PROVIDER POLICIES & PROCEDURES

LOWER LIMB ORTHOTICS AND PROSTHETICS

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 lower limb orthotics and prosthetics. 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.

A prosthetic is an artificial replacement for an absent body part and is used to restore function or may be cosmetic. Lower limb prosthetics include the thighs, knees, ankles, and feet.

An orthotic is an external device that attaches to the affected area or joint to assist with gait, reduce pain, control movement, minimize weight bearing, and correct or prevent worsening progression of deformity.

A *prefabricated* orthotic is an item that is manufactured in quantity without a specific individual in mind. A prefabricated orthotic may be considered an off-the-shelf or a custom fitted device that may be trimmed, bent, molded (with or without heat), or otherwise modified for use by a specific individual. An orthotic that is assembled from prefabricated components is considered prefabricated.

A *custom fabricated* item is one that is made for a specific individual. No other individual would be able to use this item. A custom fabricated item is a device which is fabricated based on clinically derived and rectified castings, tracings, measurements, and/or other images (such as X-rays) of the body part.

HUSKY Health primarily uses Change Healthcare's InterQual® Criteria when reviewing prior authorization requests for coverage of most lower limb orthotics and prosthetics. HUSKY Health will use this policy to review requests for lower limb orthotics and prosthetics for which InterQual® Criteria are not available.

Note:

- Coverage guidelines for therapeutic and orthopedic footwear and inserts are available **here**.
- Coverage guidelines for a microprocessor-controlled knee-ankle-foot orthosis are available **here**.

CLINICAL GUIDELINE

Coverage guidelines for lower limb orthotics and prosthetics will be 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 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:

Concentric Adjustable Torsion Style Mechanisms (HCPCS Code L2861)
A concentric adjustable torsion style mechanism, as an addition to a custom ankle-foot orthosis or knee-

ankle-foot orthosis, may be considered medically necessary when the individual requires ankle plantar or dorsiflexion, or knee joint extension assist in the absence of any co-existing joint contracture.

Axial Rotation Unit (HCPCS Code L5982)
An axial rotation unit may be considered medically necessary when the individual is motivated to ambulate and has a functional level of K - 2 or above (see below section on *Level of Function*).

Positional Rotation Unit (HCPCS L5926)
A positional rotation unit as an addition to a lower limb prosthesis may be considered medically necessary when the individual is motivated to ambulate and has a functional level of K - 3 or above (see below section on *Level of Function*).

Level of Function
Potential functional ability is based on the reasonable expectations of the prosthetist and treating practitioner and considers the following: individual's history (including prior prosthetic use if applicable); current condition including the status of the residual limb; impact of other medical conditions; and desire to ambulate. The classification levels are as follows:

- K - 0: the individual does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
- K - 1: the individual has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence (i.e., limited, and unlimited household ambulator).
- K - 2: the individual has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs, or uneven surfaces (i.e., limited community ambulator).
- K - 3: the individual has the ability or potential for ambulation with variable cadence with the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion (i.e., community ambulator).
- K - 4: the individual has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels to the extent that is typically seen with the demands of the child, active adult, or athlete.

Not Medically Necessary
The following devices are considered investigational and not medically necessary as there is insufficient evidence in published peer-reviewed medical literature supporting their safety and efficacy:

- The OPRA™ Implant System (HCPCS code L5991)
- The UNFO foot brace (HCPCS code L3161)
- The DAW® Sure Stance Knee (HCPCS code L5841)

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

Requests for coverage of lower limb orthotics and prosthetics will be reviewed in accordance with procedures in place for reviewing requests for durable medical equipment. Coverage determinations will be based upon a review of requested and/or submitted case-specific information.

The following information is needed to review requests for lower limb orthoses and prothesis:

1. Fully completed authorization request via web portal;
2. A signed prescription, written within the past 12 months, from the treating physician, advanced practice registered nurse (APRN), or physician assistant (PA) enrolled in the Connecticut Medical Assistance Program (CMAP);
3. Progress note written within the past 12 months from the treating physician, physician assistant (PA); or advanced practice registered nurse (APRN);
4. Documentation from the ordering practitioner that supports the medical necessity of the requested item as described in the *Clinical Guidelines* section of this policy including the condition of the residual limb, the individual's current "K" level of function or anticipated level with use of the requested device, the individual's level of motivation to ambulate; and
5. For items that require manual pricing only: a detailed product description including manufacturer, model/part number, product description, HCPCS code and units(s), actual acquisition cost (AAC), and manufacturer's suggested retail pricing (MSRP) including documentation disclosing all discounts per the *Connecticut Department of Social Services (DSS) Pricing Policy*.

