MOLINA
H E A L T H C A R E

Subject: Robotically Assisted Surgery		Original Effective Date: 4/2/14
Guidance Number: MCG-161	**Revision Date(s):**	This MCG replaces the following MCG's that have been archived: 90, 98, 99, 100, 101 &102
Medical Coverage Guidance Approval Date: 4/2/14		

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. [1][3]

According to the FDA summary and notification (K050802) issued on June 29, 2005, the da Vinci Surgical System is indicated for adult and pediatric use and is intended for use by trained physicians in an operating room: "to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave ablation probes and accessories during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, general noncardiovascular thoracoscopic surgical procedures, and thoracoscopically assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization." [1]

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

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 medical coverage guidance (MCG) document and provide the directive for all

Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

CMS does not have a National Coverage Determination or a Local Coverage Determination for Robotic-Assisted Surgery for any indication. [9]

INITIAL COVERAGE CRITERIA

❑ 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. [3 4 5 6 7 21-26]

  ◊ 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. [33]

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.

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

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. [3]

The proposed major advantages of robot-assisted over conventional laparoscopy are: [21]

- 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 have been reported as follows: [21]

- 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).

GENERAL INFORMATION

Summary of Medical Evidence

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.

Abdominal Surgery

Maeso et al (2010) conducted a systematic review and meta-analysis of the literature regarding the safety and efficacy of the da Vinci surgical system in abdominal surgery. Thirty-one articles met the inclusion criteria and were published between 2002 and 2009. Six were randomized clinical trials (RCT's); the remaining 25 articles were observational cohort monitoring studies (not considered acceptable quality via Molina policy). Surgical procedures included in the studies comprised of Heller myotomy, Roux-en-Y gastric bypass, fundoplication,

splenectomy, bariatric procedures, cholecystectomy, colorectal resection and rectopexy. The overall quality of the studies included in the review was considered less than satisfactory as many had no randomization, blinding or suitable control groups. The authors indicated that approximately 40% of the controlled studies used historic controls, limiting their comparability, and introducing bias as the patient care may have improved over the years due to aspects unrelated to the surgical procedures employed. A cautious interpretation of the positive findings is warranted until better quality studies are performed and can confirm any advantages of the procedure. Robotic surgery has been associated with fewer perforations in Heller myotomy, a quicker intestinal recovery and shorter hospital stay for gastrectomy (although surgery times are longer), shorter hospital stay with the exception of cholecystectomy, more surgical conversions were required with gastric bypass, and a longer surgery time for colorectal resections. Robotic surgery is also more costly than conventional surgery. The authors also concluded that robotic surgery is a developing technology and not ready to be a substitute for conventional procedures. [10]

Bariatric Surgery

A systematic review of robotic bariatric surgery was conducted by Cirocchi et al (2013). Twenty-two comparative and non-comparative studies were included, irrespectively of their size, publication status and language, which included patients who underwent robotic bariatric surgery . Comparative studies were included if they focused on selected outcomes of interest, irrespectively of the type of surgical approach used for comparative group (laparoscopic or open). Primary outcomes included surgical (conversion to open surgery, anastomotic leakage, re-intervention for complications, mortality), bariatric (postoperative Body Mass Index), and metabolic (type 2 DM remission). Anastomotic leak rate was 8.51% in biliopancreatic diversion. 30-day reoperation rate was 1.14% in Roux-en-Y gastric bypass and 1.16% in sleeve gastrectomy. Major complication rate in Roux-en-Y gastric bypass resulted higher than in sleeve gastrectomy (4,26% vs. 1,2%). The mean hospital stay was longer in Roux-en-Y gastric bypass (range 2.6-7.4 days). The major limitation of the analysis is due to the small number and the low quality of the studies, the small sample size, heterogeneity of the enrolled patients and the lack of data from metabolic and bariatric outcomes. Despite the use of the robot, the majority of these cases are completed with stapled anastomosis. The assumption that robotic surgery is superior in complex cases is not supported by the available present evidence. The major strength of the robotic surgery is strongly facilitating some of the surgical steps (gastro-jejunostomy and jejunojejunostomy anastomosis in the robotic Roux-en-Y gastric bypass or the vertical gastric resection in the robotic sleeve gastrectomy). The major disadvantage of the robotic bariatric surgery "still remains the high operational and acquisition cost of the system" [39]

