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

2023 Signature Confirmation

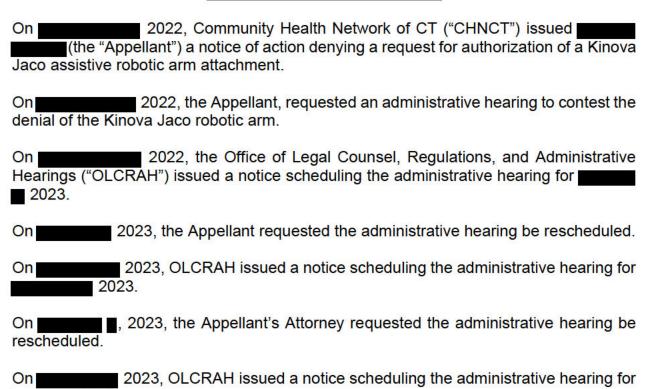
Case ID # 1
Client ID #
Request # 205625

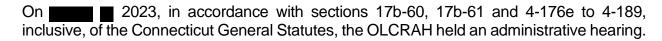
NOTICE OF DECISION

PARTY

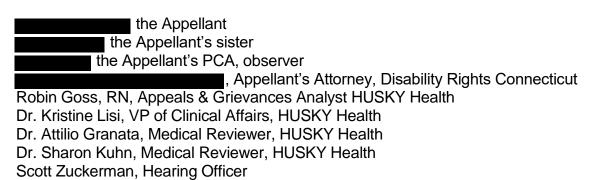


PROCEDURAL BACKGROUND





The following individuals attended the administrative hearing:



The hearing remained open for CHNCT to submit additional documentation to the Appellant to review and comment on and for the Appellant to provide an unedited home trial video for CHNCT to review and comment on. On 2023, the record closed.

STATEMENT OF ISSUE

The issue to be decided is whether the HUSKY Health Program's decision to deny a Kinova Jaco Robotic 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"). (Hearing Summary)
- 3. The Kinova Jaco assistive robotic arm is considered DME by the HUSKY health program. (Hearing Record)
- 4. The Appellant is years old (DOB ______). (Exhibit 1: Prior Authorization request)
- 5. The Appellant has a diagnosis of Athetoid/quadriplegic Cerebral Palsy. Dependent on caregivers for all of Activities of daily living ("ADLs") and Instrumental Activities of Daily Living ("IADLs). The Appellant's cerebral palsy diagnosis has resulted in severe weakness and impaired isolated motor control in trunk and bilateral upper extremities. This limits ability to be independent while performing tasks at home, requiring to have someone assist

to 15 hours daily of caregiver assistance for eating, dressing, grooming, bathing, transfers in and out of power wheelchair, toileting, and ambulating through her home. (Exhibit 1: Prior authorization request / Letter of Medical Necessity)

- The Appellant wishes to utilize the DME to assist in completing ADLs and IADLs and rely less on caregiver assistance as she wishes to live independently. (Exhibit 10)
- 7. The Appellant demonstrates significantly impaired motor control of isolated movements of Upper Extremities due to frequent movements of upper extremities.

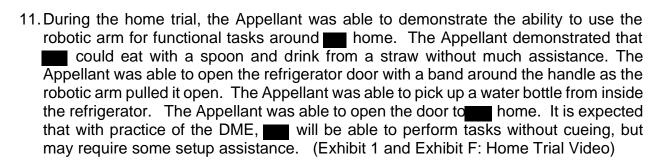
 is unable to be independent with self-feeding and self-care. (Exhibit 1)
- 8. "The Appellant is able to operate power wheelchair by using a conventional joystick and switches for power seat function. These abilities are necessary functions to be able to control the Kinova Jaco Robotic Arm." (Hearing Record and Exhibit 1-Note from Physical Therapist, 2022)
- 9. The Appellant participated in two trials of the Jaco Robotic Arm, one in home and one at the clinic. The DME was mounted to wheelchair and was able to demonstrate proficiency with the device. (Exhibit 1)
- 10. During the trials and with the integration of the robotic arm with the power wheelchair the Appellant was able to perform the following ADLs, IADLs, and other tasks with either verbal cueing, or with some assistance.

