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

[redacted] **2017**
SIGNATURE CONFIRMATION

REQUEST #798387
CLIENT ID #[redacted]

NOTICE OF DECISION

PARTY

[redacted]

PROCEDURAL BACKGROUND

On [redacted] 2016, Community Health Network of Connecticut ("CHNCT") sent [redacted] (the "Appellant") a Notice of Action ("NOA") denying as not medically necessary a prior authorization request for approval of hypoglossal nerve neurostimulator implantation.

On [redacted] 2016, the Appellant requested an administrative hearing to contest CHNCT's denial of prior authorization for hypoglossal nerve neurostimulator implantation.

On [redacted] 2016, the Office of Legal Counsel, Regulations, and Administrative Hearings ("OLCRAH") issued a notice scheduling the administrative hearing for [redacted] 2016.

On [redacted] 2016, OLCRAH issued a notice dismissing the hearing because the Appellant failed to appear.

On [redacted] 2017, OLCRAH issued a notice rescheduling the hearing for [redacted] 2017, because the Appellant appeared at the wrong location for the earlier scheduled hearing.

On [redacted] 2017, in accordance with sections 17b-60, 17-61 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
Robin Goss, Clinical Quality Analyst for CHNCT
James Hinckley, Hearing Officer

The hearing record was held open until [redacted] 2017 for the Appellant to submit additional medical information, and until [redacted] 2017 for CHNCT to complete a new medical review. On [redacted] 2017, the hearing record closed.

On [redacted] 2017, the hearing record was reopened to accept new information from [redacted] MD, and for CHNCT to complete another medical review in consideration of the new information. On [redacted] 2017, the review was completed and the hearing record closed.

STATEMENT OF THE ISSUE

The issue to be decided is whether CHNCT's denial of a prior authorization request for Medicaid approval for hypoglossal nerve neurostimulator implantation as not medically necessary was correct in accordance with state statute and regulations.

FINDINGS OF FACT

1. The Appellant is a recipient of medical assistance under the Medicaid (Husky D) program. CHNCT is the administrative services organization ("ASO") for the Department of Social Services (the "Department"). (Hearing Record)

2. The Appellant is 60 years old. (Hearing Record)

3. About twenty years ago, the Appellant was diagnosed with obstructive sleep apnea ("OSA"), a sleep disorder characterized by pauses in breathing due to airflow collapse, and resulting in poor sleep and low blood oxygen during sleep. (Appellant testimony, Hearing Record)

4. OSA is a chronic disease that leads to increased risk of cardiovascular incidents (heart attack and stroke) and worsening of several co-morbidities such as cardiac arrhythmias, diabetes, hypertension and daytime functions. (Hearing Record)

5. A positive airway pressure ("PAP") device is a machine that delivers pressurized room air into the upper airway by way of a facial or nasal mask in order to prevent collapse of the airway during sleep. (Hearing Record)

6. About twenty years ago, the Appellant tried to use a PAP device to treat his OSA but "put it in the closet" almost immediately because the device was uncomfortable to use and he could not tolerate it. (Appellant testimony)

7. On [redacted] 2015, the Appellant had a sleep study performed which made findings, among which were that he has moderate OSA with an overall Apnea-Hypopnea Index ("AHI") of 21.2 events per hour and a lowest recorded blood oxygen saturation of 67%. (Ex. 1: Prior Authorization request with attachments – 77 pages, p. 19: Nocturnal Polysomnogram results)

8. Moderate-to-severe obstructive sleep apnea, defined as an apnea-hypopnea index (AHI) score of 15 or more apnea or hypopnea events per hour, is an independent risk factor for insulin resistance, dyslipidemia, vascular disease, and death. (Ex. 1, p.33: Upper-Airway Stimulation for Obstructive Sleep Apnea, *New England Journal of Medicine* [redacted]/14)

9. The Appellant's sleep study ruled out that his condition had any neurological cause (was "central sleep apnea" or "complex sleep apnea"). (Ex. 1, p.19)

10. The Appellant's sleep study did not include the performance of a nasal continuous positive airway pressure ("CPAP") trial, and included the recommendation that "the patient should undergo a CPAP titration study". (Ex. 1, p. 19)

11. Following his sleep study, the Appellant tried to use a PAP device again but was unable to tolerate it. He reports that he had difficulty exhaling against the forced air and suffered chest pain and headaches. He tried the PAP device on multiple occasions but never wore it throughout an entire night. (Appellant testimony, Hearing Record)