Bailey et al (2013) conducted another systematic review of robotic versus laparoscopic Roux-en-Y gastric bypass (RYGB) in obese adults ages 18 to 65 years. Studies comparing robotic versus laparoscopic RYGB involving patients ages 18-65 years who met the National Institutes of Health (NIH) criteria for bariatric surgery were included in the study if they reported overall or major complication rates. Outcomes were pooled using random-effects metaanalysis. A decision-tree economic analysis was performed to calculate expected costs associated with each technique. The systematic search strategy returned 1,374 potentially relevant studies. The

inclusion criteria were met by 10 of these studies, which included results from 2,557 patients. The overall major and minor complications did not differ significantly between the robotic and laparoscopic groups. The rates for anastomotic leak, bleeding, stricture, and reoperation did not differ significantly. An economic analysis found that the expected costs for robotic RYGB ($15,447) were higher than for laparoscopic RYGB ($11,956). Sensitivity analyses produced similar results. The authors concluded that the complication rates did not differ significantly between robotic and laparoscopic RYGB, but the expected costs were greater for robotic RYGB. Further cost effectiveness analyses are recommended before adoption of a robotic approach to RYGB. [40]

Cardiac Surgery

One of the largest available uncontrolled study of robotically assisted MV repair was conducted by Ramzey et al. (2013). For this study 300 consecutive robotic-assisted mitral repairs performed from June 2005 to October 2012 and to compare the surgical outcomes of previously reported initial 120 cases with the subsequent 180 procedures. Every patient in need of isolated mitral valve repair underwent this procedure. All patients received an annuloplasty band and 1 or more of the following: leaflet resection, secondary chordal transposition, or polytetrafluoroethylene neochordal replacement and edge-to-edge repair. All 300 patients had preoperative echocardiographic findings of severe mitral regurgitation. There were no differences (P = not significant) between the initial and the recent cohorts for preoperative characteristics, including age (58.4 ± 10.5 years vs 59.9 years), female gender (35.8% vs 36.1%), ejection fraction (61.9% vs 60.6%), congestive heart failure (35.0% vs 36.7%), creatinine (0.94 mg/dL vs 0.98 mg/dL), and New York Heart Association class. The incidence of anterior and posterior leaflet prolapse was similar in both groups, whereas Barlow syndrome was higher in group 2 (5.8% vs 27.8%). There was 1 (0.33%) hospital mortality and no deaths in the last 180 cases. Overall, 8 patients (2.7%) required subsequent mitral valve replacement via a median sternotomy, 6 (5.0%) in the first group and 2 (1.1%) in the second group (P = .06). One patient in each group had mitral valve re-repair through a right mini-thoracotomy, and 1 patient in the first group required a mitral valve replacement via a mini-thoracotomy during the original procedure. Two of the 180 patients had documented cerebrovascular accident, but both fully recovered clinically. There was no cerebrovascular accident in the last 120 patients. Crossclamp times decreased from 116 minutes to 91 minutes in the second group despite starting a training program with a junior associate performing part of the procedure at the console in the last 100 cases. Post-pump echocardiograms showed no/trace mitral regurgitation in 86.1% of the last 180 patients and mild mitral regurgitation in 11.1%. Follow-up echocardiography for the last 180 patients from 1 month to more than 1 year showed no/trace mitral regurgitation in 64.6% of patients and mild mitral regurgitation in 23.1% of patients. Seven patients (10.8%) had moderate mitral regurgitation, and 1 patient (1.5%) had severe mitral regurgitation. The majority of complications and reoperations occurred early in our experience, especially using the first-generation da Vinci robot (Intuitive Surgical Inc, Sunnyvale, Calif). The newer da Vinci Si HD system with the addition of an adjustable left atrial roof retractor together with increased experience has made robotic-assisted mitral repair of all types of degenerative mitral valve pathology reproducible. The training of young surgeons in a stepwise fashion in high-volume centers will help to avoid the complications encountered during the introduction of this technology. [33]