ADL	Level of Independence without Jaco robotic arm	Level of Independence when using the Jaco Robotic Arm	Expected level of independence with training of the Jaco Robotic Arm	Comments
Self-Feeding	*Dependent	**Standby Assistance	Setup Assistance	Practiced eating yogurt, completed with verbal cueing
Hydration	Maximal Assistance	Standby Assistance	Modified Independent	Practiced with cup and straw
Brushing Teeth	Substantial/Maximal Assistance	Minimal Assistance	Setup Up Assistance	
Combing Hair	Maximal Assistance	Minimal Assistance	***Modified Independent	
Turning on the Faucet	Maximal Assistance	Standby Assistance	Modified Independent	Practiced during trials and able to complete

				with verbal cueing
Temperature	Dependent	Moderate	Minimal	
Regulation	Assistance	Assistance	Assistance	
Adjusting	Dependent –	Minimal	Modified	
glasses and clothing	Maximal Assistance	Assistance		
Nasal	Dependent –	Minimal	Modified	
Hygiene	Maximal Assistance	Assistance	Independent	
Independent	Level of	Level of	Level of	
Activity of	Independence	independence	Independence	
Daily Living	without the Jaco	demonstrated	expected to be	
	robotic arm	when using the	achieved with	
		Jaco robotic	additional	
		arm.	training of the	
			Jaco robotic	
Taldes	Danasalast	NAS a second	arm	
Taking	Dependent	Minimal	Set up	
Medication	Assistance	Assistance	Assistance	TI
Opening	Maximal Assistance	Standby	Modified	The
doors		Assistance	Independent	Appellant
				was able to
				open the
				door in the
				home
				without verbal
Simple meet	Donandant	Minimal	Cotup	cueing
Simple meal	Dependent assistance		Set up	
preparation	assistance	assistance	assistance	

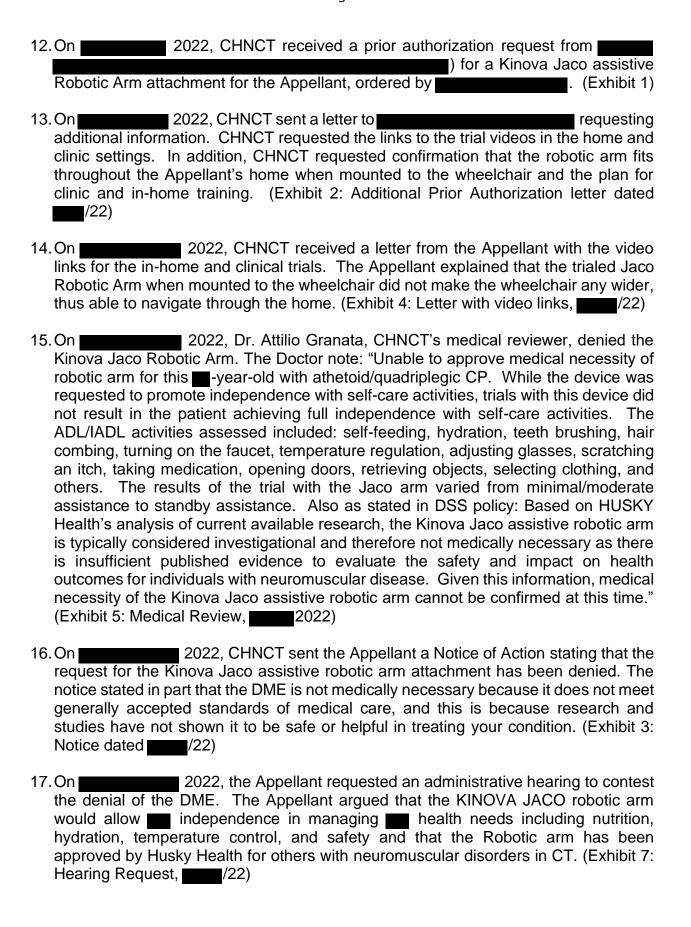
^{*} Requires 100% assistance to complete the task

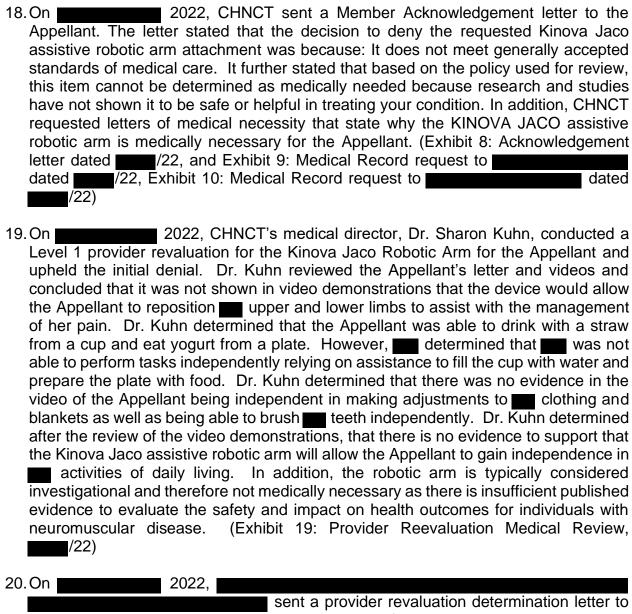
(Exhibit 1: Prior Authorization Packet, Ex. D: Home trial video; Ex. E: Clinic trial video and Ex. F: Unedited trial video)



