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

[redacted], 2021
Signature Confirmation

CLIENT ID# [redacted]
REQUEST # [redacted]

NOTICE OF DECISION

PARTY

[redacted]

PROCEDURAL BACKGROUND

On [redacted], 2021, the HUSKY Health Program issued [redacted] (the "Appellant") a notice of action denying a request for authorization of a Jaco V2 Robotic arm and Kinova lift arm.

On [redacted] 2021, the Appellant requested an administrative hearing to contest the denial of the Jaco V2 Robotic arm and Kinova lift arm.

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 to reschedule the hearing.

On [redacted] 2021, the 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, the OLCRAH held an administrative hearing. The following individuals attended the administrative hearing:

[redacted], Appellant
Caroline Butler, Nurse Consultant, CT Office of the Healthcare Advocate
Robin Goss, RN, Appeals & Grievances Analyst HUSKY Health
Attorney Patricia McCooey, Staff attorney DSS

Dr. Lawrence Magras, Chief Medical Officer HUSKY Health
Dr. Kristine Lisi, VP of Clinical Affairs HUSKY Health
Roberta Geller, RN, Assoc. VP Utility Manager HUSKY Health
Roberta Gould, Hearing Officer

The hearing record remained open for the submission of additional evidence. On [redacted], 2021, the hearing record closed.

STATEMENT OF ISSUE

The issue to be decided is whether the HUSKY Health Program's decision to deny a Jaco V2 Robotic arm and a Kinova lift arm for the Appellant is correct.

FINDINGS OF FACT

1. The Appellant is a participant in the Medicaid program, as administered by the Department. (Hearing summary)

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

3. The Appellant is 30 years old, born on [redacted]. (Exhibit 1: Prior Authorization request dated [redacted]/2020)

4. [redacted], M.D. is the Appellant's physician at the Neuromuscular Center at the Hospital for Special Care, New Britain, CT. (Exhibit 1)

5. The Appellant has a diagnosis of Spinal Muscular Atrophy type 2 ("SMA"), flaccid quadriparesis with preservation of finger, wrist and arm flexor movements, congenital kyphoscoliosis, neuromuscular scoliosis, asthma and restrictive airway disease. (Exhibit 1 and Hearing summary)

6. The Appellant lives alone in an accessible apartment and receives approximately 45 hours of personal care assistance ("PCA") per week. She transfers with an aide, requires custom seating and support, uses a vest with cough assist device and a nebulizer, and is power wheelchair dependent. (Exhibit 1, Appellant's Exhibit A: Letter from Caroline Butler, Office of the Healthcare Advocate dated [redacted]/2021 and Hearing summary)

7. The Appellant works full time as a graphic designer at [redacted], and drives independently using a handicap-accessible van equipped with joy sticks and a specialized computer system. (Appellant's testimony)

8. The Appellant had a service dog, but the dog passed away in [redacted] of 2021. She has had two service dogs over a period of 13 years. (Exhibit 11: Letter dated [redacted]/2021 and Appellant's testimony)

9. On [redacted], 2020, the Appellant's Occupational Therapist ("OT"), [redacted], M.S., OTR, conducted an evaluation to determine the Appellant's strength and range of motion. It was determined that SMA has resulted in severe weakness in her trunk and bilateral upper extremities, limiting her ability to be fully independent with activities of daily living ("ADL's") and some instrumental activities of daily living ("IADL's"). (Exhibit 1)

10. During the OT evaluation on [redacted] 2020, the Appellant participated in a 2-hour trial of the Jaco Kinova Robotic Arm, which was mounted on her power wheelchair. She was able to use the joystick on her wheelchair to feed herself, brush her teeth, reach her thermostat, adjust her glasses and clothing, take medications, open doors, perform simple meal preparation, pick up a telephone, use a suction machine to manage secretions, reposition her legs, use an inhaler, and turn the pages of a book. (Exhibit 1 and Appellant's Exhibit F: video of in-home Jaco evaluation)

11. On [redacted] 2020, [redacted], M.D. prescribed a Jaco Kinova Robotic Arm for the Appellant. (Exhibit 1)

12. The Jaco V2 Robotic Arm and Kinova Lift Arm is the first of its kind technology and is designed to be used by individuals with upper extremity mobility limitations who use a power wheelchair. (Appellant's Exhibit A)

