Anthem

Medical Policy

Subject: Robotic Arm Assistive Devices
Document #: DME.00044
Status: Reviewed

Publish Date: 09/27/2023
Last Review Date: 08/10/2023

Description/Scope

This document addresses the use of a robotic arm that is mounted to a wheelchair or located on another surface such as a table and is intended to assist individuals with upper extremity disability and mobility limitations due to neurologic conditions, trauma, or other problems.

This document does not address the use of devices worn by the individual (seeOR-PR.00005 Upper Extremity Myoelectric Orthoses).

Note: Please see the following related documents for additional information:

- CG-DME-10 Durable Medical Equipment
- CG-DME-34 Wheeled Mobility Devices: Wheelchair Accessories
- OR-PR.00005 Upper Extremity Myoelectric Orthoses

Position Statement

Investigational and Not Medically Necessary:

The use of a robotic feeding assistive device or wheelchair mounted robotic arm is considered**investigational and not medically necessary** for all indications.

Rationale

Tetraplegia and quadriplegia are equivalent terms referring to weakness or paralysis of all four extremities. It can be caused by trauma, stroke, cerebral palsy, or other conditions affecting the nervous system. People with tetraplegia face significant challenges in all activities of daily living (ADL). Rehabilitation engineers have developed a variety of devices to assist these individuals. The robotic feeding assistive device, also known as an independent eating assistive device, has been proposed to assist with feeding independence for individuals with upper extremity limitations. Makers of a wheelchair-mounted robotic arm (WMRA) propose that this device can help people with upper-extremity weakness to do such things as picking up objects and opening doors.

The Obi® (DESIN LLC, Jacksonville, FL) is an independent eating assistive device intended for those individuals with disability or disease affecting upper extremity strength and mobility limitations. The Obi is intended to increase independence and confidence by providing choice among four compartments of food and delivering the food to a region in front of the user's mouth. The device requires a caregiver to prepare food, position the user and device for optimal use, determine the appropriate customizable accessibility switches, power on the device, teach the appropriate food delivery location in front of the user's mouth, monitor use, and clean the device.

To date, there is no published literature addressing the clinical utility of the independent eating assistive device.

Available published evidence addressing the clinical utility of WMRAs is insufficient to permit reasonable conclusions concerning the effect of these devices. To date, available published evidence does not demonstrate that the independent eating assistive device or WMRA use leads to improvement in net health outcome, facilitates independent function related to ADL or overall caregiver burden for individuals with tetraplegia.

The WMRA evidence is limited to outcomes reported in one retrospective uncontrolled study with 31 participants (Maheu, 2011), one case series of 7 participants reported by Beaudoin and colleagues (2019) and case reports. While several participants in these studies were able to use the WMRA to perform some tasks, extensive set-up support continued to be needed. There is insufficient evidence to evaluate long-term durability, tolerability, or to show improvements in net health outcomes. Further research is needed to see if the long-term use of the device could reduce caregiver assistance and increase user autonomy.

Maheu and colleagues (2011) reported findings from a retrospective uncontrolled study of 31 users (ages 18 to 64 years) that completed the trial; 2 participants were unable to complete basic tasks due to technical issues (n=29). The study evaluated the ability of users with upper extremity disabilities to manipulate the robotic arm in a controlled setting. Seventy-nine percent of users were able to accomplish JACO's 16 movements (all possible actions of the robotic arm) twice (test #1), and 93% of users accomplished test #2 JACO six tasks. Participants were then asked to complete a questionnaire, study specific to regarding caregiver support during ADL; their perception of ability to complete ADL tasks with the JACO arm system; current use of assistive devices to accomplish tasks; and sociodemographic profile. Although the authors estimated that the use of the JACO arm system could potentially reduce caregiver time by 41%, this was based on self-reported estimates by the study participants. The study did not directly observe reductions in caregiver time.

In 2019, Beaudoin and colleagues reported findings from a case series of 7 JACO robotic arm users 14 years of age or older who used the device for at least 6 months. The study also reported results for 5 main caregivers for these users. User performance was evaluated with a measurement developed for this study based on an upper extremity performance test (TEMPA). Three tasks taken from the TEMPA included picking up and moving a jar, handling coins, and picking up and moving small objects. The authors reported JACO's impact for users and their family caregivers after 6 months or more:

> Participants reported positive impacts from using JACO, even though some difficulties were encountered….Users' increased participation in their life habits may decrease the amount of caregiver assistance required, if only slightly. Users reported being generally satisfied with their device and that using JACO has positive psychosocial impacts.

The Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) has published several position papers concerning manual wheelchairs, power wheelchairs, wheelchair components and accessories, and other assistive technologies. RESNA's key position papers do not include recommendations for accessories such as a wheelchair mounted robotic arm (WMRA).

The Veterans Association Health Care Rehabilitation and Prosthetic Services clinical practice recommendations for motorized wheeled mobility devices do not provide guidance on use of an WMRA.

Mechanical wheelchairs and accessories are classified as Class I medical devices by the U.S. Food and Drug Administration (FDA); wheelchair accessories not intended for use in a protective restraint capacity are exempt from the premarket notification process. Power wheelchairs and power operated vehicles are classified as Class II medical devices.