^{**} Requires verbal cueing only from the caregiver

^{***} Requiring a medical device to complete the task, 0% caregiver assistance



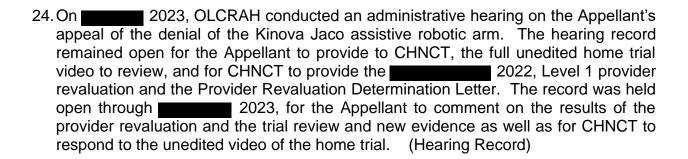


sent a provider revaluation determination letter to upholding the denial of the Robotic arm attachment. Dr. Magras determined after the review of the video demonstrations and the Appellant's letter, that there is no evidence to support that the Kinova Jaco assistive robotic arm will allow the Appellant to gain independence in activities of daily living. In addition, the robotic arm is typically considered investigational and therefore not medically necessary as there is insufficient published evidence to evaluate the safety and impact on health outcomes for individuals with neuromuscular disease. (Exhibit 20: Provider Revaluation Determination Letter,

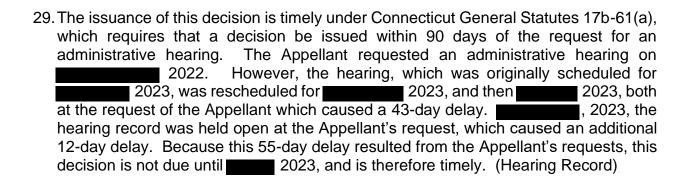
21.On 2022, CHNCT requested information for the appeal review. The medical reviewer determined that based on the information presented the Kinova Jaco Robotic Arm is not considered medically necessary. The Jaco assistive device is not expected to provide benefits in terms of optimizing Mobility-related ADLs and reducing

the need for caregiver assistance. It is not strongly supported by medical peerreviewed science. It is not medically necessary and is experimental and investigational. The external reviewer cited: "Based on Husky Health's analysis of current available research (including the clinical studies cited below), clinical guidelines, and other relevant factors, at this time, the Kinova Jaco assistive robotic arm is typically considered investigational and therefore not medically necessary as there is insufficient published evidence to evaluate the safety and impact on health outcomes for individuals with neuromuscular disease. Requests will be reviewed on a case-by-case basis and determinations will be based a person-centered assessment of the individual's unique healthcare needs and the potential benefits and harms from use of the device for that person and other evidence that may be included together with each request in order to determine whether or not the device is medically necessary for that person..." (Exhibit 15: Medical review request with external review / DSS Provider Policies and Procedures for Wheelchair – Mounted assistive Robotic Arm Attachment, (22)

- 22. On 2022, CHNCT's Medical Director, Julie O'Connor, conducted an appeal review. Dr. O'Connor reviewed the Appellant's Appeal letter and trial videos and determined they do not support claim of independence with ADLs. "The videos demonstrate limited ability to self-feed, even with optimal setup. There was no demonstration of ability to independently perform oral hygiene, readjust body position for prevention of pressure injuries, add/subtract clothing for temperature regulation, or using a cell phone. Additionally, the submitted evaluation from the physical therapist supports that the member will not achieve independence. The evaluation therapist letter specifically states "...the robotic arm can be expected to assist with self-care, household tasks, and social activities which will dramatically improve I independence, safety, and will reduce the need for constant caretaker attention." Lastly, based on all current available literature, Husky Health's analysis of the Kinova Jaco assistive robotic arm, is that this device is typically considered investigational. Devices considered investigational do not meet the DSS definition of medical necessity given insufficient published evidence to evaluate the safety and impact on health outcomes for individuals with neuromuscular disease. Given the above, medical necessity of the Kinova Jaco assistive robotic arm is not supported at this
- 23. On 2022, CHNCT sent a Determination letter to the Appellant upholding the 2022, denial of the Kinova Jaco Robotic Arm because the information provided did not support the medical necessity for the requested Kinova Jaco assistive robotic arm attachment because: At this time according to current peerreviewed literature (research articles and Husky Health's policy, the Kinova Jaco assistive robotic arm is considered investigational. Devices considered investigational do not meet the DSS definition of medical necessity. Additionally, the videos and testing results sent by your providers indicate you have limited ability to perform all of your activities of daily living independently. (Exhibit 17: Determination Letter dated 22)