Wiedemann et al. (2012) evaluated the effect of extended operation times on the outcome of patients undergoing totally endoscopic coronary artery bypass grafting (TECAB.) From 2001 to 2009, 325 patients underwent TECAB with the da Vinci telemanipulation system. Correlations between operative times and preoperative, intraoperative, and early postoperative parameters were investigated. Receiver operating characteristic analysis was used to define the threshold of the procedure duration above which intensive care unit stay and ventilation time were prolonged. Demographic data, intraoperative and postoperative parameters, and survival data were compared. Patients with prolonged operative times more often underwent multivessel revascularization (P < .001) and beating-heart TECAB (P =.023). Other preoperative parameters were not associated with longer operative times. Incidences of technical difficulties and conversions (P < .001) were higher among patients with longer operative times. Prolonged intensive care unit stay, mechanical ventilation, hospital stay, and with requirement of blood products were associated with longer operative times. Receiver operating characteristic analysis showed operative times >445 minutes and >478 minutes to predict prolonged (>48 hours) intensive care unit stay and mechanical ventilation, respectively. Patients with procedures >478 minutes had longer hospital stays and higher perioperative morbidity and mortality. Kaplan-Meier analysis revealed decreased survival among patients with operative times >478 minutes. The authors concluded that multivessel revascularization and conversions lead to prolonged operative times in totally endoscopic coronary artery bypass grafting. Longer operative times significantly influence early postoperative and midterm outcomes. [32]

Fundoplication

Mi et al (2010) conducted a systematic review to assess the feasibility and efficiency of robot-assisted laparoscopic fundoplication (RALF) for gastroesophageal reflux disease (GERD). Two reviewers independently searched and identified seven randomized controlled trials (RCTs) and four clinical controlled trials (CCTs) of RALF versus conventional laparoscopic fundoplication (CLF) for GERD. The main outcomes were operating time, complication rate, hospital stay and costs. Of 533 patients, 198 underwent RALF and 335 underwent CLF. The results showed that the postoperative complication rate is lower for RALF, but the total operating time is longer for RALF compared with those for CLF. Statistically, there was no significant difference between the two groups with regard to perioperative complication rate and length of hospital stay. The authors concluded that while RALF is a feasible and safe alternative to surgical treatment of GERD, it lacks obvious advantages with respect to operating time, length of hospital stay and cost. [28]

Gynecological Surgery

Wright et al. (2013) sought to analyze the uptake of robotically assisted hysterectomy, to determine the association between use of robotic surgery and rates of abdominal and laparoscopic hysterectomy, and to compare the in-house complications of robotically assisted hysterectomy vs abdominal and laparoscopic procedures. A cohort study was conducted of 264,758 women who underwent hysterectomy for benign gynecologic disorders at 441 hospitals across the United States from 2007 to 2010. Uptake of and factors

associated with utilization of robotically assisted hysterectomy included complications, transfusion, reoperation, length of stay, death, and cost for women who underwent robotic hysterectomy compared with both abdominal and laparoscopic procedures were analyzed. The results showed that use of robotically assisted hysterectomy increased from 0.5% in 2007 to 9.5% of all hysterectomies in 2010. During the same time period, laparoscopic hysterectomy rates increased from 24.3% to 30.5%. Three years after the first robotic procedure at hospitals where robotically assisted hysterectomy was performed, robotically assisted hysterectomy accounted for 22.4% of all hysterectomies. The rates of abdominal hysterectomy decreased both in hospitals where robotic-assisted hysterectomy was performed as well as in those where it was not performed. In a propensity score-matched analysis, the overall complication rates were similar for robotic-assisted and laparoscopic hysterectomy (5.5% vs 5.3%; relative risk [RR], 1.03; 95% CI, 0.86-1.24). Although patients who underwent a robotic-assisted hysterectomy were less likely to have a length of stay longer than 2 days (19.6% vs 24.9%; RR, 0.78, 95% CI, 0.67-0.92), transfusion requirements (1.4% vs 1.8%; RR, 0.80; 95% CI, 0.55-1.16) and the rate of discharge to a nursing facility (0.2% vs 0.3%; RR, 0.79; 95% CI, 0.35-1.76) were similar. Total costs associated with robotically assisted hysterectomy were $2189 (95% CI, $2030-$2349) more per case than for laparoscopic hysterectomy. The authors concluded that between 2007 and 2010, the use of robotically assisted hysterectomy for benign gynecologic disorders increased substantially. Robotically assisted and laparoscopic hysterectomy had similar morbidity profiles, but the use of robotic technology resulted in substantially more costs. [13]

