Molina Clinical Policy
Robotically Assisted Surgery: Policy No. 161
Last Approval: 04/09/2025
Next Review Due By: April 2026

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) is a form of minimally invasive surgery that enhances a surgeon's capabilities using robotic systems. In RAS, the surgeon operates from a console equipped with a high-definition, 3D view of the surgical site, controlling robotic arms that hold and manipulate surgical instruments. The setup allows for greater precision, flexibility, and control than traditional laparoscopic surgery. RAS is typically used in laparoscopy rather than open surgery and aims to overcome the limitations of conventional laparoscopy by addressing challenges such as limited dexterity and visualization. Some limitations of RAS include higher costs, increased operating room time, additional training, lack of tactile feedback, and risk of mechanical failure (Paraiso and Falcone 2022). There is no standardized credentialing system for evaluating a surgeon's proficiency in RAS. Instead, individual hospitals establish and implement their own training requirements for credentialing RAS surgeons. A review of credentialing policies from 42 geographically dispersed U.S. hospitals found significant variation: while most hospitals required completion of a RAS training course and a modest number of proctored cases, few policies included continuous objective performance assessments or patient outcome monitoring (Huffman et al. 2021).

Between 2000 and 2013, over 1.75 million RAS procedures were performed in the United States. During this period, 10,624 adverse events related to RAS systems and instruments were reported in the U.S. Food and Drug Administration (FDA) MAUDE database, with 98% of events being reported by device manufacturers or distributors. This included 8,061 device malfunctions (75.9%), 1,391 patient injuries (13.1%), and 144 deaths (1.4%). Device malfunctions accounted for the majority of reports and included issues such as burnt or broken instrument fragments falling into patients (14.7%), electrical arcing (10.5%), unintended instrument operation (8.6%), and system errors (5%). In 7.3% of cases, procedures were converted to non-robotic techniques due to system malfunctions, while 2.5% were rescheduled (Alemzadeh et al. 2016). In 2019 the FDA issued a communication cautioning that the efficacy and safety of RAS devices for mastectomy and other cancer-related surgeries have not been established. In addition, the FDA urged health care providers to complete the appropriate training for the specific RAS procedure performed and recommended that patients and health care providers discuss the benefits, risks, and alternative procedure options to make informed treatment decisions (FDA, 2019).

Regulatory Status
RAS devices are primarily regulated as Class II devices by the FDA under 510(k) premarket notification or De Novo authorization. The FDA has cleared RAS devices for use by in various surgical disciplines, including general surgery, cardiac, colorectal, gynecologic, head and neck, thoracic, and urologic surgery. Common procedures include gall-bladder removal, hysterectomy, and prostatectomy. The FDA has not granted marketing authorization for any RAS device for the prevention or treatment of cancer (FDA, 2022). Notable milestones in RAS development include the FDA approval of the Automated Endoscopic System for Optimal Positioning (AESOP) in 1993, the ZEUS Robotic Surgical System in 2001, and the da Vinci Surgical System in 2001, which has become the most extensively used surgical robot worldwide and has undergone several modifications and subsequent clearances, such as the da Vinci Si in 2009 and the da Vinci Xi in 2016. Other notable FDA cleared or FDA authorized RAS devices include the Senhance Surgical Robotic System in 2017 and the MIRA Surgical System and Versius Surgical System in 2024. For more information on RAS devices with FDA marketing authorization, refer to the 510(k) or De Novo database.

