

Subject: Robotically Assisted Surgery		Original Effective Date: 4/2/14
Policy Number: MCR-161 <i>This MCR replaces the following MCR's that have been archived: 90, 98, 99, 100, 101 & 102</i>	Revision Date(s): <i>This MCR is no longer scheduled for revisions.</i>	
Review Date: 4/2/14, 12/16/15, 6/15/16, 9/19/17, 3/8/18, 6/19/19		
MCPC Approval Date: 3/8/18, 6/19/19		

DISCLAIMER

This Molina Clinical Review (MCR) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Review (MCR) document and provide the directive for all Medicare members. ¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL ²⁹⁻³¹

Robotically assisted surgery is minimally invasive surgery performed remotely from a computerized workstation where the surgeon views the operative field through a specialized camera arrangement. The surgeon manipulates robotic arms to hold and position an endoscope to grasp, cut, dissect, cauterize, and suture tissue using hand controls and foot switches. Robotically assisted surgery is intended as an alternative to conventional laparoscopic surgical procedures to extend the capabilities of surgeons and address difficulties and morbidities associated with conventional laparoscopic technology.

The proposed major advantages of robot-assisted over conventional laparoscopy are:

- Enhanced visualization: D versus two-dimensional (2D) imaging of the operative field.
- Mechanical improvements: A fulcrum effect is created when rigid conventional instruments pass through the incision, leading to inversion of movement from the surgeon's hand to the working end of the instrument. Robotic instruments have seven degrees of freedom, similar to the human arm and hand, while rigid conventional instruments have four degrees of freedom.
- Stabilization of instruments within the surgical field: Small movements by the surgeon are amplified (including errors or hand tremor) using conventional laparoscopy procedures.

- Improved ergonomics for the operating surgeon: The surgeon can be seated with telerobotic systems limiting pain, numbness or fatigue in their arms, wrists, or shoulders as compared to performing conventional laparoscopic procedures.

The limitations of robotic surgery may include:

- Additional required surgical training for this technique
- Increased costs and operating room time
- Bulkiness of the devices
- Instrumentation limitations (e.g., lack of a robotic suction and irrigation device, size, cost)
- Lack of tactile feedback
- Risk of mechanical failure
- Limited number of energy sources (e.g., less than with conventional laparoscopy)
- Surgical limitations (Not designed for abdominal surgery involving more than one quadrant; the device needs to be re-docked and repositioned to change quadrants).

FDA Indications: Robotic surgical systems are approved by the FDA as a 510 (k), Class II devices. The da Vinci® Surgical System (Intuitive Surgical Inc.) has received FDA 510(k) premarket approval. Since its original approval in 1997, numerous modifications have been made to the system and its accessories, resulting in multiple subsequent 510(k) approvals. ^{2 28}

RECOMMENDATION ^{3 4-23}

- ❑ Robotically assisted surgery may NOT be authorized in adults and children for any indication because it is considered equivalent to but not superior to a standard minimally invasive surgical approach.
 - This includes any type of robotically assisted surgery for any indication such as: abdominal, bariatric, cardiac, general surgery, gynecological, gastrointestinal, orthopedic, otolaryngology, prostate, spinal, thoracic, and urology.
- ❑ When a surgical procedure is performed using robotic-assisted technique, additional professional or technical reimbursement will not be made for the robotic-assisted technique. Payment will be based on the reimbursement for the standard surgical procedure(s). Any additional charges for the robotic assisted surgery will be bundled into the standard surgical procedure because it is considered to be integral to the procedure and not a separate service. ³

CONTINUATION OF THERAPY

N/A

COVERAGE EXCLUSIONS

Robotically assisted surgery for any indication may not be authorized because it is considered equivalent to but not superior to a standard minimally invasive surgical approach.

SUMMARY OF MEDICAL EVIDENCE ⁴⁻²⁴

There is insufficient evidence from large well-designed randomized-control or prospective cohort/comparison studies comparing robotically assisted procedures with conventional procedures. Weaknesses of the available studies include small sample size, lack of long-term follow-up, lack of randomization and lack of direct comparison of robotic-assisted procedures with conventional open procedures. In addition, comparison of results among studies was difficult due to differences in surgical procedures, types of robotic systems utilized, operative techniques, differences in patient characteristics, and differences in reporting of outcomes. Well-designed long term studies are needed to determine whether robotically assisted procedures are safer, more effective and provide greater benefits than conventional procedures.

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
	N/A

HCPCS	Description
S2900	Surgical techniques requiring use of robotic surgical system (list separately in addition to code for primary procedure)

ICD-10	Description: [For dates of service on or after 10/01/2015]
8E090CZ	Robotic Assisted procedure head neck region open
8E0W0CZ	Robotic Assisted procedure trunk region open
8E0Y0CZ	Robotic Assisted procedure lower extremity open approach
8E0W4CZ	Robotic Assisted procedure trunk region Perq Endo
8EO93CZ	Robotic Assisted procedure head neck region Perq
8EOW3CZ	Robotic Assisted procedure trunk region Perq
8EOY3CZ	Robotic Assisted procedure lower extremity Perq
8EO94CZ	Robotic Assisted procedure head neck region Perq Endo
8EO98CZ	Robotic Assisted procedure H&N Nat/Art opening Endo
8EOW8CZ	Robotic Assisted procedure trunk Nat/Art opening Endo
8EOY4CZ	Robotic Assisted procedure lower extremity Endo approach
8EO97CZ	Robotic Assisted procedure head neck Nat/Art opening
8EO9XCZ	Robotic Assisted procedure of head neck region
8E0W7CZ	Robotic Assisted procedure trunk region Nat/Art opening
8E0WXCZ	Robotic Assisted procedure trunk region
8E0YXCZ	Robotic Assisted procedure lower extremity

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Revision/Review History: 3/8/18 & 6/19/19: Policy reviewed, no changes to criteria.