Molina Clinical Policy
Robotically Assisted Surgery: Policy No. 161

Last Approval: 4/13/2022
Next Review Due By: April 2023

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.[1] References included were accurate at the time of policy approval and publication.

OVERVIEW

Robotic-assisted surgery (RAS), often known as laparoscopic robotic-assisted surgery, is a technological advancement derived from conventional laparoscopy, which facilitates the application of minimally invasive techniques. RAS is minimally invasive surgery (MIS) 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. RAS 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)

There is no standardized credentialing system for evaluating a surgeon’s proficiency for performing RASD procedures. Individual hospitals are currently establishing and implementing training requirements to credential their surgeons to perform robotic surgery procedures. In a representative sample from 42 geographically dispersed US hospitals reviewed, there were significant variation in credentialing policies (Huffman et al. 2021). the majority of policies require completion of a robotic surgery training course and a modest number of proctored cases, continuous objective performance assessments and patient outcome monitoring were rarely mentioned.

Between 2004 and 2013, the number of malfunctions and adverse events caused by robotic systems increased by 2.2% in the United States (Alemzadeh et al., 2016). According to a literature search of data published between 2005 and 2014 on robotic system malfunctions (18 articles), 386 malfunctions were reported out of 14,141 procedures and 20.9% of which was damage caused by malfunction of the robotic surgery arms and instruments. The total percentage of conversion in reported cases was about 2% (Ferrarese et al. 2016). In some circumstances, such as mastectomy surgeries, survival rates in robotic-assisted MIS were lower than in open surgery (Ramirez et al. 2016), prompting the FDA (2021) to issue a safety communication for robotically assisted surgical devices used in mastectomy in 2019:

- The safety and effectiveness of RAS devices has yet to be established in the prevention and treatment of breast cancer. The agency reiterated that use of these devices has been cleared for procedures such as hysterectomy, prostatectomy, and colectomy based on data from 30-day patient follow-up. However, RAS devices have not been evaluated as safe or effective based on outcomes of overall survival, recurrence, and disease-free survival in cancer.

Regulatory

RASD are currently regulated as Class II 510(k) devices, under the "Endoscope and accessories" regulation (21 CFR 876.1500). FDA clearance for a new or modified RASD must deemed as "substantially equivalent" to a predicate device. The new device must be equally safe and effective as the predicate device, or that any differences in technological characteristics do not raise new safety and efficacy problems. The FDA has cleared RAS devices for use in laparoscopic surgical procedures across multiple disciplines including general surgery, cardiac, colorectal, gynecologic, head & neck, thoracic, and urologic surgery (FDA, 2021).

The FDA approved the Automated Endoscopic System for Optimal Positioning (AESOP) for clinical use in 1994. AESOP is a voice-controlled robotic arm that holds an endoscope and allows for precise positioning during endoscopic surgery. In 1996, Computer Motion, the same US company that made AESOP, developed ZEUS, a master-slave robotic system. With three robotic arms, surgeons may execute surgical functions remotely. The da Vinci Surgical System (Intuitive Surgical Inc.) was FDA cleared in 2000, and it has been reported as the most extensively used surgical robot in RAS. It received FDA 510(k) premarket approval in 2000 and has continued with numerous modifications to the system and its accessories resulting in multiple subsequent 510(k) approvals.

- Da Vinci Si Surgical System (Intuitive Surgical Inc.)
  - Original clearance: K081137 Intuitive Surgical da Vinci Si Surgical System. Cleared 2/18/2009.
- Da Vinci Xi Surgical System (Intuitive Surgical Inc.)
  - Original clearance: K151794 da Vinci Xi Surgical System. Cleared 1/15/2016.

Refer to the FDA 510(k) Premarket Notification for FDA cleared RAS devices or systems.

COVERAGE POLICY

Additional or separate reimbursement for the use of robotic surgical devices (e.g., da Vinci® Surgical System, ZEUS™ Robotic Surgical System) is not authorized.

1. Robotically assisted surgery **may not be authorized** separately in adults and children for any indication because it is considered equivalent to but not superior to a standard minimally invasive surgical approach. Robotic-assisted surgical devices have been proposed for a number of procedures, including (but not limited to) abdominal, bariatric, cardiac, general, gynecological, gastrointestinal, neurosurgery, ophthalmology, orthopedic, otolaryngology, prostate, spinal, thoracic, and urology surgery.

2. 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.

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

Large, well-designed randomized-control or prospective cohort/comparison studies comparing robotically assisted procedures to conventional procedures are needed. Small sample size, lack of long-term follow-up, lack of randomization, and lack of direct comparison of robotic-assisted procedures with open procedures are all flaws in the existing studies. Furthermore, due to variances in surgical procedures, types of robotic systems used, operating techniques, patient characteristics, and reporting of outcomes, comparing results across trials was challenging. To evaluate whether robotically assisted treatments are safer, more successful, and deliver larger benefits than conventional procedures, well-designed long-term studies are required.

Rassier et al. (2021) in a current peer-review published in UpToDate, conventional rather than robotic laparoscopy was recommended for women undergoing hysterectomy for benign indications unless otherwise dictated by patient characteristics or surgeon preference.

National and Specialty Organizations

American College of Obstetricians and Gynecologists (ACOG) published a Committee Opinion (Number 701, June 2017; reaffirmed 2021) stating the preference of minimally invasive approaches to hysterectomy (laparoscopic hysterectomy), whenever feasible, based on their well-documented advantages over abdominal hysterectomy. However, the Committee also indicated the function of robotic assistance in the performance of laparoscopic hysterectomy has not been fully defined, and additional data is required to discover the most relevant evidence-based applications for this technology.