COVERAGE POLICY

Robotic-assisted surgery (RAS) is considered equivalent to conventional minimally invasive surgical techniques and **does not warrant separate or additional reimbursement**:

1. Authorization: RAS is **not separately authorized** for adults or children for any indication, as it is considered equivalent and not superior to standard minimally invasive surgical techniques

2. Reimbursement: When a surgical procedure is performed using a RAS device or technique (e.g., da Vinci Surgical System, ZEUS Robotic Surgical System)**, no additional professional or technical reimbursement will be provided**. Payment is based on reimbursement for the standard surgical procedure(s), and any additional charges related to RAS are bundled into the standard surgical procedure, as RAS is considered integral to the surgery 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

While randomized controlled trials (RCTs) and other prospective studies evaluating robotic-assisted surgery (RAS) exist for many surgical disciplines, much of the available evidence comes from retrospective studies and database analyses. Systematic reviews and meta-analyses largely indicate that RAS does not provide significant clinical advantages over other minimally invasive surgical techniques, with most studies showing no significant differences in perioperative or postoperative outcomes. Some evidence suggests that RAS is associated with a shorter hospital stay; however, this benefit is offset by the higher costs associated with RAS. Comparing results across studies also remains challenging due to variations in surgical procedures, robotic devices, operative techniques, patient characteristics, and outcome reporting. While many national and specialty organizations recognize the rapid growth of RAS, they emphasize that well-designed, long-term studies are needed to determine its optimal use and whether it offers superior clinical benefits over conventional surgical approaches.

Randomized Controlled Trials

Olavarria et al. (2020) performed a multicenter, blinded RCT comparing robotic ventral hernia repair (RVHR) to laparoscopic ventral hernia repair (LVHR), which included 124 (n = 124) adult patients randomized into two groups. The primary outcome measure was the number of hospital days within 90 days post-surgery. Secondary outcomes included emergency department visits, operating room time, wound complications, hernia recurrence, reoperation rates, abdominal wall quality of life, and healthcare costs. Results showed no significant difference in hospital days between the two groups (median 0 days for both; relative rate 0.90, 95% CI 0.37 to 2.19, p = 0.82). No significant differences were observed in emergency department visits, wound complications, hernia recurrence, or reoperation rates. RVHR required significantly longer operative times than LVHR (mean 141 minutes vs. 77 minutes; mean difference 62.89 minutes, 95% CI 45.75 to 80.01; p ≤ 0.001). Healthcare costs were significantly higher for RVHR ($15,865 vs. $12,955). Two cases of intraoperative enterotomy occurred in the RVHR group compared to none for LVHR. Abdominal wall quality of life, measured using the modified Activity Assessment Scale, showed less improvement in the RVHR group than in the LVHR group at one-month follow up (median improvement of 3 points vs. 15 points). A higher percentage of patients in the RVHR group experienced a major worsening in abdominal wall quality of life scores (28% vs. 14%; relative risk (2.07, 95% CI 0.98 to 4.41; p = 0.058), while more patients in the LVHR group reported a major improvement (44% vs. 53%; relative risk 1.20, 95% CI 0.83 to 1.74; p = 0.33). Pain scores, assessed using a visual analog scale, did not differ significantly between groups. The authors concluded that there was no clinical, patient-centered, or economic benefit to RVHR compared to LVHR. The study is registered at ClinicalTrials.gov under NCT03490266.

Soto et al. (2017) performed a multicenter, RCT comparing RAS and conventional laparoscopic surgery for the treatment of endometriosis. A total of 73 patients were randomized (n = 73), with 35 undergoing RAS and 38 undergoing laparoscopic surgery. The primary outcome was operative time, defined as the duration from incision to closure. Secondary outcomes included perioperative complications, intraoperative and postoperative blood loss, conversion to laparotomy, and quality of life, which was measured using the 12-Item Short Form Health Survey (SF-12) and the Endometriosis Health Profile-30 (EHP-30) questionnaire at baseline, six weeks, and six months postoperatively. The mean operative time for RAS was 106.6 ± 48.4 minutes compared to 101.6 ± 63.2 minutes for laparoscopy (p = 0.71), indicating no significant difference between the two approaches. Estimated blood loss was slightly higher in the RAS group (100.9 ± 229.8 mL) compared to the laparoscopic group (43.8 ± 39.8 mL), though this difference was not statistically significant. There were no differences between groups in rates of intraoperative complications, conversion to laparotomy, or postoperative complications. Both approaches resulted in significant improvements in quality of life, with patients in both groups showing improvement in EHP-30 domains, including pain, emotions, social support, self-image, and treatment satisfaction, at six weeks and six months postoperatively. The SF-12 mental health component remained stable over time in both groups, while the physical health component showed a slight improvement in the laparoscopic group at six weeks, reaching near statistical significance (p = 0.055). The authors concluded that RAS did not provide any significant advantage over conventional laparoscopy for the treatment of endometriosis. The study is registered at ClinicalTrials.gov under NCT01556204.

