

# PROVIDER POLICIES & PROCEDURES

### WHEELCHAIR - MOUNTED ASSISTIVE ROBOTIC ARM ATTACHMENT

The primary purpose of this document is to assist providers enrolled in the Connecticut Medical Assistance Program (CMAP) with the information needed to support a medical necessity determination for a wheelchair-mounted assistive robotic arm attachment (i.e., KINOVA JACO<sup>®</sup> assistive robotic arm). By clarifying the information needed for prior authorization of services, HUSKY Health hopes to facilitate timely review of requests so that individuals obtain the medically necessary care they need as quickly as possible.

The KINOVA JACO assistive robotic arm is a wheelchair-mounted assistive device purported to improve levels of independence for individuals with loss of upper body motor function. The device features 6 interlinking segments corresponding to shoulder, elbow, and wrist. Using a joystick or other control interface (e.g., sip and puff, head control, head array), the arm and hand can be moved in 3-dimensional space and the two or three fingers can be opened and closed for gripping. The robotic arm is intended to mimic a fully functioning arm.

#### **CLINICAL GUIDELINE**

Coverage guidelines for the KINOVA JACO assistive robotic arm are made in accordance with the DSS definition of Medical Necessity. <u>The following criteria are guidelines *only*</u>. Coverage determinations are based on an assessment of the individual and their unique clinical needs. If the guidelines conflict with the definition of Medical Necessity, the definition of Medical Necessity shall prevail. The guidelines are as follows:

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 on 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. HUSKY Health will periodically evaluate any new published evidence, clinical guidelines, and other relevant factors on an ongoing basis that may become available to determine if any revisions to these guidelines are appropriate in the future.

If after a case specific review, a request for a KINOVA JACO assistive robotic arm is found to be medically necessary (or if a denial of a request is overturned on appeal), approval will be given for a three-month rental/trial period. At the end of the three-month trial period, a request for purchase may be submitted along with unedited video and medical record documentation showing ongoing, safe use of the

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device.

### NOTE: EPSDT Special Provision

Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) is a federal Medicaid requirement that requires the Connecticut Medical Assistance Program (CMAP) to cover services, products, or procedures for Medicaid enrollees under 21 years of age where the service or good is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination. The applicable definition of medical necessity is set forth in Conn. Gen. Stat. Section 17b-259b (2011) [ref. CMAP Provider Bulletin PB 2011-36].

# PROCEDURE

Prior authorization of the KINOVA JACO assistive robotic arm is required. Requests for coverage are reviewed in accordance with procedures in place for reviewing requests for durable medical equipment. Coverage determinations are based upon a review of requested and/or submitted case-specific information.

# The following information is needed to review requests for the KINOVA JACO assistive robotic arm:

- 1. Fully completed authorization request via web-based authorization portal; and
- 2. Documentation from the requesting provider supporting the medical necessity of the device including:
  - Signed prescription by a physician, advanced practice registered nurse (APRN), or physician assistant (PA) within the past twelve (12) months; and
  - Physical and/or occupational therapy evaluations and treatment notes
  - Results of device trials in both clinic and home settings to include length of trial and links to trial videos
- 3. A detailed product description including manufacturer, model number, product description, actual acquisition cost (AAC), and manufacturer's suggested retail pricing (MSRP), as outlined in the DSS Pricing Policy for MEDS Items. **Ref:** DSS Pricing Policy for MEDS Items

Review Process for Request for Purchase after 3 months of Initial Approved Use:

- 1. Requests for the KINOVA JACO assistive robotic arm will be reviewed by CHNCT in accordance with procedures in place for reviewing requests for DME.
- 2. If the KINOVA JACO assistive robotic arm is approved or has been approved due to a denial of a request being overturned on appeal, a rental trial period will allow the member to use this device for three months within their customary environment(s).
- 3. The rental fee for each monthly trial period will be \$4,194.00 for this device. These monthly fees will be deducted from the purchase price, if CHNCT approves the purchase.
- 4. After the three-month trial period, a request for purchase of the device may be submitted along with unedited video and medical record documentation showing ongoing, safe use of the device.

# EFFECTIVE DATE

This policy for the prior authorization for the KINOVA JACO assistive robotic arm for individuals covered under the HUSKY Health Program is effective July 1, 2021.