13. On [redacted], 2020, CHNCT received a prior authorization request from ATG/NuMotion for a Jaco V2 Robotic Arm and Kinova Lift Arm. (Exhibit 1 and Hearing summary)

14. The Jaco V2 Robotic Arm and Kinova Lift Arm are "durable medical equipment" as defined in state law. (Hearing record)

15. On [redacted], 2021, [redacted], M.D. wrote a letter in support of the Appellant's medical necessity for a Jaco V2 Robotic Arm and Kinova Lift Arm because she has depended on a wheelchair for mobility her entire life, the device would help her maintain her independence while working, and the robotic arm would also allow her to be less dependent on a PCA for daily needs. He also stated that an oral medication, Evrysdi, has become available for treatment of SMA and helps to produce a protein that is lacking in this medical condition. (Appellant's Exhibit C: Kinova product specs and letter dated [redacted]/2021)

16. On [redacted], 2021, CHNCT received additional clinical documentation regarding the Appellant's capabilities and the necessity for adaptive equipment that allows her independence with ADL's due to decreased functional use of her upper extremities. (Exhibit 2: Additional medical documentation and Hearing summary)

17. On [redacted], 2021, CHNCT reviewed the prior authorization request for a Jaco V2 Robotic Arm and Kinova Lift Arm. (Hearing summary)

18. On [redacted], 2021, CHNCT denied the request for a Jaco V2 Robotic Arm and Kinova Lift Arm because it is not proven and is considered experimental, and studies have not shown how the item will help the Appellant consistently with daily activities. (Exhibit 4: Notice of action for denied services or goods dated [redacted]/2021 and Hearing summary)

19. On [redacted], 2021, [redacted], M.D., provided a statement indicating that the Appellant's diagnosis of SMA Type II is progressive and will likely result in her being unable to move her arms and neck in the future. (Appellant's Exhibit B: Medical documentation)

20. On [redacted], 2021, the Appellant requested an appeal review of her request for the Jaco V2 Robotic Arm and Kinova Lift Arm because the plan covers a prosthetic device for its members with loss of their anatomical structure and Jaco arms ordered by a physician have been covered by many funding sources in the U.S. (Exhibit 5: Appeal request dated [redacted]/2021 and Hearing summary)

21. On [redacted], 2021, CHNCT notified the Appellant, [redacted], M.D., ATG/NuMotion and [redacted] of Kinova Robotics of the Appellant's appeal and requested more medical information to support her appeal. (Exhibit 6: Acknowledgement letter dated [redacted]/2021, Exhibit 7: Medical record request dated [redacted]/2021, Exhibit 8: Medical record request dated [redacted]/2021, Exhibit 9: Medical record request dated [redacted]/2021, Exhibit 10: Medical record request dated [redacted]/2021 and Hearing summary)

22. On [redacted] 2021, the Appellant again requested an appeal for the denial of a Jaco V2 Robotic Arm and Kinova Lift Arm, reiterating that her service dog had passed away in [redacted] 2021, and stated that "service dogs can help open doors and pick-up objects off the floor, the same tasks I would be capable of with the use of a Jaco robotic arm." She indicated that she cannot feed herself, hydrate, protect herself and that she does not have a lift or transfer equipment during the times a caregiver is not present. The Appellant pointed out several physician/specialty medical societies that have recently prescribed this device including a child neurologist, doctors of Osteopathic medicine, neurogeneticists, neurologist, occupational therapists, pediatric orthopedic surgeons, psychiatrists and physical therapists. (Exhibit F)

23. On [redacted], 2021, Robin Goss, RN, Appeals and Grievances Analyst at CHNCT, requested another medical review be completed for the request of the Jaco V2 Robotic Arm and Kinova Lift Arm. It was noted that the Appellant's physician indicated she will be a candidate for an oral medication but does not indicate why. (Exhibit 13: Medical review request dated [redacted]/2021 and Hearing summary)

