Molina Clinical Policy
Wheelchair-Mounted Robotic Arm Devices
Policy No. 446

Initial Approval: 12/13/2023
Next Review Due By: December 2024

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Wheelchair-mounted robotic arm (WMRA) devices (e.g., JACO Robotic Arm, iARM) refer to robotic devices mounted on a motorized wheelchair that assist patients with neuromuscular disorders, such as tetraplegia, paraplegia, or progressive neuromuscular disorders that either limit or result in the loss of upper limb functions, gain more autonomy in activities of daily living (Hayes 2021). The WMRA device is installed on the motorized wheelchair and integrated into the wheelchair's native control method (joystick, head control, sip-and-puff, or head array system) by "rewiring" the wheelchair's controls to include the WMRA device (Kinova Inc. 2023). The device is controlled by the user using the wheelchair's native control method and some devices also allow for control via a smartphone (Assistive Innovations 2019). The device is not automated, meaning that the user must be physically and cognitively independent with the ability to control their motorized wheelchair via its native control method(s) or via a smartphone.

Each device typically consists of a fixed base (also called a "controller") that is linked to rotating actuators that control the range of motion and the "finger grippers" of the device. The actuators allow the device to mimic hand movements within the limits of the device (e.g., weight limits and range of motion) (Kinova Inc. 2023; Assistive Innovations 2019). The number of available actuators limits the device to basic motions. As a result of the limited actuators, complex tasks typically take too long to achieve, if able to be achieved within the device limits, and can leave the user's needs unmet (Campeau-Lecours et al. 2016). Advanced functionalities, such as "drinking mode," are available on the Kinova JACO Robotic Arm (Campeau-Lecours et al. 2016). In addition, users are only able to complete tasks that normally require the use of one hand and the tasks able to be completed with WMRA device assistance may take a significant amount of time due to multiple attempts required to complete the task (Routhier et al. 2014; Maheu et al. 2011).

Regulatory Status

WMRA devices are classified by the FDA as a class I medical device and are exempt from the premarket notification process. WMRA devices that are currently available include, but may not be limited to, the Kinova JACO Robotic Arm (Kinova Inc. 2023) and the Assistive Innovations iARM (Assistive Innovations 2019).

COVERAGE POLICY

Wheelchair-mounted robotic arm devices (e.g., JACO Robotic Arm, iARM) are **considered experimental, and investigational**. There is insufficient evidence in the peer-reviewed literature to establish long term safety, efficacy, and effect on net health outcomes.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

The peer-reviewed published literature for WMRA devices is limited to mostly case reports and small observational studies that do not assess long-term outcomes. Additional studies focused on the long-term outcomes of WMRA device usage are needed to adequately determine safety, efficacy, and effects on health outcomes. A summary of relevant studies is summarized below.

An interventional study (NCT04323449) sponsored by the VA Office of Research and Development is currently being completed with an estimated completion date of June 2024. The study aims to evaluate the vision-guided shared control for a WMRA device in 16 participants (ClinicalTrials.gov 2023).

The EMPATIA @ Lecco project completed an interventional study (NCT04313049) in 2019 in Italy that sought to evaluate the vocal control and joystick features of the JACO 2 device. The study enrolled 20 participants that were ≥ 10 years of age with muscular dystrophy. No study information has been formally published (ClinicalTrials.gov 2020).