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#### LIMITATIONS

Not Applicable

#### CODE:

Code	Description
E1399	Durable medical equipment, miscellaneous

#### DEFINITIONS

- 1. **HUSKY A**: Connecticut children and their parents or a relative caregiver; and pregnant women may qualify for HUSKY A (also known as Medicaid). Income limits apply.
- 2. **HUSKY B**: Uninsured children under the age of 19 in higher income households may be eligible for HUSKY B (also known as the Children's Health Insurance Program) depending on their family income level. Family cost-sharing may apply.
- 3. **HUSKY C**: Connecticut residents who are age 65 or older or residents who are ages 18-64 and who are blind, or have another disability, may qualify for Medicaid coverage under HUSKY C (this includes Medicaid for Employees with Disabilities (MED-Connect), if working). Income and asset limits apply.
- HUSKY D: Connecticut residents who are ages 19-64 without dependent children and who: (1) do not qualify for HUSKY A; (2) do not receive Medicare; and (3) are not pregnant, may qualify for HUSKY D (also known as Medicaid for the Lowest-Income populations).
- 5. **HUSKY Health Program**: The HUSKY A, HUSKY B, HUSKY C, HUSKY D and HUSKY Limited Benefit programs, collectively.
- 6. **HUSKY Limited Benefit Program or HUSKY, LBP**: Connecticut's implementation of limited health insurance coverage under Medicaid for individuals with tuberculosis or for family planning purposes and such coverage is substantially less than the full Medicaid coverage.
- 7. HUSKY Plus Physical Program (or HUSKY Plus Program): A supplemental physical health program pursuant to Conn. Gen. Stat. § 17b-294, for medically eligible members of HUSKY B in Income Bands 1 and 2, whose intensive physical health needs cannot be accommodated within the HUSKY Plan, Part B.
- 8. Medically Necessary or Medical Necessity: (as defined in Connecticut General Statutes § 17b-259b) 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 physicianspecialty 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.

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 Prior Authorization: A process for approving covered services prior to the delivery of the service or initiation of the plan of care based on a determination by CHNCT as to whether the requested service is medically necessary.

### REFERENCES

- Beaudoin M, Lettre J, Routhier F, Archambault PS, Lemay M, Gélinas I. Long-term use of the JACO robotic arm: a case series. *Disabil Rehabil Assist Technol*. 2019;14(3):267-275. doi:10.1080/17483107.2018.1428692
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- Sauzin D, Vigouroux N, Vella F. Usability of JACO Arm Interfaces Designed with a User-Centred Design Method. *Stud Health Technol Inform.* 2017;242:573-582.

Status	Date	Action Taken
Original Publication	June 2021	Approved by Medical Policy Review Committee on May 26, 2021. Approved at the June 21, 2021 Clinical Quality Subcommittee meeting. Approved by DSS on June 28, 2021.
Update	October 2021	<ul> <li>Update to guidelines section</li> <li>Added the following language: based on HUSKY Health's analysis of current available research (including the clinical studies cited below), clinical guidelines, and other relevant factors</li> <li>Added typically to the statement The KINOVA JACO assistive robotic arm is typically considered investigational and therefore not medically necessary</li> <li>Removed for all indications from the statement The KINOVA JACO assistive robotic arm is typically considered investigational and therefore not medically necessary for all indications</li> </ul>

# PUBLICATION HISTORY

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		<ul> <li>Added the following statement: Requests will be reviewed on a case-by-case basis and determinations made based on a person-centered assessment of the individual's unique healthcare needs and the potential benefits and harms from use of the device.</li> <li>Added the following language: 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. HUSKY Health will periodically evaluate any new published evidence, clinical guidelines, and other relevant factors on an ongoing basis that may become available to determine if any revisions to these guidelines are appropriate in the future.</li> <li>Update to Procedures section:         <ul> <li>Clarified documentation needed from ordering provider</li> <li>Added code E1399 durable medical equipment, miscellaneous</li> </ul> </li> <li>Approved at the CHNCT Medical Reviewer meeting on October 27, 2021. Approved by the CHNCT Clinical Quality Subcommittee on October 28, 2021. Approved by DSS on October 29, 2021.</li> </ul>
Review	September 2022	Reviewed and approved without changes at the August 10, 2022 CHNCT Medical Reviewer meeting. Reviewed and approved without changes by the CHNCT Clinical Quality Subcommittee on September 19, 2022. Approved by DSS on September 28, 2022.
Update	March 2023	Updates to the Clinical Guideline and Procedure sections. Device remains investigational. Added language to address need for rental period prior to purchase for any request approved after a case specific review or overturned as part of the Member appeal process. Changes approved at the March 8, 2023, CHNCT Medical Reviewer meeting. Changes approved by the CHNCT Clinical Quality Subcommittee on March 20, 2023. Approved by DSS on March 27, 2023.
Update	March 2024	Update to Procedure section to include requirement of a signed prescription and to include hyperlink to DSS Pricing Policy. Changes approved at the March 13, 2024 CHNCT Medical Reviewer meeting. Changes approved by the CHNCT Clinical Quality Subcommittee on March 18, 2024. Approved by DSS on March 28, 2024.

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