STATE OF CONNECTICUT
DEPARTMENT OF SOCIAL SERVICES
OFFICE OF LEGAL COUNSEL, REGULATIONS, AND ADMINISTRATIVE HEARINGS
55 FARMINGTON AVE.
HARTFORD, CT 06105-3725

[redacted] 2021
Signature Confirmation

Client ID # [redacted]
Case ID # [redacted]
Request # 171511

NOTICE OF DECISION

PARTY

[redacted]

PROCEDURAL BACKGROUND

On [redacted] 2021, Community Health Network of Connecticut ((“CHNCT”) sent [redacted] (the “Appellant”) a Notice of Action (“NOA”) denying a request for authorization for a Cefaly Dual Device for treatment of migraine headaches for his minor child.

On [redacted], 2021, the Appellant requested an administrative hearing to contest CHNCT’s decision to deny the authorization request for the Cefaly Dual device.

On [redacted], 2021, the Office of Legal Counsel, Regulations, and Administrative Hearings (“OLCRAH”) issued a notice scheduling the administrative hearing for [redacted] 2021.

On [redacted] 2021, the Appellant requested the administrative hearing be rescheduled.

On [redacted] 2021, OLCRAH issued a notice scheduling the administrative hearing for [redacted], 2021.

On [redacted], 2021, in accordance with sections 17b-60, 17b-61 and 4-176e to 4-189 inclusive, of the Connecticut General Statutes, OLCRAH held an administrative hearing.

The following individuals were present at the hearing:

[redacted], Appellant
[redacted], the Appellant's spouse
Heather Shea, CHNCT Representative
Scott Zuckerman, Fair Hearing Officer

The hearing record remained open at the request of the Appellant for CHNCT to provide additional evidence. The hearing record closed on [redacted], 2021.

STATEMENT OF THE ISSUE

The issue to be decided is whether CHNCT's denial of the authorization request through the Medicaid program for a Cefaly Dual device as not medically necessary, was in accordance with state law.

FINDINGS OF FACT

1. The Appellant is the father of [redacted] (the "child"). (Hearing Record)

2. The child (D.O.B. [redacted]2004) is seventeen (17) and is a participant in the Medicaid program as administered by the Department of Social Services (the "Department"). (Hearing Record)

3. CHNCT is the Department's contractor for reviewing medical requests for authorization of durable medical equipment ("DME"). (Hearing Record)

4. [redacted] is the Appellant's treating physician (the "treating physician"). (Exhibit 1: Prior Authorization, Exhibit: 3: Clinical Information received [redacted]/2020)

5. The Appellant has a diagnosis of Headache and Chronic Migraine without aura without status migainosus. In addition, she has a history of narcolepsy anxiety and asthma (Hearing Record)

6. In the summer of 2018, the child was evaluated for headaches by [redacted] where she received her diagnosis of chronic migraine. She received and failed at Cyproheptadine, Amitriptyline and Topiramate. (Exhibit 3)

7. The child when having a migraine headache needs to go into her room, be quiet with a low noise level in the home. (Appellant's testimony)

8. In [redacted] 2019, the child's medication regime to prevent migraine headaches was Lamictal, Risperidon, Coenzyme Q10 and Riboflavin. The child received Zolmitriptan for rescue. (Exhibit 3)

9. On [redacted] 2019, the child received her first botox treatment for migraine pain management. (Exhibit 3)

10. On [redacted] 2019, the child received her second botox injections and reported worsening of pain for several weeks after the injections. Biofeedback training was useful to the child. (Exhibit 3: Clinical notes)

11. On [redacted], 2019, the child's physician discontinued additional Botox injections due to worsening of headaches during both treatments. (Exhibit 3)

12. On [redacted], 2020, the child reported headaches grew more debilitating. The medication regime consisted of Zyrtec, vitamin D, co – enzyme Q10, gabapentin 100mg capsule, Lamictal 150mg, loestric FE, propranolol. (Exhibit 3)

13. In [redacted]2020, the child trialed a Cefaly device with electrodes and reported improvement in headaches for six weeks when she borrowed the loaner model. (Appellant's testimony and Exhibit 3)

14. A Cefaly device with electrodes, known as a supraorbital transcutaneous neurostimulation stimulator provides non-invasive nerve stimulation for acute pain relief during migraine attacks. (Hearing Record)