Although the KINOVA JACO® Assistive robot (Kinova Inc., Boisbriand, Quebec, Canada) is commercially available, its potential impact in individuals with upper-extremity disabilities is still poorly understood. (Beaudoin, 2018). An interventional clinical trial that studied the benefits of the JACO2 mechanical arm in 20 individuals with Muscular Dystrophy over the age of 10 years was completed in Italy in 2019, (NCT04313049); no results have been published at this time. Another interventional clinical trial, (NCT04323449) comparing two control methods (new vision-guided control vs the default control) for WMRA in 16 individuals with spinal cord injury/disorder is estimated to complete in June 2024.

Background/Overview

According to the Centers for Disease Control and Prevention (2020) there are three dimensions of disability: impairment, activity limitations, and participation restrictions. In the Americans with Disabilities Act the census estimated that over 4% of the United States population has moderate to severe disability requiring an individual to use a wheelchair to assist with mobility (Census, 2012).

A WMRA such as the JACO Assistive Robot is intended to allow individuals with loss of upper limb functions to improve quality of their life. The JACO device is mounted on a motorized wheelchair. The user can control the arm using the chair's joystick, head control, sip-and-puff, or head array system. The robotic arm features 6-axis movement corresponding to shoulder, elbow, and wrist, 16 movements in all, to mimic a fully functioning human hand.

Definitions

Activities of daily living (ADLs): Self-care activities such as transfers, toileting, grooming and hygiene, dressing, bathing, and eating.

Functional mobility: The ability to consistently move safely and efficiently, with or without the aid of appropriate assistive devices (such as prosthetics, orthotics, canes, walkers, wheelchairs, etc.), at a reasonable rate of speed to complete an individual's typical mobility-related activities of daily living; functional mobility can be altered by deficits in strength, endurance sufficient to complete tasks, coordination, balance, speed of execution, pain, sensation, proprioception, range of motion, safety, shortness of breath, and fatigue.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure code, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

HCPCS	
E1399	Durable medical equipment, miscellaneous [when specified as a robotic arm assistive device such as a wheelchair mounted robotic arm or a robotic feeding assistive device]
ICD-10 Diagnosis	
	All diagnoses

References

Peer Reviewed Publications:

1. Beaudoin M, Lettre J, Routhier F, et al. Impacts of robotic are use on individuals with upper extremity disabilities: a scoping review. Can J Occup Ther. 2018; 85(5)397-407.
2. Beaudoin M, Lettre J, Routhier F, et al. Long-term use of the JACO robotic arm: a case series. Disabil Rehabil Assist Technol. 2019; 14(3):267-275.
3. Maheu VS, Archambault P, Frappier J, et al. Evaluation of the JACO robotic arm: Clinico-economic study for powered wheelchair users with upper-extremity disabilities. IEEE Int Conf Rehabil Robot. 2011; 1-5.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Centers for Disease Control and Prevention. Disability and health overview. September 16, 2020. Available at: https://www.cdc.gov/ncbddd/disabilityandhealth/disability.html. Accessed on June 22, 2023.
2. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination for Durable Medical Equipment Reference List. NCD #280.1. Effective May 5, 2005. Available at: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. Accessed on June 22, 2023.
3. Centers for Medicare & Medicaid Services. National Coverage Decision (NCD) for Mobility Assistive Equipment (MAE) NCD# 280.3. Effective May 5, 2005. Available at: https://www.cms.gov/medicare-coverage-database/search.aspx?redirect=Y&from=Overview. Accessed on June 22, 2023.
4. CGS Administrators, LLC. Jurisdiction J-C. Local Coverage Determination for Wheelchair Seating (L33312). Revised January 1, 2020. Available at: https://www.cms.gov/medicare-coverage-database/search.aspx?redirect=Y&from=Overview&from=alphalmrp&letter=A. Accessed on June22, 2023.
5. National Census Bureau. Facts for Features: 22nd Anniversary of Americans with Disabilities Act: July 25, 2012. Available at: http://www.census.gov/newsroom/releases/archives/facts_for_features_special_editions/cb12-ff16.html. Accessed on June 22, 2023.
6. National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR). Last updated 04/27/2022. Available at: https://www.acl.gov/about-acl/about-national-institute-disability-independent-living-and-rehabilitation-research.Accessed on June 22, 2023.
7. Rehabilitation Engineering and Assistive Technology Society of North America. Benefits of JACO Robotic Arm on independent

living and social participation: an exploratory study. 2014 Available at: https://www.resna.org/sites/default/files/conference/2014/PDF%20Versions/Robotics/Routhier.pdf. Accessed on June 22, 2023.
8. Rehabilitation Engineering and Assistive Technology Society of North America. RESNA position on the application of power mobility devices for pediatric users- update 2017. Available at: https://www.resna.org/Portals/0/Documents/Position%20Papers/RESNA%20Ped%20Power%20Paper%2010_25_17%20-BOD%20approval%20Nov2_2017.pdf. Accessed on June 22, 2023.
9. Veterans Association Health Care. Rehabilitation and prosthetic services. Rehabilitation and prosthethetic services clinical practice recommendations for motorized wheeled mobility devices. Available at: Clinical Practice Recommendations (CPR) - Rehabilitation and Prosthetic Services (va.gov). Accessed on June 22, 2023.

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee. Updated Discussion, References, and Websites sections.
Revised	08/11/2022	MPTAC review. Retitled to: Robotic Arm Assistive Devices. Rescoped topic to also address robotic feeding assistive device. Revised INV/NMN statement to address robotic feeding assistive devices. Updated Description, Rationale, Coding, References and Index sections.
New	11/11/2021	MPTAC review. Initial document development.