Systematic Reviews and Meta-Analyses

Negrut et al. (2024) conducted a systematic review and meta-analysis to compare the efficacy, safety, and perioperative outcomes of laparoscopic versus RAS for colon cancer. 21 studies between 2020 to 2024 were included, including 50,771 patients total, with 11,059 (21.75%) undergoing RAS and 39,712 (78.25%) undergoing laparoscopic surgery. Primary outcomes included operative time, hospital stay, conversion rates, anastomotic leak rates, and number of harvested lymph nodes. Results suggest RAS was associated with significantly longer operative times (SMD = -1.27, p < 0.00001) compared to laparoscopic surgery. RAS led to shorter hospital stays (MD = 0.42, p – 0.003) and had a lower likelihood of conversion to open surgery (OR = 2.02, p < 0.00001). There as no significant difference in anastomotic leak rates between the two surgical techniques. RAS was associated with a slightly higher number of harvested lymph nodes (MD = -0.65, p = 0.04), although the clinical significance of this difference is unclear. Risk of bias was assessed using the Joanna Briggs Institute Critical Appraisal Checklist, with 6 studies identified as moderate risk and the remainder low risk. Publication bias was detected through funnel plot asymmetry and Egger's test (p = 0.006), indicating a potential overrepresentation of studies with positive results. The authors found that both surgical approaches demonstrated comparable oncological outcomes, including no significant differences in specimen size, resection margin positivity, or 30-day mortality rates. The authors concluded that robotic surgery is associated with longer operative times but tends to result in shorter hospital stays, and that both robotic and laparoscopic surgeries are viable options for the treatment of colon cancer, and the decision on which to choose should be guided by a multidisciplinary team to optimize patient outcomes. The authors concluded that both surgical approaches are competent, showing no substantial differences in outcomes that would distinctly favor one technique over the other.

Anyomih et al. (2024) performed a systematic review to compare the outcomes of RAS compared to laparoscopic surgery in emergency general surgery settings. A total of six studies were reviewed, including five retrospective cohort studies and one retrospective case series, for a total of 1,063 patients. All patients underwent emergency abdominal surgery such as cholecystectomy, ileocecal resection, subtotal colectomy, hiatal hernia repair, and perforated gastrojejunal ulcer repair. The results showed that operative times were generally longer for RAS compared to laparoscopic procedures, except for cholecystectomies, where no significant difference was observed. RAS was associated with shorter hospital stays, and in some cases lower complication rates. However, the costs associated with RAS were significantly higher. Conversion rates from minimally invasive to open surgery were comparable between robotic and laparoscopic groups, with no significant differences in intraoperative complication rates. Laparoscopic bowel resection in patients with inflammatory bowel disease had higher complications compared to robotic surgery, but for other procedures, there were no statistically significant differences in complication rates. Postoperative complications, including wound infections and incisional hernias, were slightly higher in the robotic group, but the differences were not statistically significant. Limitations include small retrospective studies, potential publication bias, and high potential for selection bias. The authors concluded that RAS in emergency general surgery is feasible and not inferior to laparoscopic surgery in selected cases, particularly for clinically stable patients. However, the higher costs and longer operative times remain key concerns. While RAS may offer certain advantages, stronger evidence from larger, well-powered prospective studies is needed to provide definitive recommendations.