15. A Cefaly device with electrodes is not standard treatment for migraine headaches. (Hearing Record)

16. Cefaly Technology is the Durable Medical Equipment Provider (the "DME Provider"). (Exhibit 3)

17. On [redacted] 2020, CHNCT received an outpatient prior authorization request for Cefaly Dual device ordered by the treating physician for the diagnosis of Headache and Chronic Migraine without aura without status migainousus. (Exhibit 1: Prior Authorization request, [redacted]2020)

18. On [redacted] 2020, the treating physician provided a letter of medical necessity. The letter stated, the child tried other therapies which she reported ineffective and caused the pain to be worse such as Botox, peripheral Nerve Blocks, Aimovig. Treatments of Imitrex Gabapentin, Inderal, Zomig and Robovlavin have not provided reductions in migraines and chronic daily headaches. (Exhibit 2: Physicians letter of Medical Necessity dated [redacted] 2020)

19. On [redacted], 2020, the treating physician provided additional information consisting of clinical notes. (Exhibit 3)

20. On [redacted] 2021, the medical reviewer reviewed the prior authorization for the request of the Cefaly device. The reviewer determined the device is investigational and there is insufficient evidence in peer-reviewed medical literature showing a significant health benefit with the use of this device. (Exhibit 5: Medical Director Note, [redacted]/2021)

21. On [redacted] 2021, CHNCT denied the Appellant's appeal for authorization for a Cefaly Dual device for the treatment of migraine headaches from Cefaly Technology. The notice stated, the device requested is not medically necessary, it does not meet generally accepted standards of medical care. The information sent by the provider did not show the medical need for the device. The use of the device is considered investigational and experimental and there is not enough evidence that shows that the use of this device will improve the child's health. (Exhibit 6: Notice of Action, [redacted]2021)

22. On [redacted] 2021, the Medical reviewer performed a peer to peer review with the treating physician for the request for a supraorbital transcutaneous electrical nerve stimulator, the Cefaly Dual Device. The treating physician discussed studies in peer reviewed publications. The reviewer determined the studies are limited by small effect size, low patient numbers, and uncertainty in concealing treatment allocation. The reviewer determined the device is not current standard of care and is considered investigational. (Exhibit 7: Peer to Peer review note, [redacted]/2021 and Exhibit 11: Clinical Information and Medical Records)

23. On [redacted] 2021, CHNCT reviewed the Appellant's appeal and upheld the denial. The Cefaly device with electrodes has not been credibly shown to medically effective. (Exhibit 13: Medical Review, [redacted]2021)

24. On [redacted] 2021, CHNCT denied the Appellant's appeal of the request for authorization for the Cefaly Dual device and notified the Appellant. The notice stated the use of the device is considered investigational and experimental. There was not enough evidence that shows the use of the device will improve the health of the child. (Exhibit 14: Determination Letter, [redacted]2021)

25. On [redacted] 2021, OLCRAH conducted an administrative hearing. (Hearing Record)

26. On [redacted], 2021, CHNCT provided a response to questions from the Appellant. (Exhibit 15: Post hearing questions and responses)

27. A treatment would be standard of care if it is suggested by doctors of the same specialty, for the patients with the same condition, also know as best practice. Treatments become the standard of care when there is a lot of research about it and societies of a particular group of medical providers say that this an appropriate treatment for the condition. The Cefaly device is not a recommended treatment for Migraines in children and Adolescents per a 2019 publication in the American Academy of Neurology and the American Headache Society. (Exhibit 15)

28. For a treatment to be considered the standard of care there must be trials of the treatment that show it is safe and effective in treating the condition. Trials give the treatment to some and not the others. Then the two groups are compared to see if the treatment helped the condition. (Exhibit 15)

29. The issuance of this decision is timely under Connecticut General Statutes 17b-61(a), which requires that a decision be issued within 90 days of the request for an administrative hearing. The Appellant requested an administrative hearing on [redacted], 2021. Therefore, this decision is due not later than [redacted] 2021. However, the hearing, which was originally scheduled for [redacted] 2021, was rescheduled for [redacted] 2021, at the request of the Appellant, which caused a 16-day delay. On the date of the hearing the Appellant requested the hearing record remain open for CHNCT respond to questions. This caused an additional 14-day delay. Because this 30 - day delay resulted from the Appellant's requests, this decision is not due until [redacted] 2021, and is therefore timely. (Hearing Record)

CONCLUSIONS OF LAW

1. Connecticut General Statute ("C.G.S.") § 17b-2 provides that the Department of Social Services is designated as the state agency for the administration of the Medicaid program pursuant to Title XIX of the Social Security Act.