24. On [redacted] 2021, CHNCT completed a medical review. The denial for the Jaco V2 Robotic Arm and Kinova Lift Arm was upheld. The medical reviewer noted that the OT evaluation conducted in [redacted] of 2020, indicated that the Appellant trialed the device and was able to open doors, pick up a cup and other items, that the device

would optimize hydration and nutrition by enabling her to perform activities such as using cups and utensils, and that the robotic arm would enable her to be more independent. However, the medical reviewer also noted that the Jaco V2 Robotic Arm and Kinova Lift Arm is unproven, experimental or of research in nature as studies have shown inconsistent results and there is insufficient clinical evidence for the efficacy of this device. The medical reviewer also stated that documentation submitted is insufficient to demonstrate that this device will enhance the Appellant's function beyond the assistive devices already in place, or decrease the amount of home care needed, and that such documentation is insufficient to show how the device will allow her either greater or more prolonged independence. (Exhibit 14: Medical review dated [redacted]/2021 and Hearing summary)

25. The Appellant is expected to continue to require increased assistance from caregivers due to the progressive nature of her disorder and has progressive decline in muscle strength. (Exhibit 1)

26. On [redacted] 2021, Lawrence Magras, M.D., CHNCT's Chief Medical Officer, denied the request for a Jaco V2 Robotic Arm and Kinova Lift Arm because the information submitted does not support the medical necessity for this item, it is considered to be unproven and experimental and there is not enough documentation to indicate how this device will meet her medical needs. Dr. Magras also stated that the robotic arm is not a covered item in the HUSKY Health program, studies of the device have shown inconsistent results, there is not enough clinical evidence to establish the medical necessity of the robotic arm to meet her medical needs as her condition progresses, and documentation submitted does not show how it will improve her ability to function and meet her medical needs beyond the assistive devices and services already being provided. (Exhibit 15: Determination letter dated [redacted]/2021 and Hearing summary)

27. On [redacted] 2021, CHNCT issued a notice of denial to the Appellant for prior authorization of a Jaco V2 Robotic Arm and Kinova Lift Arm because it was not medically necessary, and is of unproven, experimental or research in nature. (Exhibit 15 and Hearing summary)

28. The Centers for Medicare and Medicaid Services ("CMS") uses a Healthcare Common Procedure Coding System ("HCPCS") to establish preliminary coding recommendations on all code applications. (Exhibit 16: Email with application summaries for DME from Attorney McCooey dated [redacted]/2021)

29. On [redacted] 2017, CMS reviewed an application from Partners in Medicine, LLC to establish a new Level II HCPCS code for the Jaco durable robotic arm. CMS issued a final decision that a national program operating need for the Jaco robotic arm was not identified by Medicare, Medicaid, or the private insurance sector to establish a Level II code and that jurisdiction for Medicaid claims is maintained by the Medicaid agency in the state in which a claim is filed. (Exhibit 16)

30. To date, CMS has not assigned a HCPCS code to the Jaco V2 Robotic Arm and Kinova Lift Arm. (Exhibit 16 and Attorney McCooey's testimony)

31. Arizona, California, Colorado, Florida, Idaho, Illinois, Indiana, Kentucky, Louisiana, Minnesota, Ohio, South Carolina, Texas and Washington state's Medicaid plans cover the Jaco V2 Robotic Arm and Kinova Lift Arm. (Appellant's Exhibit D: Email with attachments from Caroline Butler, Office of the Healthcare Advocate dated [redacted]/2021)

32. The Jaco V2 Robotic arm and Kinova lift arm is not a covered item under Connecticut's HUSKY Health Medicaid program. (Hearing record)

33. On [redacted], 2018, the Office of Medicare Hearings and Appeals ("OMHA") issued a decision regarding the denial of coverage for a Jaco V2 Robotic Arm and Kinova Lift Arm for an individual with SMA Type II. After conducting a de novo review of the evidence, an Administrative Law Judge ruled that coverage under the **Medicare** program must be extended for the Jaco robotic arm because it is medically necessary and appropriate, is in accordance with generally accepted standards of medical practice, is considered clinically appropriate, and considered effective for the patient's illness, injury or disease. (Appellant's Exhibit B)

34. CHNCT conducted research of the psycho-social impact, caregiver burdens, and additional evidence pertaining to the Jaco V2 Robotic Arm and Kinova Lift Arm including a 2010 thesis study, a study by the manufacturer, and an independent research study that has not been peer-reviewed. CHNCT's Chief Medical Officer determined that the three study's results were inconclusive, all called for additional research and such research is investigational at this point. (Lawrence Magras, M.D.'s testimony and Kristine Lisi, M.D.'s testimony)

35. There was no medical evidence presented that the Jaco V2 Robotic Arm and Kinova Lift Arm meet the definition of medical necessity.

