKLE

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP Providers) with the information needed to support a medical necessity determination for functional electrical stimulation (FES) for the foot and ankle. 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.

Neuromuscular electrical stimulation (NMES) involves the use of a device to transmit electrical impulses to selected muscle groups via electrodes. The type of NMES that is used to enhance the ability to walk is commonly referred to as functional electrical stimulation (FES).

FES is the application of electrical currents to either generate or suppress activity in the nervous system. An FES device for the foot and ankle (e.g. WalkAide® System, NESS L300™ Foot Drop System, ODFS Dropped Foot Stimulator) are battery-operated, electrical stimulators used for purposes of providing FES treatment or therapy. These portable devices stimulate a foot lift at the appropriate time during the walking cycle in cases of foot drop. A foot drop occurs when a person is unable to actively lift the foot, resulting in the foot slapping on the floor or the toes dragging during walking. Historically, foot drop has been treated with bracing, utilizing an ankle foot orthosis (AFO). The FES device can serve as a replacement for a traditional AFO by working to re-engage an individual's existing nerve pathways and muscles. The FES device stimulates a nerve as it passes below the knee and activates the muscles that raise the foot.

CLINICAL GUIDELINE

Coverage guidelines for FES are made in accordance with the Department of Social Services (DSS) definition of Medical Necessity. The following criteria are guidelines only. Coverage determinations are based on an assessment of the individual and his or her 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:

FES for the foot and ankle may be considered medically necessary for an individual who has a medical condition that resulted in foot drop and has an intact peroneal nerve, who can demonstrate:

1. Muscle and joint stability for weight bearing at upper and lower extremities and ability to balance and control to maintain an upright support posture independently;
2. Brisk muscle contraction and have sensory perception electrical stimulation sufficient for muscle contraction;
3. An ability to transfer independently;
4. Standing tolerance for at least 3 minutes;
5. Hand and finger function to manipulate controls; and
6. Motivation, compliance, commitment and cognitive ability to use and manage the FES device, as

evidenced during evaluation trials within customary environment(s).

FES is generally or typically *contraindicated* in individuals with certain conditions; however, FES may be considered medically necessary based on an assessment of the individual.

Initial Coverage:
Initial coverage of the FES device is typically limited to a 2-week period for those individuals who demonstrate medical necessity, and based on an initial evidence-based assessment of the individual's potential to use FES.

Continuing Coverage:
Continuing coverage of an FES device is typically intended for those individuals, who during the initial 2-week coverage period, (a) were compliant with the prescribed device trial; (b) demonstrated the ability to manage the technology and equipment; and (c) demonstrated an improvement in the quantity (distance) and quality of ambulation. However, this item may be considered medically necessary for individuals not yet meeting the above criteria based on an assessment of the individual and his or her unique situation.

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 FES is required. Requests for coverage of FES will be reviewed in accordance with procedures in place for reviewing requests for durable medical equipment (DME). Coverage determinations will be based upon a review of requested and/or submitted case-specific information to include evidence-based evaluations, both qualitative and quantitative, performed in the individual's customary environment(s). A two week trial is typically utilized to assess compliance prior to purchase.

The following information is needed to review requests for FES:
1. Prescription/ signed letter of medical necessity;
2. Completed State of Connecticut, Department of Social Services Outpatient Prior Authorization Request Form or fully completed authorization request via on-line web portal;
3. Current list of ambulatory aids/orthotics with current skill level for each;
4. Individual's self-assessment of current health status, functional abilities, level of activity and level of comfort;
5. Treatment history;
6. Clinical assessment to include:
    - Primary diagnosis leading to foot drop
    - Possible contraindications (e.g. seizures, pacemaker)
    - Current indications and safety when ambulating
    - "Mini-Stim" assessment
    - Current range of motion of ankle and foot
    - Current muscle strength of bilateral lower extremities and trunk
    - Observational gait assessment (swing and stance phase)

- Gait speed (with and without FES device)
- Timed walk endurance evaluation (with and without FES device) in all three evaluation sessions and

7. As applicable, documentation from the individual's primary care provider and/or physician specialist for medical clearance regarding other conditions which are generally or typically contraindicated for use of FES; and
8. Other pertinent information as requested by CHNCT.

Review Process:

1. Requests for the FES device will be reviewed by CHNCT.
2. If approved, a rental trial period will allow the individual to use the device for 14 days within their customary environment(s).
3. After the 2 week period, the individual should return to the DME provider for an evaluation of the benefits/limitations of the trial and the level of compliance with the device. The resulting data will be compared to the data obtained during the initial evaluation session.
4. The DME provider may request a prior authorization for an additional 2-week rental, pending the functional results of the first 2 week trial.
5. CHNCT will review the results of the entire evaluation trial period after the rentals are complete to determine if the purchase of the FES device will be authorized. Determinations for medical necessity are based upon a comparison of the baseline data and two subsequent evaluations, given two 2-week trials within the individual's customary environment(s).

EFFECTIVE DATE

This policy is effective for prior authorization requests for FES for the foot and ankle for individuals covered under the HUSKY Health Program on or after September 1, 2012.