EFFECTIVE DATE

This Clinical Guideline is effective for prior authorization requests for individuals covered under the HUSKY A, B, C, and D programs on or after February 1, 2025.

LIMITATIONS

N/A

CODES:

Codes Reviewed Using Policy

Code	Description
L2861	Addition to lower extremity joint, knee or ankle, concentric adjustable torsion style mechanism for custom fabricated orthotics only
L3161	Foot, adductus positioning device, adjustable
L5841	Addition, endoskeletal knee-shin system, polycentric, pneumatic swing, and stance phase control
L5926	Addition to lower extremity prosthesis, endoskeletal, knee disarticulation, above knee, hip disarticulation, positional rotation unit, any type
L5982	All exoskeletal lower extremity prostheses, axial rotation unit
L5991	Addition to lower extremity prostheses, osseointegrated external prosthetic connector

Codes/Code Ranges Reviewed Using InterQual Criteria

L1832	L1834	L1840-L1847	L1860	L1970	L4397
L4361	L5000-L5782	L5785-L5925	L5930-L5981	L5984-L5990	

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. **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. prescription.
8. **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:

- Ankle-Foot/Knee-Ankle-Foot Orthosis- (L33686) Cms.gov. Published 2020. Accessed July 17, 2024
- ClinicalTrials.gov. NCT06076499, A Post-Market Study for Long-Term Effectiveness and Safety of the NTX100 for RLS (THRIVE). Available at https://clinicaltrials.gov/study/NCT06076499 Accessed 23 July 2024.
- ClinicalTrials.gov. NCT01600183, Safety and Efficacy of the Universal Neonatal Foot Orthosis in the Treatment of Metatarsus Adductus (MTA). Available at https://clinicaltrials.gov/study/NCT01600183 . Accessed 23 July 2024.
- Kannenberg A, Zacharias B, Pröbsting E. Benefits of microprocessor-controlled prosthetic knees to limited community ambulators: systematic review. J Rehabil Res Dev. 2014;51(10):1469-96. doi: 10.1682/JRRD.2014.05.0118. PMID: 25856664.
- Lower Limb Prostheses (L33787). Cms.gov. Published 2020. Accessed July 17, 2024.

- Mohamed J, Reetz D, van de Meent H, et al. What are the risk factors for mechanical failure and loosening of a transfemoral osseointegrated implant system in patients with a lower-limb amputation? Clin Orthop Relat Res. 2022;480(4):722-731
- Ontario Health (Quality). Osseointegrated Prosthetic Implants for People With Lower-Limb Amputation: A Health Technology Assessment. Ont Health Technol Assess Ser. 2019 Dec 12;19(7):1-126. PMID: 31911825; PMCID: PMC6939984
- Ontario Health (Quality). Stance-control knee-ankle-foot orthoses for people with knee instability: A health technology assessment. Ont Health Technol Assess Ser. 2021;21(11):1-96.
- "OpraTM Implant System." Integrum, 25 Sept. 2021, integrum.se/about-us/our-technology/opra-implant-system/
- "Premarket Approval (PMA)." Accessdata.Fda.Gov, www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P190009. Accessed 23 July 2024.
- Raijmakers B, Brehm MA, Nollet F, Koopman FS. Safety, walking ability, and satisfaction outcomes of the NEURO TRONIC stance-control knee-ankle-foot orthosis (SCKAFO): A comparative evaluation to the E-MAG active SCKAFO. Prosthet Orthot Int. 2024;48(1):30-38
- "Rotation Adapter: Functional Adapter for Enhanced Safety and Comfort." Ottobock, www.ottobock.com/en-us/product/4R57. Accessed 25 July 2024.
- "Sure StanceTM Knee." DAW Industries, 23 May 2023, daw-usa.com/knee/sure-stance/
- UNFO med ltd. Metatarsus Adductus, Metatarsus Varus and Pigeon toed Treatment Shoes – UNFO-S (Short). Accessed June 21, 2022. Available at URL address: Pigeon Toed Treatment Shoes | UNFO foot brace (unfo-med.com)
- UptoDate. Approach to the child with in-toeing. Last updated February 21, 2024.

PUBLICATION HISTORY

Status	Date	Action Taken
Original publication	December 2024	Approved at the December 11, 2024 CHNCT Medical Reviewer meeting. Approved at the December 16, 2024 CHNCT Clinical Quality Subcommittee meeting. Approved be DSS on December 27, 2024.