36. 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. However, the Appellant requested to reschedule the hearing and the hearing record remained open through [redacted], 2021, to allow for the submission of an additional information. Because of the delay in the close of the hearing record, this final decision is not due until [redacted] 2021, and is therefore timely.

CONCLUSIONS OF LAW

1. Section 17b-2 of the Connecticut General Statutes designates the Department of Social Services to be the state agency for the administration of the Medicaid program pursuant to Title XIX of the Social Security Act.

2. Conn. Gen. Stat. § 17b-262 states, in part, that the Commissioner may make such regulations as are necessary to administer the Medical Assistance Program.

3. Sections 17b-262-672 to 17b-262-682, inclusive, of the Regulations of Connecticut State Agencies set forth 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 Statutes.

4. For the purposes of sections 17b-262-672 to 17b-262-682, inclusive, of the Regulations of Connecticut State Agencies, the following definitions apply:

   "Client" means a person eligible for goods or services under the Medicaid program.

   "Department" means the Department of Social Services or its agent.

   "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; and (D) is nondisposable.

   "Medicaid" means the program operated by the Department of Social Services, pursuant to section 17b-260 of the Connecticut General Statutes and authorized by Title XIX of the Social Security Act.

   "Prior authorization" or "PA" means approval for the service or the delivery of goods from the department before the provider actually provides the service or delivers the goods.

   "Provider" means the vendor or supplier of durable medical equipment who is enrolled with the Department as a medical equipment, devices, and supplies supplier.

5. Conn. Agencies Regulations § 17b-262-676(a)(1) 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.

6. Conn. Agencies Regulations § 17b-262-676(a)(4) 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.

CHNCT correctly determined that the prior authorization for a Jaco V2 Robotic

Arm and Kinova Lift Arm required a physician's prescription and documentation showing the Appellant's medical need for this item.

9. Conn. General Statutes § 17b-259b(a) provides that for the 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.

10. Section 17b-262-676(b)(1) of the Regulations of Connecticut State Agencies 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.

CHNCT correctly determined that the Jaco V2 Robotic Arm and Kinova Lift Arm are unproven and of an experimental or research nature.

CHNCT was correct when it denied the provider's request for authorization of a Jaco V2 Robotic Arm and Kinova Lift Arm as not medically necessary on the basis that there is not enough clinical evidence to establish the medical necessity of the robotic arm to meet her medical needs as her condition progresses, and documentation submitted does not show how it will improve her ability to function and meet her medical needs beyond the assistive devices and services already being provided.

On [redacted], 2021, CHNCT correctly denied the Appellant's provider's request for authorization of payment for a Jaco V2 Robotic Arm and Kinova Lift Arm through the Medicaid program.

DISCUSSION

After reviewing the evidence and testimony presented at this hearing, I find that CHNCT's action to deny the request for authorization for a Jaco V2 Robotic Arm and Kinova Lift Arm is upheld. The Appellant currently possess a power wheelchair with custom seating and support, a vest with cough assist device, a nebulizer, and has PCA assistance approximately 45 hours per week. Although the OMHA issued a favorable decision regarding the denial of coverage for a Jaco V2 Robotic Arm and Kinova Lift Arm for an individual with SMA Type II under Medicare, this does not affect coverage under State Medicaid programs. In 2017, CMS established that jurisdiction for Medicaid claims is maintained by the Medicaid agency in the state in which a claim is filed. Currently the Jaco V2 Robotic arm and Kinova lift arm is not a covered item under Connecticut's HUSKY Health Medicaid program.

In [redacted] of 2020, the Appellant successfully participated in a 2-hour trial of the Jaco Kinova Robotic Arm, which was mounted on her power wheelchair. Although the robotic arm has been demonstrated to assist individuals with upper extremity mobility limitations who use a power wheelchair, Regulations of Connecticut State Agencies clearly state that the department shall not pay for anything of an unproven, experimental or research nature. Three separate studies were inconclusive and all called for additional research. Testimony by the Chief Medical Officer of HUSKY Health indicates that the Jaco robotic arm is still unproven, experimental or of research in nature and that there is insufficient clinical evidence for the efficacy of this device.

DECISION

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

Roberta Gould
Hearing Officer

cc: Dr. Brad Richards, DSS, Central Office
Robin Goss, CHNCT

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.