12. On [redacted] 2016, the Appellant was seen by [redacted] M.D., an otolaryngologist, to be evaluated for alternative modalities of treatment for his OSA due to his poor success with PAP. (Ex. 1, p. 17: Letter from Dr. [redacted])

13. On [redacted] 2016, a flexible laryngoscopy was performed on the Appellant which revealed that the base of his tongue and epiglottis were the likely areas causing his obstruction. His examination on that date also determined that his BMI was 31.5. (Ex. 1, pp. 13-16: examination results)

14. On [redacted] 2016, a drug induced sleep endoscopy was performed on the Appellant to evaluate his upper airway anatomy during observed occurrences of obstructive apnea. Multiple episodes of obstructive apnea were observed and no evidence of concentric collapse was seen. (Ex. 1, pp.23-24: Operative Report)

15. Between [redacted] 2016 and [redacted] 2016, the Appellant was a patient at [redacted], and his discharge summary noted, "Redemonstrated chronic cortical infarct in the left precentral gyrus" (evidence of a stroke). (Ex. B: [redacted] Discharge Summary)

16. Dr. [redacted] determined that the Appellant was not a suitable candidate for surgeries such as uvulopalatopharyngoplasty with tonsillectomy or transoral robotic lingual

tonsillectomy with partial reduction of tongue base, but because of the characteristics of his condition (moderate to severe OSA with no concentric collapse, central or complex sleep apnea have been ruled out, BMI < 32 and no other contraindications), he was an excellent candidate for hypoglossal nerve stimulator implantation surgery (also "Inspire" implantation surgery). (Hearing Record)

17. Inspire implantation surgery involves the implantation of a programmable neurostimulator, a stimulation lead that delivers energy to the hypoglossal nerve, and a pressure sensing lead that detects respiration; the system works by stimulating tongue protrusion during sleep at intervals timed with breathing events, thereby preventing obstruction caused by tongue prolapse. (Hearing Record)

18. On [redacted] 2016, CHNCT received a prior authorization request from Timothy O'Brien MD for implantation of a hypoglossal nerve neurostimulator to treat the Appellant's OSA. (Hearing Summary, Ex. 1)

19. On [redacted] 2016, CHNCT's medical reviewer denied the prior authorization request and gave as reasons for the denial that the procedure is still considered to be investigational and experimental and is not consistent with generally accepted standards of medical practice. (Ex. 2: Medical Review)

20. On [redacted] 2016, CHNCT sent a NOA to the Appellant informing him that his provider's request for authorization for hypoglossal nerve neurostimulator implantation was denied because it was not medically necessary, because it did not meet generally accepted standards of care, because the treatment was still considered to be investigational. (Ex. 3: [redacted] 2016 NOA)

21. On [redacted] 2016, the Appellant requested a hearing to contest the denial of prior authorization for implantation of the Inspire device, and submitted extensive medical literature including clinical studies documenting the effectiveness of the Inspire device. (Hearing Request)

22. On [redacted] 2016, CHNCT spoke with the Appellant regarding his appeal and discussed his intolerance of CPAP, and the Appellant explained that he never followed up regarding his issues with the ordering pulmonologist or with his medical equipment provider, Lincare, but adjusted the CPAP settings by calling the manufacturer and confirming the settings with the doctor's office. CHNCT reminded the Appellant that Lincare has respiratory therapists on staff that may be able to explore other options to improve tolerance which the Appellant stated was not necessary since he has explored all the options. (Ex. 17: [redacted] 2016 Member Appeal)

23. On [redacted] 2016, CHNCT received a new letter of medical necessity from Dr. [redacted]. (Hearing Summary, Ex. 16: Letter from Dr. [redacted])

24. On [redacted] 2016, CHNCT sent the new information to its medical reviewer for an appeal Medical Review. (Ex. 17)

25. On [redacted] 2016, CHNCT's medical reviewer upheld the denial. The uphold concluded that the Inspire implant is consistent with generally accepted standards of medical practice and is not considered investigational/experimental. The reason given for the denial was that the treatment was not medically necessary because the requested procedure is more costly than an alternative service 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. The alternative treatment recommended for the Appellant was an oral appliance/mandibular advancement device. The review also noted that there was no submission of a compliance study for use of positive pressure ventilation. (Ex. 18: Medical Review)

26. On [redacted] 2017, CHNCT submitted the Appellant's [redacted] records showing evidence of a chronic cortical infarct and a [redacted] 2016 letter of medical necessity from [redacted] MD, the Appellant's pulmonologist, for reconsideration Medical Review. (Ex. 20: [redacted] [redacted] 2017 referral for reconsideration review)