2. State statute provides that for purposes of the administration of the medical assistance programs by the Department of Social Services, "medically necessary" and "medical necessity" mean 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. [C.G.S. § 17b-259b(a)]

3. State statute provides that clinical policies, medical policies, clinical criteria or any other generally accepted clinical practice guidelines used to assist in evaluating the medical necessity of a requested health service shall be used solely as guidelines and shall not be the basis for a final determination of medical necessity. [C.G.S. § 17b-259(b)]

4. State statute provides that upon denial of a request for authorization of services based on medical necessity, the individual shall be notified that, upon request, the Department of Social Services shall provide a copy of the specific guideline or criteria, or portion thereof, other than the medical necessity definition provided in subsection (a) of this section, that was considered by the department or an entity acting on behalf of the department in making the determination of medical necessity. [C.G.S. § 17b-259b(c)]

5. State statute provides that the Department of Social Services shall amend or repeal any definitions in the regulations of Connecticut state agencies that are inconsistent with the definition of medical necessity provided in subsection (a) of this section, including the definitions of medical appropriateness and medically appropriate, that are used in administering the department's medical assistance program. The commissioner shall implement policies and procedures to carry out the provisions of this section while in the process of adopting such policies and procedures in regulation form, provided notice of intent to adopt the regulations is published in the Connecticut Law Journal not later than twenty days after implementation. Such policies and procedures shall be valid until the time the final regulations are adopted. [C.G.S. § 17b-259b(d)]

6. Regulations of Connecticut State Agencies ("Regs. Conn. State Agencies") § 17b-262-672 provides that sections 17b-262-672 through 17b-262-682 of the Regulations of Connecticut State Agencies set forth the Department of Social Services requirements for the payment of durable medical equipment (DME) to providers, for clients who are determined eligible to receive services under Connecticut Medicaid pursuant to section 17b-262 of the Connecticut General States (CGS).

7. State regulation defines durable medical equipment or DME as equipment that meets all of the following requirements:
   a. Can withstand repeated use;
   b. Is primarily and customarily used to serve a medical purpose;
   c. Generally is not useful to a person in the absence of an illness or injury; and
   d. Is nondisposable. [Regs. Conn. State Agencies § 17b-262-673(8)]

8. State regulation defines prior authorization or PA as approval for the services or the delivery of goods from the department before the provider actually provides the service or delivers the goods. [Regs. Conn. State Agencies § 17b-262-673(20)]

9. State regulation provides that payment for DME and related equipment is available for Medicaid clients who have a medical need for such equipment which meets the department's definition of DME when the item is prescribed by a licensed practitioner, subject to the conditions and limitations set forth in sections 17b-262-672 to 17b-262-682, inclusive, of the Regulations of Connecticut State Agencies. [Regs. Conn. State Agencies § 17b-262-675]

10. State regulation provides that the department shall pay for the purchase or rental and the repair of DME, except as limited by sections 17b-262-672 to 17b-262*682, inclusive, of the Regulations of Connecticut State Agencies, that conforms to accepted methods of diagnosis and treatment and is medically necessary and medically appropriate. [Regs. Conn. State Agencies § 17b-262-676(a)(1)]

    State regulation provides DME services are available to all clients who live at home. Additionally, the department shall pay for ventilators, customized wheelchairs, and Group 2 Pressure Reducing Support Services for residents of nursing facilities and ICF's/MR. [Regs. Conn. State Agencies § 17b-262-676(a)(2)]

11. State regulation provides that when the item for which Medicaid coverage is requested is not on the department's fee schedule, prior authorization is required by the department. The recipient requesting Medicaid coverage for a prescribed item not on the list shall submit such prior authorization

request to the department through an enrolled provider of DME. Such request shall include a signed prescription and shall include documentation showing the recipient's medical need for the prescribed item. If the item for which Medicaid coverage is requested is not on the department's fee schedule, the provider shall also include documentation showing that the item meets the department's definition of DME and is medically appropriate for the client requesting coverage of such item. [Regs. Conn. State Agencies § 17b-262-676(a)(4)]