LIMITATIONS

Not Applicable

CODE:

Code	Definition
E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified

DEFINITIONS

1. **FES (functional electrical stimulation) devices for foot and ankle:** A type of neuromuscular electrical stimulation used to enhance the ability to walk in individuals with foot drop. FES devices are surface units that use electrical impulses to activate paralyzed or weak muscles in precise sequence. Devices used to treat foot drop consist of a gait sensor, leg cuff and hand held control. When the heel lifts, signals from the gait sensor are sent to the stimulation unit in the leg cuff that stimulates the nerve for muscle action, which in turn lifts the foot while walking.
2. **Foot drop:** A condition characterized by weakness or paralysis of the muscles involved in lifting the front part of the foot. It causes a person to either drag the foot and toes or engage in a high-stepping walk called steppage gait.

3. **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.
4. **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.
5. **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.
6. **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).
7. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
8. **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.
9. **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 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.
10. **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.

ADDITIONAL RESOURCES AND REFERENCES:

- CMS, Health Care Procedural Coding System Level II Manual: 2019
- CMS.gov, National Coverage Determination for Neuromuscular Electrical Stimulation (NMES), NCD # 160.12, effective 10/1/06.
- Functional Electrical Stimulation (FES) - Coverage and HCPCS Coding – Revised https://www.cgsmedicare.com/jc/pubs/news/2014/0714/cope26209.html
- van der Linden ML, Hooper JE, Cowan P, Weller BB, Mercer TH. Habitual Functional Electrical Stimulation Therapy Improves Gait Kinematics and Walking Performance, but Not Patient-Reported Functional Outcomes, of People with Multiple Sclerosis who Present with Foot-Drop. PLoS ONE 2014: 9(8): e103368. doi:10.1371/journal.pone.0103368. Available at: https://www.ncbi.nlm.nih.gov/pubmed/25133535
- Sheffler LR, Hennessey MT, Naples GG, Chae J. Peroneal Nerve Stimulation versus an Ankle Foot Orthosis for Correction of Footdrop in Stroke: Impact on Functional Ambulation. Neurorehabil Neural Repair 2006;20(3):355-360. Available at: https://www.ncbi.nlm.nih.gov/pubmed/16885421

- Moll I, Vles JSH, Soudant DLHM, Witlox AMA, Staal HM, Speth LAWM, Janssen-Potten YJM, Coenen M, Koudijs SM, Vermeulen RJ. **Functional** electrical stimulation of the **ankle** dorsiflexors during walking in spastic cerebral palsy: a systematic review. Dev Med Child Neurol. 2017 Dec;59(12):1230-1236. doi: 10.1111/dmcn.13501. Epub 2017 Aug 17. Available at: https://www.ncbi.nlm.nih.gov/pubmed/28815571

PUBLICATION HISTORY

Status	Date	Action Taken
Original publication	September 2012	
Reviewed	September 2013	Clinical Quality Sub-Committee Review. References Updated.
Reviewed	September 2014	Clinical Quality Sub-Committee review. Reference updated. These changes approved at the September 15, 2014 Clinical Quality Subcommittee meeting.
Updated	August 2015	Updated definitions for HUSKY A, B, C and D programs at request of DSS.
Reviewed	September 2015	Clinical Quality Subcommittee Review. Reference Updated. Removed "included use on varied terrain" as part of criteria for customary environment from Procedure section. Added need for information from PCP or specialist regarding conditions which typically indicate a contraindication for FES in Information Required For Review section. These changes approved at the September 21, 2015 Clinical Quality Subcommittee meeting.
Updated	March 2016	Updates to language in introductory paragraph pertaining to purpose of policy. Updates to Clinical Guideline section pertaining to definition of Medical Necessity. Updates throughout policy to reflect importance of person-centeredness when reviewing requests for FES. These changes approved at the March 21, 2016 Clinical Quality Subcommittee meeting. Updates by DSS in Clinical Guideline section removing references to specific medical conditions. All changes approved by DSS on May 23, 2016.
Updated	February 2017	Updated reference. Change approved at the February 23, 2017 Medical Policy Review Committee meeting. Approved by Clinical Quality Subcommittee on March 20, 2017. Approved by DSS on March 27, 2017.
Updated	April 2018	Medical Policy Committee review. Updated reference. Update to *Procedures* section, #7, under "*The following*

		information is needed to review requests for FES:" Added *"As applicable,"* to beginning of sentence. Approved by CHNCT Medical Policy Review Committee on February 14, 2018. Approved by CHNCT Clinical Quality Subcommittee on March 19, 2018. Approved by DSS on April 5, 2018.
Updated	February 2019	Medical Policy Committee review. Changes throughout Policy to limit the focus of the FES policy to guidelines pertaining to HCPCS code E0770, based on updated guidance from CMS regarding use of this HCPCS code. Removed brand name Walkaide to allow for inclusion of other FDA approved devices for this purpose. Omitted specific diagnoses to change focus to the medical conditions and other criteria needed for medical necessity determinations. Updates to reference section. Changes approved at the February 13, 2019 Medical Reviewer meeting. Changes approved by the CHNCT Clinical Quality Subcommittee on March 18, 2019. Approved by DSS on March 27, 2019.