27. On [redacted] 2017, CHNCT's medical reviewer completed the reconsideration review and responded that the new information from Dr. [redacted] and from [redacted] did not alter the prior determination to uphold denial of implantation of hypoglossal nerve stimulator for the Appellant. (Ex. 21: [redacted] 2017 Review Decision)

28. On [redacted] 2017, a new letter of medical necessity from Dr. O'Brien was accepted for the hearing record and CHNCT resubmitted the case to its medical reviewer with the new information. The letter from Dr. [redacted] explained that the Appellant "is not a candidate for a mandibular advancement device (oral appliance for sleep apnea) often times made by a dentist or oral surgeon because he does not have the proper dentition to facilitate the usage of the device". (Ex. C: [redacted] 2017 letter from [redacted] MD)

29. On [redacted] 2017, CHNCT's medical reviewer again upheld the original denial. The text of the upheld decision was: "The initial uphold included 2 factors: 1) lack of trial of an oral appliance and 2) lack of formal documentation of CPAP or BiPAP intolerance in a controlled environment such as a sleep study with titration or CPAP tolerance/quality study. The provider has stated that the member cannot use an oral appliance due to dentition, but has not provided documentation of intolerance of CPAP or BiPAP, the gold standard for treatment of sleep apnea". (Ex. 22: [redacted] 2017 Review Decision)

30. One of the research studies of hypoglossal nerve stimulation that the Appellant submitted for consideration for his appeal states in part that: "Positive airway pressure remains the standard first-line therapy for the management of moderate to

severe OSA, but nonacceptance or inadequate adherence remains a significant challenge that often necessitates the exploration of alternative treatment modalities. Our reported success rates, based on objective outcome measures and objective adherence monitoring, are high in a cohort of patients previously intolerant of PAP. Hypoglossal nerve stimulation is currently considered second-line therapy, and all patients being considered for implantation at our center must have previously demonstrated thorough efforts to make PAP therapy successful. In our academic sleep medicine and surgery practice, PAP intolerance is a common complaint. Our patients undergo PAP mask refits, pressure or therapeutic mode adjustments, repeat PAP titrations, disease and therapy education, and close clinical follow-up with objective data card monitoring before being considered for alternative treatment strategies". (Ex. 1, p. 77: "Upper Airway Stimulation for OSA: Early Adherence and Outcome Results of One Center", *American Academy of Otolaryngology Foundation* [redacted]/16)

31. The Appellant has not fully investigated whether PAP therapy may be successful for him. (Hearing Record)

CONCLUSIONS OF LAW

1. The Department is the designated state agency for the administration of the Medicaid program pursuant to Title XIX of the Social Security Act and may make such regulations as are necessary to administer the medical assistance program. [Conn. Gen. Stat. §17b-2; Conn. Gen. Stat. §17b-262]

2. 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. [Conn. Gen. Stat. § 17b-259b (a)]

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. [Conn. Gen. Stat. 17b-259b (b)]

3. Implantation of a hypoglossal nerve neurostimulator is not medically necessary for the Appellant, because it is more costly than an alternative treatment at least as likely to produce equivalent therapeutic results in treating the Appellant's condition.

4. CHNCT was correct when it denied as not medically necessary the Appellant's provider's request for prior authorization for Implantation of a hypoglossal nerve neurostimulator.

DISCUSSION

PAP therapy is not only less costly than implantation of a hypoglossal nerve neurostimulator to treat the Appellant's OSA, it is also less invasive and more likely to produce better results, if tolerated. The Appellant indisputably has a medical condition that requires treatment, and may have already suffered a medical consequence (cortical infarct) related to the untreated condition. However, PAP therapy remains the "gold standard" first-line treatment for OSA, and implantation of a neurostimulator device remains a second-line treatment that should only be considered after thorough attempts have been made to make PAP therapy successful. Although a PAP titration study was recommended at the time of the Appellant's polysomnography, he never underwent one. Instead, the Appellant has tried to adjust his machine levels on his own. By his own testimony, the Appellant has never used the equipment for even one entire night, yet he has not expressed any interest in enlisting the aid of professionals to help have equipment fitted and properly adjusted for him so that he might be able to tolerate it.

The Appellant requires a monitored study, while he sleeps, to determine whether settings can be found, and equipment properly fitted to him, so that he might be able to tolerate PAP therapy. Only after a thorough exploration of whether PAP therapy can be made successful should implantation of a hypoglossal nerve neurostimulator be considered.

DECISION

The Appellant's appeal is **DENIED.**

James Hinckley

James Hinckley
Hearing Officer

cc: CHNCT Appeals

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 06105-3725.

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, 55 Elm Street, 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.