Lenfant et al. (2023) conducted a systematic review and meta-analysis evaluating robotic-assisted benign hysterectomy compared to laparoscopic, vaginal, and open hysterectomy. The review included 24 studies published between 2010 and 2020, including 4 RCTs, for a total of 1,116,665 patients, with 110,306 undergoing robotic hysterectomy, 554,407 open, 189,237 vaginal, and 262,715 laparoscopic. The study aimed to assess perioperative outcomes, including operative time, blood loss, complications, length of hospital stay, conversions, and mortality. When compared to open hysterectomy, The primary advantage of RAS over laparoscopic and vaginal approaches was a shorter hospital stay, with an average reduction of 0.14 days compared to laparoscopic ($p < 0.0001$) and 0.39 days compared to vaginal ($p = 0.01$). Operative time was similar between RAS and laparoscopic but was longer for RAS compared to vaginal. Estimated blood loss was lower in RAS compared to vaginal and open surgeries but was comparable to laparoscopic surgery. No significant differences were found between RAS and laparoscopic approaches in terms of intraoperative complications, postoperative complications, or readmissions. However, when compared to open surgery, RAS was associated with fewer intraoperative and postoperative complications, lower mortality, and shorter hospital stays. The authors concluded that RAS provides similar perioperative outcomes to laparoscopic hysterectomy but offers benefits over open surgery. Compared to vaginal surgery, RAS had longer operative times but resulted in shorter hospital stays and lower blood loss. While RAS does not demonstrate significant superiority over laparoscopy, it may expand the minimally invasive surgical options for patients who would otherwise require open surgery, particularly those with large uteri or a history of prior abdominal surgery.

Aboudou et al. (2022) completed a meta-analysis comparing outcomes of robotic-assisted hepatectomy versus laparoscopic hepatectomy. The analysis included 19 studies with 682 patients undergoing robotic-assisted hepatectomy and 1101 patients undergoing laparoscopic hepatectomy. Results of the meta-analysis showed no significant differences in the rates of blood transfusions (8.1% robotic vs 6.15% laparoscopic), complications (15.5% robotic vs 17.9% laparoscopic), and reoperations (3.8% robotic vs 4.76% laparoscopic). Median operation time was noted to be less in patients receiving laparoscopic hepatectomy.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Lai et al. (2024) performed an overview of systematic reviews evaluating the clinical effectiveness of RAS compared to laparoscopic and open surgery across various intracavity procedures. The umbrella review included 165 systematic reviews between 2017 and 2023 with RCTs or non-RCTs reporting on clinical outcomes of RAS. The reviews covered multiple specialties such as colorectal, gynecology, upper gastrointestinal, and hepatopancreaticobiliary surgery. Results indicated that, apart from operative time, the clinical outcomes of RAS were generally positive or neutral when compared to laparoscopic and open surgery. Compared to open surgery, evidence favored RAS in most outcomes, whereas compared to laparoscopic surgery, the results were more mixed. Operative time was consistently longer for RAS across all procedures. For estimated blood loss, RAS was generally superior to open surgery, but results were mixed when compared to laparoscopic surgery, particularly in hysterectomy and hepatectomy. Conversion rates from minimally invasive to open surgery were lower with RAS compared to laparoscopic surgery, indicating greater procedural success. Length of hospital stay was either equivalent or shorter for RAS across all procedures compared to both laparoscopic and open approaches. Postoperative complications were lower with RAS compared to open surgery, but there was no significant difference between RAS and laparoscopic surgery. Oncological outcomes, including lymph node yield and resection margin, showed mixed results, with no clear superiority of RAS over other techniques. Similarly, long-term outcomes such as overall survival and disease-free survival were generally comparable across surgical approaches. The review highlighted that the quality of the included systematic reviews was generally low. The authors concluded that RAS is a clinically effective alternative to both laparoscopic and open surgery, and while RAS can expand access to minimally invasive surgery, its high capital and operational costs necessitate further economic evaluations to determine its optimal use.

