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

[redacted], 2018
SIGNATURE CONFIRMATION

Client ID # [redacted]
Hearing ID # [redacted]

NOTICE OF DECISION

PARTY

[redacted]

PROCEDURAL BACKGROUND

On [redacted], 2017, the Department of Social Services (the "Department"), through its Administrative Service Organization, Community Health Network of Connecticut, Inc. ("CHNCT"), sent [redacted] (the "Appellant") a Notice of Action ("NOA") denying her provider's request for approval of a Omnipod ambulatory insulin infusion pump and pods based on not receiving enough information to show that the replacement pump was medically necessary.

On [redacted] 2017, the Appellant requested an administrative hearing to contest the Department's denial of an Omnipod ambulatory insulin infusion pump and pods.

On [redacted] 2017, the Office of Legal Counsel, Regulations, and Administrative Hearings ("OLCRAH") scheduled an administrative hearing for [redacted] 2017.

On [redacted] 2017, 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 participated in the hearing:

[redacted], Appellant
[redacted], Observer
Robin Goss, RN, CHNCT Representative
Shelley Starr, Hearing Officer

STATEMENT OF THE ISSUE

The issue is whether CHNCT's decision to deny the Appellant's prior authorization request for a Omnipod ambulatory insulin infusion pump and pods because it is not medically necessary is correct and in accordance with statute and regulations.

FINDINGS OF FACT

1. The Appellant is [redacted]. (Exhibit 1: Prior Authorization Request dated [redacted], 2017; Appellant's Testimony)

2. The Appellant is a participant in the Medicaid program, as administered by the Department of Social Services (the "Department"). (Hearing Record; Appellant's Testimony)

3. CHNCT is the Department's contractor for reviewing medical requests for prior authorization of medical services. (Hearing Record; Department's Testimony)

4. The Appellant is a Type1 Diabetic, who was diagnosed with diabetes at the age of seven. (Exhibit 1: Prior Authorization Request, received [redacted], 2017)

5. The Appellant's treating endocrinologist for her Type 1 Diabetes is Dr. [redacted]. (Hearing Summary; Exhibit 15: Letter of Medical Necessity faxed [redacted], 2017)

6. The Appellant currently uses a Medtronic ambulatory insulin infusion pump to assist with her glucose regulation. The pump is approximately four (4) years old and should be covered under the manufacturer's warranty. (Department's Testimony; Appellant's Testimony; Hearing Record)

7. The Appellant has difficulty using her Medtronic pump as she experiences wide fluctuations with her blood glucose readings, false readings and issues with her pump shutting off due to the inaccurate signaling of her glucose levels. In addition, she has problems with her insertion sites and scar tissue formation in her abdomen. (Hearing Summary; Exhibit 1: Prior Authorization Request, received [redacted], 2017; Appellant's Testimony; Exhibit 15: Letter of Medical Necessity from [redacted]

8. The Appellant has experienced difficulty using her Medtronic pump in the past and it was replaced by the manufacturer. The pump has not been recently identified as malfunctioning by the manufacturer and the

Appellant has not inquired if the pump is currently covered under the manufacturer's warranty. (Appellant's Testimony; Hearing Record)

9. The Appellant would like to have the Omnipod replacement pump as it is a dependable, waterproof and less complex system that would enable her with a wider variety of insertion sites. (Appellant's Testimony; Exhibit 15: [redacted]; Hearing Record)

10. On [redacted], 2017, Community Heath Network of CT ("CHNCT") received a prior authorization request [redacted], a durable medical equipment ("DME") vendor, for an external Omnipod ambulatory insulin infusion pump and pods for diagnosis of coronary artery disease. (Exhibit 1: Prior Authorization Request received [redacted], 2017; Hearing Summary)

11. On [redacted], 2017, CHNCT completed an internal review of the medical information submitted and denied the prior authorization request for an Omnipod ambulatory insulin infusion pump and pods due to limited clinical information submitted and there was an inability to validate that a Omnipod pump as being medically necessary or clinically appropriate. (Exhibit 2: Medical Review dated [redacted], 2017)

12. On [redacted], 2017, CHNCT sent a Notice of Action ("NOA") to the Appellant advising her that the prior authorization request for the Omnipod ambulatory insulin infusion pump and pods was denied because not enough information was provided to show that these goods are medically necessary. (Exhibit 3: Notice of Action dated [redacted], 2017)

13. On [redacted] 2017, CHNCT notified [redacted] and [redacted] of the Appellant's appeal and requested additional information to validate medical necessity. CHNCT requested to have the diagnosis code clarified, clinical documentation from the ordering physician which supports the medical necessity for the request of a replacement pump, specifically is current pump working; clarification if the Medtronic pump is not providing accurate deliverance of insulin and a letter of Medical Necessity supporting the medical need for a replacement ambulatory pump (Omnipod). The information was due no later than [redacted] 2017. (Exhibit 6 and Exhibit 7: Medical Record Requests dated [redacted] 2017)