Beaudoin et al. (2019) published a case series focusing on the long-term impacts of the JACO Robotic Arm on its users and their caregivers. Possible participants were selected from JACO's list of clients and JACO users were assessed for inclusion if they were ≥ 14 years of age, spoke French, and had used the JACO for ≥ 6 months. Caregivers were also included if they were > 18 years of age and were the main caregiver of the JACO user. A total of seven JACO users and five caregivers were included in the case series. Each user was assessed for upper extremity performance using functional scores from the TEMPA version 2.0 and independent scores for neuro-sensorimotor skills (active range of movements, strength, gross movements, prehension, and fine movements). Users were assessed using nine tasks with the JACO and each hand without the use of the JACO. Only three of the original tasks from the TEMPA version 2.0 were able to be used for this study due to the complexity and inability of the JACO to complete the remaining six tasks. Researchers noted most of the excluded tasks required the use of both hands or could not be completed within a reasonable time limit using the JACO. Each task was pre-tested by the research team to ensure the ability of the JACO to complete the task within a reasonable time limit. Each user was then asked to complete the task within a specified time limit. Task completion was assessed using the four-point Likert scale (scores -3 to 0) of the TEMPA scale to assign functional scores. A score of -3 indicated an inability to complete the task within the specified time limit and a score of 0 indicated the successful completion without difficulty. Users completing < 25% of a task or giving up were assigned a functional score of -3 with neuro-sensorimotor skills being assessed independent of functional score. Users that were unable to complete a task without the JACO due to severe upper extremity disabilities were given a score of -3 for functional and each neuro-sensorimotor skill. User life habits, user satisfaction, psychosocial impacts for users, impacts on caregivers, and economic impacts on users and caregivers were also assessed using appropriate assessment tools for each measure. Results showed that four users were unable to complete any of the tasks without the JACO. TEMPA scores improved significantly with the use of the JACO despite some tasks being difficult to complete with the JACO. User satisfaction and psychosocial impact scores also indicated a satisfaction with the JACO for both measures. However, researchers noted that some users reported minimal positive psychosocial impact, and this was directly correlated to lower scores on the economic impact questionnaire and functional ratings on the TEMPA. Regarding economic impact within the two months preceding study participation, one user reported incurred costs associated with lowering a counter to accommodate use of the JACO. Other users reported an inability to complete tasks, such as preparing a meal or completing household chores or shopping with the JACO. Researchers noted that most users still relied upon caregivers to complete certain tasks despite being able to complete tasks they normally could not without the JACO. Certain users may also experience economic costs associated with modifying their environment to use the JACO. Limitations of this study included 1) documentation of only the preceding two months of incurred costs related to the JACO (e.g., environment modification) as significant costs could have occurred outside of the two-month period, 2) no quantification of the amount of independence provided by the JACO, and 3) a potential bias in favor of JACO due to participants being referred by the device manufacturer.

Maheu et al. (2011) completed a study involving 34 participants to assess the efficacy of completing specific motor tasks and the potential economic benefits of the JACO. Inclusion criteria included age between 18-64 years, understanding of verbal instructions in French or English, no cognitive or memory impairment, use of a powered wheelchair with a standard joystick, and capability to press command buttons on the JACO's joystick. Researchers

noted that no participants had previous experience with the JACO. Only the JACO joystick was attached to the participant's wheelchair as the JACO arm was attached to a table in front of the participant's wheelchair. Each participant was provided training on the use of the JACO prior to being asked to complete two separate tasks with the first being the 16 basic movements of the JACO. The second task involved asking each participant to successfully complete six tasks two times: "1) grasping a bottle on the left side of the table, 2) grasping a bottle on the right side of the table, on a surface near the ground and placing the bottle on the table, 3) pushing the buttons of a calculator, 4) taking a tissue from a box on the table, 5) taking a straw from a glass located on the table, and 6) pouring water from a bottle into a glass." The number of attempts to complete each task was recorded and participants were also asked to assess the perceived easiness, satisfaction, and importance of completing each task. Participant assessment of perceptions was assessed using a 4-point scale with scores of "absolutely," "very," "a little," and "not at all." Participants also had to complete an economic assessment that assessed 1) caregiver support and their ability to complete activities of daily living with the JACO, 2) their perceived value in the ability to complete tasks independently, 3) current use of assistive devices, and 4) a socioeconomic profile. Approximately 31 participants completed the study with an additional two unable to complete the basic movements and tasks due to a technical issue with the JACO, leaving a sample size of 29 participants for analysis of tasks. Economic assessment results showed a mean age of 45.6 ± 14.7 years, with 58% of participants identifying as single, 26% married, and 16% divorced, separated, or widowed. In terms of the level of adaptation of their residence, 3% reported no adaptation, 19% partially adapted, 74% adapted, and 3% living in a specialized center. Approximately 48% of participants reported living alone and 42% living with 1-2 other people. Approximately 35% of participants were diagnosed with a spinal cord injury, 23% with muscular dystrophy, 23% with multiple sclerosis, and 19% "other." Results of task completion showed that all participants (n=29) were able to perform the basic movements of the JACO and the six required tasks with a short period of training. Approximately 79%-93% of participants were able to complete both tasks (16 basic movements and 6 tasks) on the first attempt. Less than 10% of participants had more than two attempts to complete the six tasks. Participant perceptions revealed that 95% of participants thought the tasks were easy to complete with the JACO and 97% perceived JACO to be beneficial for powered wheelchair users. In terms of potential economic impact, researchers determined that the JACO could reduce caregiver hours by approximately 1.31 hours per day. Researchers noted additional studies are needed to assess the long-term outcomes associated with the use of the JACO.