Ying et al. (2023) completed a retrospective review of 106 children who underwent robotic-assisted patent ductus arteriosus ligation at Children's Hospital Zhejiang in China from August 2020 to March 2022. Data from the robotically assisted surgeries was compared to data from children who received transcatheter closure of the patent ductus arteriosus. There were no significant differences in clinical data between both groups. None of the children undergoing patent ductus arteriosus ligation via robotic assistance required conversion to a surgical thoracotomy. The authors noted that the cost of the robotic-assisted surgery was higher (US$8180) than the transcatheter closure (US$5076 ± 406) largely due to the cost of the robotic consumables. Limitations noted by the surgeons included a lack of force feedback during operation, making it necessary to take special care to not unintentionally separate the posterior wall of the ductus arteriosus or to rupture the arterial duct tissue. In addition, it was noted that this was a single-center experience with a small number of patients. The authors recommended a multi-center study be performed.

National and Specialty Organizations

The **World Society of Emergency Surgery (WSES)**, in a 2021 position paper, state that the role of robotic surgery for emergency procedures remains under investigation. They recognize the expanding use of RAS despite lack of evidence-based guidelines and recommend a strict patient selection while approaching emergent general surgery with robotics. An emergency setting should not be seen as a contraindication for RAS if adequate training of the operating surgical team is available (de'Angelis et al. 2022)

The **American College of Obstetricians and Gynecologists (ACOG)** and **Society of Gynecologic Surgeons (SGS)** (2020), in *Committee Opinion Number 810*, noted that RAS provides an alternative surgical option for minimally invasive gynecologic procedures, showing similar perioperative outcomes to laparoscopy and better outcomes than laparotomy; however, well-designed studies are needed to determine which patients are most likely to benefit from RAS over other minimally invasive approaches and to assess long-term outcomes and patient safety.

The **American College of Obstetricians and Gynecologists (ACOG)** (2017), in *Committee Opinion Number 701*, advocates for minimally invasive approaches to hysterectomy, such as laparoscopic hysterectomy, due to their documented advantages over abdominal hysterectomy. The committee notes that the role of robotic assistance in performing laparoscopic hysterectomy remains to be fully defined, and additional data are necessary to establish evidence-based applications for this technology.

The **Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)** and **Minimally Invasive Robotic Association (MIRA) Robotic Task Force** (2007), in a consensus document on robotic surgery, note that although RAS has shown promise across a broad range of surgical disciplines, no level I data exists to strongly support robotic surgery, and no studies exist to suggest any increase in complication rates compared to laparoscopic or open surgery. Overall, the major deterrents to the clinical use of RAS are cost, training issues, and lack of outcomes data. These limitations will likely ease as RAS devices evolve.

CODING & BILLING INFORMATION

HCPCS (Healthcare Common Procedure Coding System)

Code	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

04/09/2025	Policy reviewed, no change to coverage policy. Updated summary of medical evidence, overview, and edited coverage policy for clarity.
04/10/2024	Policy reviewed, no changes to coverage criteria. Updated Summary of Medical Evidence and References. IRO Peer Review on February 29, 2024, by a practicing physician board-certified in Surgery Bariatric, Surgical Critical Care, Surgery General.
04/13/2023	Policy reviewed, no changes to coverage criteria. Updated Summary of Medical Evidence and References.
04/13/2022	Policy reviewed and updated; no changes in coverage position.
04/05/2021	Policy reviewed, no changes to criteria, removed ICD-10 procedural classification system (PCS) codes.
04/23/2020	Policy reviewed, no changes to criteria.
06/19/2019	Policy reviewed, no changes to criteria.
03/08/2018	Policy reviewed, no changes to criteria.

09/19/2017 Policy reviewed, no changes to criteria.
06/15/2016 Policy reviewed, no changes to criteria.
12/16/2015 Policy reviewed, no changes to criteria.
04/02/2014 New policy. IRO peer reviewed by board-certified physician in the areas of Surgery General, Surgery Vascular, Surgical Critical Care, Surgery.

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