PROVIDER POLICIES & PROCEDURES

THERABIONIC P1

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 TheraBionic P1. 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.

The TheraBionic P1 System is a handheld, battery-operated, radiofrequency (RF) electromagnetic field (EMF) generator that includes an antenna on a cable that attaches to the generator. The TheraBionic P1 System's antenna is placed in the mouth, then the handheld generator emits EMF at specific amplitude-modulated (AM) frequencies. The EMF frequencies may stop cancer cells from dividing and making more cancer cells.

CLINICAL GUIDELINE

Coverage guidelines for TheraBionic P1 device 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:

The use of the TheraBionic P1 device is considered **investigational and therefore not medically necessary** for the treatment of any condition, including, but not limited to, advanced hepatocellular cancer as there is insufficient evidence in peer-reviewed, published medical literature supporting safety and clinical efficacy.

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 for the TheraBionic P1 device 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.

EFFECTIVE DATE

Please note that authorization is based on medical necessity at the time the authorization is issued and is not a guarantee of payment. Payment is based on the individual having active coverage, benefits and policies in effect at the time of service.

To determine if a service or procedure requires prior authorization, CMAP Providers may refer to the *Benefit and Authorization Grids* summaries on www.ct.gov/husky by clicking on "For Providers" followed by "Benefit Grids". For a definitive list of benefits and service limitations, CMAP Providers may access the CMAP provider fee schedules and regulations at www.ctdssmap.com.

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

LIMITATIONS
N/A

CODES:

Code	Description
E0767	Intrabuccal, systemic delivery of amplitude modulated, radiofrequency electromagnetic field device, for cancer treatment, includes all accessories

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:

- Camacho, Javier. “Ebiomedicine, March 2023, Volume 89.” eBioMedicine, Elsevier.
- Center for Devices and Radiological Health. “Therabionic P1 – H220001.” U.S. Food and Drug Administration, FDA, www.fda.gov/medical-devices/recently-approved-devices/therabionic-p1-h220001. Accessed 12 Sept. 2024.
- ClinicalTrials.gov. NCT04797884, Electromagnetic Fields Versus Placebo For Child-Pugh A and B Patients With Advanced Hepatocellular Carcinoma (ARTEMIS). Available at https://clinicaltrials.gov/study/NCT04797884 . Accessed 12 September 2024.
- “Guidelines for Patients.” NCCN, www.nccn.org/patientresources/patient-resources/guidelines-for-patients. Accessed 16 Sept. 2024.
- Hugo Jimenez, Minghui Wang, Jacquelyn W. Zimmerman, Michael J. Pennison, Sambad Sharma, Trevor Surratt, Zhi-Xiang Xu, Ivan Brezovich, Devin Absher, Richard M. Myers, Barry DeYoung, David L. Caudell, Dongquan Chen, Hui-Wen Lo, Hui-Kuan Lin, Dwayne W. Godwin, Michael Olivier, Anand Ghanekar, Kui Chen, Lance D. Miller, Yijian Gong, Myles Capstick, Ralph B. D'Agostino, Reginald Munden, Philippe Merle, Alexandre Barbault, Arthur W. Blackstock, Herbert L. Bonkovsky, Guang-Yu Yang, Guangxu Jin, Liang Liu, Wei Zhang, Kounosuke Watabe, Carl F. Blackman, Boris C. Pasche. Tumour-specific amplitude-modulated radiofrequency electromagnetic fields induce differentiation of hepatocellular carcinoma via targeting Cav3.2 T-type voltage-gated calcium channels and Ca2+ influx, eBioMedicine, Volume 44, 2019, Pages 209-224, ISSN 2352-3964, https://doi.org/10.1016/j.ebiom.2019.05.034.
- National Cancer Institute . “Electromagnetic Fields for the Treatment of Locally Advanced or Metastatic Liver Cancer.” Https://Www.Cancer.Gov, www.cancer.gov/research/participate/clinical-trials-search/v?id=NCI-2021-06899&r=1. Accessed 12 Sept. 2024.
- Sambad Sharma, Shih-Ying Wu, Hugo Jimenez, Fei Xing, Dongqin Zhu, Yin Liu, Kerui Wu, Abhishek Tyagi, Dan Zhao, Hui-Wen Lo, Linda Metheny-Barlow, Peiqing Sun, John D. Bourland, Michael D. Chan, Alexandra Thomas, Alexandre Barbault, Ralph B. D'Agostino, Christopher T. Whitlow, Volker Kirchner, Carl Blackman, Boris Pasche, Kounosuke Watabe, Ca2+ and CACNA1H mediate targeted suppression of breast cancer brain metastasis by AM RF EMF, eBioMedicine, Volume 44, 2019, Pages 194-208, ISSN 2352-3964, https://doi.org/10.1016/j.ebiom.2019.05.038.
- “Therabionic Inc.” TheraBionic Inc., www.therabionic.com/. Accessed 12 Sept. 2024.
- Tumor Treatment Field Therapy (TTFT) (L34823). Cms.gov. Published 2015. Accessed September 12, 2024.

PUBLICATION HISTORY

Status	Date	Action Taken
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