Routhier et al. (2014) completed an exploratory study with the primary objectives to assess the JACO's ability to improve independent living and social participation and to document each user's perceived satisfaction with the device. The study was completed by the same team that conducted the Maheu et al. (2011) study. A total of seven participants were included in this study with the inclusion criteria being the same as the Maheu et al. (2011 study) with the addition of normal or corrected vision as part of the inclusion criteria. Changes in each participant's independent living and social participation were assessed using the TEMPA, Life-H version 3.0, and a daily logbook completed by each participant. The impact on each participant's quality of life was assessed using the PIADS-10 and their perception on satisfaction with the JACO was assessed using the QUEST. Upon enrollment, each participant had the JACO device installed on their wheelchair and were provided with 1-2 60-minute training sessions depending on their individual learning needs. Participants were then asked to use the JACO for one month prior to being assessed using a modified TEMPA "to evaluate performance during the execution of five bilateral tasks and four unilateral tasks." Five additional tasks were added to the TEMPA as researchers felt those tasks "better reflect[ed] the use of the robotic arm." Participants were also asked to complete a logbook at the end of each day during the one-month period to track which tasks were completed using the JACO along with any difficulties associated with completing those tasks using the JACO. A total of 62 life habits (e.g., routine daily tasks such as activities of daily living, shopping, etc.) were identified for inclusion in analysis due to the ability of the JACO to potentially meet the requirements for performing those tasks. Results showed an improvement in 40 of the 64 Life-H items with the highest frequency for improvement in a single item (using a glass or a cup) being four participants, 17 items only improving for one participant each, and the overall mean improvement being 3.1 ± 3.2. Researchers noted that some of the TEMPA tasks required multiple attempts to complete using the JACO. The mean TEMPA improvement was 2.6 ± 2.4. In addition, logbook completion was inconsistent despite routine follow-up with each participant from the research team. The mean PIADS-10 score was 1.3 ± 0.8 with a potential for scores between -3 and 3, indicating an overall positive satisfaction with each user's perception of the JACO. The mean QUEST score was 4.2 ± 0.7 with a potential score between 0 and 5 with 0 indicating no satisfaction and 5 indicating very satisfied. Researchers noted an inability to determine if the improvements noted with the JACO were significant or not to the participants as well as an "objective measure of use for the robotic arm, such as the required time for completing a certain task with JACO." Limitations of the study included a small sample size, a lack of formal qualitative interviews throughout the study period, and a lack of perception and potential burdens experienced by caregivers.

National/Specialty Organizations

There are no current guidelines or statements from national or specialty organizations that specifically mention the use of WMRA devices.

CODING & BILLING INFORMATION

HCPCS (Healthcare Common Procedure Coding System) Codes

HCPCS	Description
E1399	Durable medical equipment, miscellaneous [when specified as a wheelchair-mounted robotic arm assistive device]
K0108	Wheelchair component or accessory, not otherwise specified [when used as a wheelchair-mounted robotic arm assistive device]

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/13/2023	New policy. IRO Peer Review on November 27, 2023, by a practicing, board-certified physician with specialties in Neuromusculoskeletal Medicine and Physical Medicine and Rehabilitation.

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