Molina Healthcare of Washington

Wheelchair-Mounted Robotic Arm Devices

(MCP-446, WAC 182-501-0165, WA Apple Health Integrated Managed Care Contract)

Effective Date: 5/1/2025
Last Approved Date: 5/1/2025

Legend:	Effective Date:	Last Approved Date:
— **Health Technology Clinical Committee (HTCC)** — Molina Clinical Policy (MCP) — Washington Administrative Code (WAC) — MCG Care Guidelines (MCG) — Other (WA Apple Health Integrated Managed Care Contract)	5/1/25	5/1/25
	Reviewed Only Date:	**Reviewed and Revised Date:**

COVERAGE CONSIDERATIONS

This supplements Molina Clinical Policy MCP-466 Wheelchair-Mounted Robotic Arm and replaces it in part. It is provided to detail the standards for reviewing this device as of this policy's effective date. This is done in accordance with the Washington State Healthcare Authority's (HCA) contractual standards for reviewing these devices.

The Wheelchair-Mounted Robotic Arm (WMRA) should be assessed under the hierarchy-of-evidence prescribed in Washington Administrative Code 182-501-0165. The hierarchy-of-evidence standard is applied by Molina pursuant to the Washington Apple Health Integrated Managed Care (IMC) contract explicitly adopting an "evidence-based medical necessity determination process which is equivalent to Washington Administrative Code (WAC) 182-501-0165," in section 11.7.5.2. In addition, Section 11.8.1 of the contract stipulates that "in determining whether a service that the Contractor considers experimental or investigational is Medically Necessary for an individual Enrollee, the Contractor must have and follow policies and procedures that mirror the process for HCA's medical necessity determinations for its FFS program described in WAC 182-501-0165."

APPROACH TO CLINICAL REVIEW

For clinical review of WMRA devices:

- Reviewers will follow the hierarchy-of-evidence process outlined in WAC 182-501-0165.
- Reviewers shall consider the device under the standards of the hierarchy of evidence as described in this document and shall not classify or consider the device as "experimental and investigational" in their review.
- The WAC 182-501-0165 language states that its use is for "Fee-for-Service Prior Authorization." MCP-446 has the designation of "experimental and investigational." Because the review is under the hierarchy of evidence analysis, the WAC should not be cited in the letter detailing the review. MCP-446 may be used for its summary of the evidence and relevant studies, but this Merge policy should guide the review of evidence and how the hierarchy of evidence is applied.
- Reviewers will cite this Merge policy as their criteria for reviews of WMRA.
- The evidence to be considered is outlined in MCP-446 Wheelchair-Mounted Robotic Arms.

The following process (from WAC 182-501-0165) will be followed to evaluate the evidence (from MCP-446 Wheelchair-Mounted Robotic Arms) to determine whether a requested WMRA is medically necessary:

(a) **Hierarchy of evidence - How defined.** The agency uses a hierarchy of evidence to determine the weight given to available data. The weight of medical evidence depends on objective indicators of its validity and reliability including the nature and source of the evidence, the empirical characteristics of the studies or trials upon which the evidence is based, and the consistency of the outcome with comparable studies. The hierarchy (in descending order with Type I given the greatest weight) is:

(i) Type I: Meta-analysis done with multiple, well-designed controlled studies;

(ii) Type II: One or more well-designed experimental studies;

(iii) Type III: Well-designed, quasi-experimental studies such as nonrandomized controlled, single group pre-post, cohort, time series, or matched case-controlled studies;

(iv) Type IV: Well-designed, nonexperimental studies, such as comparative and correlation descriptive, and case studies (uncontrolled); and

(v) Type V: Credible evidence submitted by the provider.

(b) **Hierarchy of evidence - How classified.** Based on the quality of available evidence, the agency determines if the requested service is effective and safe for the client by classifying it as an "A,""B,""C," or "D" level of evidence:

(i) "A" level evidence: Shows the requested service or equipment is a proven benefit to the client's condition by strong scientific literature and well-designed clinical trials such as Type I evidence or multiple Type II evidence or combinations of Type II, III or IV evidence with consistent results (An "A" rating cannot be based on Type III or Type IV evidence alone).

(ii) "B" level evidence: Shows the requested service or equipment has some proven benefit supported by:

(A) Multiple Type II or III evidence or combinations of Type II, III or IV evidence with generally consistent findings of effectiveness and safety (A "B" rating cannot be based on Type IV evidence alone); or

(B) Singular Type II, III, or IV evidence in combination with agency-recognized:

(I) Clinical guidelines;

(II) Treatment pathways; or

(III) Other guidelines that use the hierarchy of evidence in establishing the rationale for existing standards.

(iii) "C" level evidence: Shows only weak and inconclusive evidence regarding safety, or efficacy, or both. For example:

(A) Type II, III, or IV evidence with inconsistent findings; or

(B) Only Type V evidence is available.

(iv) "D" level evidence: Is not supported by any evidence regarding its safety and efficacy, for example that which is considered investigational or experimental.

(c) **Hierarchy of evidence - How applied.** After classifying the available evidence, the agency:

(i) Approves "A" and "B" rated requests if the service or equipment:

(A) Does not place the client at a greater risk of mortality or morbidity than an equally effective alternative treatment; and

(B) Is not more costly than an equally effective alternative treatment.

(ii) Approves a "C" rated request only if the provider shows the requested service is the optimal intervention for meeting the client's specific condition or treatment needs, and:

(A) Does not place the client at a greater risk of mortality or morbidity than an equally effective alternative treatment;

(B) Is less costly to the agency than an equally effective alternative treatment; and

(C) Is the next reasonable step for the client in a well-documented tried-and-failed attempt at evidence-based care.

(iii) Denies "D" rated requests unless:

(A) The requested service or equipment has a humanitarian device exemption from the Food and Drug Administration (FDA); or

(B) There is a local institutional review board (IRB) protocol addressing issues of efficacy and safety of the requested service that satisfies both the agency and the requesting provider.

CODING INFORMATION

The codes listed in the Merge document are for reference purposes only. Listing of a service or device code in this document does not imply that the service described by this code is covered or non-covered. Coverage is determined by the benefit document. This list of codes may not be all-inclusive.

HCPCS	Healthcare Common Procedure Coding System (HCPCS) Descriptions
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]

SOURCES

1. Molina Clinical Policy MCP-446 Wheelchair-Mounted Robotic Arm Devices. Initial approval 12/11/24.
2. Washington Administrative Code WAC 182-500-0070 Definitions – M. “Medically necessary.” https://app.leg.wa.gov/wac/default.aspx?cite=182-500-0070
3. Washington Administrative Code WAC 182-501-0165 Medical and dental coverage – Fee-for-service (FFS) prior authorization – Determination process for payment. “Hierarchy of evidence – How defined, How classified, How applied.” https://app.leg.wa.gov/wac/default.aspx?cite=182-501-0165
4. Washington State Health Care Authority. Washington Apple Health—Integrated Managed Care Contract. Sections 11.7.5.2 and 11.8.1. Updated 1/1/25.

APPROVAL HISTORY

Date	Summary of Changes
5/1/25	— New Merge Criteria