- 25. On 2023, Dr. Julie O'Connor, CHNCT's medical director, upheld the denial of the Kinova Jaco Robotic arm attachment, after reviewing the appeal documents and unedited videos of the home trial. "The unedited video, demonstrates the member's use of the robotic arm with eating a spoonful of yogurt, taking a sip of water from a glass, opening and retrieving a bottle of water from the refrigerator". Dr. O'Connor commented that the greatest barrier identified was not knowledge of how to control the joystick but her underlying conditions ... (Exhibit 21: Medical Director Note)
- 26. On 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 Spinal Muscular Atrophy ("SMA") Type II, a genetic disease causing extreme muscle weakness in all extremities. 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: Office of Medicare Hearings and Appeals)
- 27. On 2021, The Department of Social Services (the "Department"), CHNCT Medical Reviewers, and Clinical Quality Subcommittee approved changes to the Husky Health guidelines for the Wheelchair mounted assistive robotic arm attachment. The changes added and removed language and statements to the guidelines. In addition, it added the E1399 durable equipment, and miscellaneous code to identify the requested DME by the Medicaid system. (Exhibit 15)
- 28. On 2022, The Department of Social Services, OLCRAH, issued a Notice of Decision regarding the denial of coverage for a Kinova Jaco Robotic arm attachment for an individual with upper extremity mobility limitations. The hearing officer granted the Appellant's appeal. The hearing officer cited in a finding of fact from CHNCT's Dr. Lawrence Magras, Md, Senior VP Husky Health population that, "He states his reason for the denial, in this case, is no longer that the Jaco V2 Robotic arm and Kinova Lift Arm are considered investigational". (Appellant's Exhibit A: DSS, OLRAH, Notice of Decision dated 22)



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. Section 17b-262 of the Connecticut General Statutes, 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. Section 17b-262-676(a)(1) of the Regulations of Connecticut State Agencies 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.
- 6. Section 17b-262-676(a)(4) of the Regulations of Connecticut State Agencies 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.
- 7. Section 17b-259b(a) of the Connecticut General Statutes 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.
- 8. 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.
- Section 17b-259b(b) of the Connecticut General Statutes stated in part 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 request

health service shall be used solely as guidelines and shall not be the basis for a final determination of medical necessity."

Based on the trial videos, the Appellant was able to operate the robotic arm attachment with a joystick and buttons attached to her wheelchair. was able to lift a cup of water from the kitchen counter toward her mouth, and then drink from the straw, and place it back down. demonstrated that she could use the robotic arm to feed and open the refrigerator door and remove a bottle of water. demonstrated the ability to turn on a faucet and open the front door.

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.

The Jaco V2 Robotic Arm and Kinova Lift Arm are proven and no longer considered an experimental or research nature.

Based on the Appellant's unique healthcare needs, it has been proven that the Jaco Robotic Arm and Kinova Lift Arm ameliorated medical condition. The requested device would help maintain her achievable health independence, and the robotic arm would also allow to be less dependent on the caregivers for daily needs.

CHNCT incorrectly denied the provider's request for authorization of a Jaco Robotic Arm and Kinova Lift Arm as not medically necessary on the basis that research studies have not shown it to be safe or helpful in treating your condition. It will not eliminate the necessity for caregivers to assist in most activities of daily living and allow the Appellant to gain independence in all of her ADLs.

On 2022, CHNCT incorrectly denied the Appellant's provider's request for authorization of payment for a Jaco Robotic Arm and Kinova Lift Arm through the Medicaid program.

DECISION

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

ORDER

- 1. CHNCT shall rescind the denial notice for the Jaco 2 Robotic arm and a Kinova lift arm.
- 2. CHNCT shall issue a notice to the Appellant approving the DME.
- 3. Compliance with this order shall be submitted to the undersigned no later than 2023 and consist of a copy of the notice approving the DME.

Scott Zuckerman Hearing Officer

cc: Dr. Brad Richards, Department of Social Services, 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 <u>specific</u> grounds for the request: for example, indicate <u>what</u> error of fact or law, <u>what</u> new evidence, or <u>what</u> 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.