12. State regulation provides that the department shall not pay for anything of an unproven, experimental or research nature or for services in excess of those deemed medically necessary by the department to treat the recipient's condition or for services not directly related to the recipient's diagnosis, symptoms, or medical history. [Regs. Conn. State Agencies § 17b-262-676(b)(1)]

13. State regulation provides that the Department shall not pay DME providers for: any service or item not identified as covered in sections 17b-262-672 to 17b-262-682, inclusive, of the Regulations of Connecticut State Agencies, unless it is approved in accordance with section 17b-262-676(a)(4) of the Regulations of Connecticut State Agencies. [Regs. Conn. State Agencies § 17b-262-677(5)]

14. State regulation provides that in order to receive reimbursement from the department a provider shall comply with all prior authorization requirements. The department in its sole discretion determines what information is necessary in order to approve a prior authorization request. Prior authorization does not, however, guarantee payment unless all other requirements are met. [Regs. Conn. State Agencies § 17b-262-678(a)]

15. State regulation provides that the department requires prior authorization for: 1) any item identified on the department's published fee schedule as requiring prior authorization; and 2) any item requested under section 17b-262-676(a)(4a) or the Regulations of Connecticut State Agencies. [Regs. Conn. State Agencies § 17b-262-678(b)]

16. State regulation provides that a PA request, on forms and in a manner as specified by the department, shall include documentation of medical need and shall be signed by the prescribing licensed practitioner and the supplier. A copy of the prescription from the licensed practitioner may be attached to the completed PA request in lieu of the actual signature of the licensed practitioner on the PA request form. The licensed practitioner's original prescription shall be on file with the provider and subject to review by the department. [Regs. Conn. State Agencies § 17b-262-678(c)]

The Appellant's request for prior authorization for the Cefaly Dual device with electrodes for the treatment of migraine headaches does not meet the criteria of medical necessity as established in state statute. The device is not consistent with generally accepted standards of medical practice. The device has not been credibly shown to be medically effective and is considered experimental and investigational.

CHNCT was correct to deny prior authorization request for the Cefaly Dual Device with electrodes because the device does not meet the medical necessity criteria in accordance with state statutes and regulations.

On [redacted], 2021, the CHNCT correctly denied the Appellant's request for prior authorization of the Cefaly device with electrodes and issued a notice of denial to the Appellant.

DECISION

The Appellant's appeal is denied.

Scott Zuckerman
Fair Hearing Officer

CC: CHNCT, appeals@chnct.org
Fatmata Williams, DSS, Central Office

RIGHT TO REQUEST RECONSIDERATION

The appellant has the right to file a written reconsideration request within **15** days of the mailing date of the decision on the grounds there was an error of fact or law, new evidence has been discovered or other good cause exists. If the request for reconsideration is granted, the appellant will be notified within **25** days of the request date. No response within 25 days means that the request for reconsideration has been denied. The right to request a reconsideration is based on § 4-181a (a) of the Connecticut General Statutes.

Reconsideration requests should include specific grounds for the request: for example, indicate what error of fact or law, what new evidence, or what other good cause exists.

Reconsideration requests should be sent to: Department of Social Services, Director, Office of Administrative Hearings and Appeals, 55 Farmington Avenue Hartford, CT 06105.

RIGHT TO APPEAL

The appellant has the right to appeal this decision to Superior Court within **45** days of the mailing of this decision, or **45** days after the agency denies a petition for reconsideration of this decision, provided that the petition for reconsideration was filed timely with the Department. The right to appeal is based on § 4-183 of the Connecticut General Statutes. To appeal, a petition must be filed at Superior Court. A copy of the petition must be served upon the Office of the Attorney General, 165 Capitol Avenue, Hartford, CT 06106 or the Commissioner of the Department of Social Services, 55 Farmington Avenue Hartford, CT 06105. A copy of the petition must also be served on all parties to the hearing.

The 45 day appeal period may be extended in certain instances if there is good cause. The extension request must be filed with the Commissioner of the Department of Social Services in writing no later than 90 days from the mailing of the decision. Good cause circumstances are evaluated by the Commissioner or the Commissioner's designee in accordance with § 17b-61 of the Connecticut General Statutes. The Agency's decision to grant an extension is final and is not subject to review or appeal.

The appeal should be filed with the clerk of the Superior Court in the Judicial District of New Britain or the Judicial District in which the appellant resides.