ACOG and Society of Gynecologic Surgeons (SGS), in the Committee Opinion (Number 810; September 2020), noted that RAS provides an alternative surgical option for minimally invasive gynecologic surgery and has been shown similar perioperative outcomes to laparoscopy and better than laparotomy; however, well-designed studies are needed to determine which patients are most likely to benefit from RAS over other minimally invasive approaches. Furthermore, the Committee indicates that comparative studies are needed to assess long-term outcomes and patient safety, and to identify specific subgroups of patients who would benefit from a robot-assisted approach.

The **American Urological Association's (AUA)** suggests a systematic training program for urologists without residency or fellowship experience in robotic surgery. This program should include a combination of online courses, observation of robotic surgeries, hands-on experience, and guidance from experienced robotic surgeons. Core Curriculum for urology residencies now incorporates RAS. According to the AUA's Standard Operating Procedures for Urological Robotic Surgery, those who have received training in robotic surgery during their residency or fellowship must demonstrate experience with a minimum of 20 robotic cases.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes – N/A

HCPCS Code

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

Modifier 22 (Increased Procedural Services) may be used to report uncommon problems or issues during surgery that are not associated with the use of robotic assistance equipment. Modifier 22 may be used only when significant additional work (i.e., greater intensity, duration, technical difficulty of procedure, severity of patient's condition, and

physical and mental effort required) is performed manually by a surgeon rather than with robotic help. Modifier 22 should not be used only for the purpose of reporting and billing for the usage of robotic assistance.

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

4/13/2022	Policy reviewed and updated; no changes in coverage position; updated Overview, Summary of Evidence and References sections.
4/5/2021	Policy reviewed, no changes to criteria, removed ICD-10 procedural classification system (PCS) codes.
3/8/2018, 6/19/2019, 4/23/2020	Policy reviewed, no changes to criteria.
12/16/2015, 6/15/2016, 9/19/2017	Policy reviewed, no changes to criteria.
4/2/2014	New policy. IRO peer reviewed by board-certified physician in the areas of Surgery General, Surgery Vascular, Surgical Critical Care, Surgery.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: robot; robotic; robotically assisted). No NCD identified. Available from CMS. Accessed March 2022.
2. United States Food and Drug Administration (FDA). Computer-assisted surgical systems. Available from FDA. Published August 20, 2021. Accessed March 2022.
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   - 510(k) premarket notification database (search: intuitive surgical in 'Applicant Name' field). Available from FDA.
   - Intuitive surgical da Vinci: 501(k) premarket notification. Available from FDA. Published December 16, 2009.
   - ZEUS robotic surgical system: 501(k) premarket notification. Available from FDA. Published October 5, 2001.

Other Evidence Based Reviews and Publications

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   - Comparative Effectiveness Review: Robotically Assisted Hysterectomy. Aug 31, 2017. Updated Oct 1, 2021.
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   - Pediatric robotic-assisted surgery. Published July 2, 2010. Updated 2014. Archived 2015.
   - Robotic assisted prostatectomy. Updated 2012. Archived 2013.
   - Robotically Assisted Mitral Valve Repair Using the da Vinci Surgical System (Intuitive Surgical Inc.). Updated 2015. Archived 2016.
   - Robotically Assisted Atrial Septal Defect Repair Using the da Vinci Surgical System (Intuitive Surgical Inc.). 2010. Updated 2012. Archived 2013.
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   - Klein E. Radical prostatectomy for localized prostate cancer. Updated 2021.
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3. Intuitive Surgical. da Vinci® overview. Available from Intuitive. Accessed March 2022.

Peer Reviewed Publications

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2. Alemzadeh, H, Raman, J, Leveson, N, Kalbarczyk, Z, Iyer, RK, et al. Adverse events in robotic surgery: a retrospective study of 14 years of FDA data. PLoS One 2016;11:e0151470. https://doi.org/10.1371/journal.pone.0151470.
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6. Tang K, Jiang K, Chen H, Chen Z, Xu H, Ye Z. Robotic vs. retropubic radical prostatectomy in prostate cancer: A systematic review and an meta-analysis update. Oncotarget. 2017;8(19):32237-32257. doi: 10.18632/oncotarget.13332.
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National and Specialty Organizations

1. American Medical Association. Current Procedural Terminology (CPT®) Professional Edition.
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5. American Urological Association (AUA). Robotic surgery (urologic) standard operating procedure (SOP). Available from AUA. Reaffirmed October 2018. Accessed March 2022.
6. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Davinci Surgical System (Intuitive Surgical, Sunnyvale, CA). SAGES daVinci Safety and Effectiveness Subcommittee. Available from SAGES. Published July 24, 2015. Accessed March 2022.
7. Herron D, Marohn M, Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), Minimally Invasive Robotic Association (MIRA), SAGES-MIRA Robotic Surgery Consensus Group. A consensus document on robotic surgery. Available from SAGES. Published 2007. Accessed March 2022.

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

Centers for Medicare and Medicaid Services (CMS)

No National Coverage Determinations (NCDs) were identified on the CMS website addressing coverage for robotic-assisted surgeries in a search conducted on March 2022 (search CMS Advanced Search Database by keyword *robot robotic; robotically assisted*).