14. On [redacted], 2017, CHNCT received a Letter of Medical Necessity from the Appellant and duplicate medical records from her Endocrinologist. (Exhibit 10: Appellant's Letter of Medical Necessity received [redacted], 2017; Exhibit 8: Letter of Medical Necessity dated [redacted], 2017)

15. On [redacted] 2017, CHNCT sent the appeal for a Medical Review. (Exhibit 11: Medical Review Request dated [redacted], 2017)

16. On [redacted], 2017, CHNCT completed an internal medical review and the denial was upheld. The reviewer noted a lack of evidence that the information provided still does not clarify exactly what is wrong with the current pump. Medtronic has not identified a malfunctioning pump. (Exhibit 11: Medical Review Request dated [redacted] 2017; Exhibit 13: Medical Review dated [redacted], 2017)

17. On [redacted], 2017, CHNCT received a Letter of Medical Necessity from [redacted]. (Exhibit 15: Letter of Medical Necessity received [redacted], 2017).

18. On [redacted], 2017, CHNCT sent the additional information for a reconsideration review. (Exhibit 16: Reconsideration Request dated [redacted], 2017)

19. On [redacted], 2017, the internal review was completed and the denial was upheld. The reviewer noted that the Letter of Medical Necessity from [redacted], was considered and determined that there is no new information sufficient to reverse the denial of the requested Omnipod insulin pump and sensors. (Exhibit 17: Reconsideration Review Results dated [redacted]2017)

20. CHNCT recommended that if future findings change and true current pump malfunction is documented which cannot be rectified by the manufacturer, a request for replacement should be submitted and will be given prompt and careful review. (Exhibit 16: Reconsideration Review Review Request dated [redacted] 2017; Exhibit 17: Reconsideration Review Results dated [redacted], 2017)

21. There is lack of evidence in the hearing record, that the replacement Omnipod ambulatory insulin infusion pump and pods system is medically necessary and clinically appropriate for the Appellant. (Hearing Record)

22. The repair and replacement of the Medtronic pump may still be under warranty by the manufacturer. (Department's Testimony; Appellant's Testimony)

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(6); 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)]

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

3. Durable medical equipment or “DME” means 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;
   (D) is nondisposable [Conn Agencies Regs. § 17b-262-673 (8)]

4. Payment for DME and related equipment is available for Medicaid clients who have a medical need for equipment that 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. [Conn Agencies Regs. § 17b-262-675]

5. 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. [Conn Agencies Regs. § 17b-262-676(a)(1)]

   Examples of DME covered by Medicaid are, but not limited to:

   (A) wheelchairs and accessories;
   (B) walking aides, such as walkers, canes, and crutches;
   (C) bathroom equipment such as commodes and safety equipment;
   (D) inhalation therapy equipment such as IPPB machines, suction machines, nebulizers, and related equipment;
   (E) hospital beds and accessories; and
   (F) enteral/parenteral therapy equipment [Conn Agencies Regs. § 17b-262-676 (a)(d)]

   The Omnipod ambulatory insulin infusion pump and pods is "durable medical equipment" or "DME", as "durable medical equipment" or "DME" is defined in state regulations governing the administration of the Medicaid program.

6. 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. [Conn Agencies Regs. § 17b-262-676 (b)(1).

   CHNCT correctly determined that the Appellant did not provide medical documentation to establish that an Omnipod ambulatory insulin infusion pump and pods is medically necessary.

   CHNCT correctly determined that based on the provided documentation, a replacement pump is not medically necessary.

   CHNCT correctly denied the request for the authorization of an Omnipod ambulatory insulin infusion pump and pods as it is not medically necessary for the Appellant because the clinical information submitted does not validate this request.

DISCUSSION

The medical documentation submitted by the Appellant's durable medical equipment vendor and endocrinologist, in addition to the testimony given by the Appellant, does not support the approval of the prior authorization request for an Omnipod ambulatory insulin infusion pump and pods.

While the Omnipod pump could be beneficial to the Appellant because of its less complex design and features, the clinical information received was minimal and did not demonstrate that the Omnipod replacement pump is medically necessary and clinically appropriate.

The Appellant indicated at the hearing that she has not contacted her current Medronic pump manufacturer to inquire if her pump is under warranty. In addition, no documentation has been provided regarding the malfunctioning of her pump and why a replacement pump is necessary.

CHNCT's decision to deny the authorization of the Ominipod ambulatory insulin infusion pump and pods is upheld. The Appellant is encouraged to contact her current Medronic pump manufacturer and discuss her pump malfunctioning issues and options.

DECISION

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

Shelley Starr
Hearing Officer

cc: appeals@chnct.org
Fatmata Williams, DSS

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 Legal Counsel, Regulations, and Administrative Hearings, 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, 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 his 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.