A meta-analysis by Reza et al (2010) was conducted to compare the safety and effectiveness of robotic surgery, open surgery and conventional laparoscopic surgery in gynecology. Sixteen retrospective or prospective observational studies provided quantitative data that could be used in the meta-analysis. Surgical procedures included hysterectomy for the staging of endometrial cancer, hysterectomy for benign disease, radical hysterectomy for cervical cancer, sacrocolopexy, myomectomy, fallopian tube reanastomosis and adnexectomy. The following findings were identified in hysterectomy for staging of endometrial cancer versus conventional procedures: There were significantly fewer complications with robotic surgery versus open but no difference between robotics and the laparoscopic approach. Robotics surgery for endometrial cancer resulted in shorter hospital stays compared with both laparoscopic or open procedures. The duration of operation was longer in robotics compared with open procedures and no difference with laparoscopic approach. Robotic procedures held greater risks for conversions to another surgery type in robotics procedures versus open but a reduced risk of conversion compared with laparoscopic procedures. There was an increased number of resected lymph nodes in robotics compared with open surgery but no significant difference compared with laparoscopic procedures and no differences in the number of pelvic lymph nodes or aortic lymph nodes resected for either comparison. Similar findings were identified in radical hysterectomy for cervical cancer. There were no significant differences in operation duration for either open or laparoscopic procedures compared with robotics. Complication frequency, need for conversions, and number of lymph nodes resected were not significantly different among the three procedure comparisons. Review of fallopian tube reanastomosis identified significantly longer duration of operation for robotics compared with open procedures. There were no significant differences for hospital stay, complications, blood loss, pregnancy rate, miscarriage and ectopic and uterine pregnancies. There were increased robotic costs for this procedure when compared with open or laparoscopic approaches. Myomectomy procedures identified significantly lower blood loss for robotics versus laparoscopic procedures with no significant difference in surgery duration. Robotic procedure costs were higher than conventional procedures. A large study for benign disease reported significantly longer duration of operation, shorter hospital stay duration and lower blood loss for robotics versus the laparoscopic approach.

Sacrocolopexy procedures had longer operation duration, shorter hospital stay and lower blood loss but higher risk of postoperative fever in robotics procedures versus open surgery. Adenextomy procedures had longer surgery duration for robotics versus laparoscopic procedures. The authors concluded that robotic surgery offered limited advantages over classical surgical techniques. However, due to evidence limitations the study results were limited and conclusions should be treated with caution. [11]

Pediatric Surgery

Cundy et al. (2013) performed a systematic review to critically appraise the current status of robot-assisted minimally invasive surgery (MIS) for pediatric solid tumors. A systematic search of multiple electronic literature databases was undertaken, supplemented by several relevant secondary sources. A total of 23 publications met eligibility criteria, reporting 40 cases overall. Indications for surgery were widely varied, with over 20 different pathologies described. One-third of tumors were classified as malignant. Most procedures involved abdominal or retroperitoneal located tumors in adolescent patients (age range, 1-18 years). The collective complication and conversion rates were 10% and 12.5%, respectively. Oncological adverse events involved two isolated events of tumor spillage and residual disease. The evidence is limited to case reports and small case series only. The authors concluded that for the diverse and highly selective cases in this review, robot-assisted MIS seems safe and feasible. Current status is low volume, in a relatively static state of adoption, and without any apparent index pathology or procedure. The benefits of robot assistance seem well suited but remain unsubstantiated by evidence. Higher quality studies are needed to determine true safety and efficacy. [31]

Alqahtani et al. (2010) assessed the safety and feasibility of performing robot-assisted pediatric surgery using the da Vinci Surgical System in a variety of surgical procedures. A retrospective review of 144 procedures included the following: 39 fundoplications; 34 cholecystectomies; 25 gastric bandings; 13 splenectomies; 4 anorectal pull-through operations for imperforate anus; 4 nephrectomies; 4 appendectomies; 4 sympathectomies; 3 choledochal cyst excisions with hepaticojejunostomies; 3 inguinal hernia repairs; two each of the following: liver cyst excision, repair of congenital diaphragmatic hernia, Heller's myotomy and ovarian cyst excision; and one each of the following: duodeno-duodenostomy, adrenalectomy and hysterectomy. A total of 134 procedures were successfully completed without conversion; 7 additional cases were converted to open surgery and 3 were converted to laparoscopic surgery. There were no system failures. There was one esophageal perforation and two cases of transient dysphagia following Nissen fundoplication. The mean patient age was 8.9 years, and the mean patient weight was 57 kg. The authors concluded that robot-assisted surgery appears to be safe and feasible for a number of pediatric surgical procedures. Further system improvement and randomized studies are required to evaluate the benefits, if any, and the long-term outcomes of robotic surgery. [30]

Prostatectomy

Ramsey et al. (2012) conducted a systematic review to determine the relative clinical effectiveness and cost-effectiveness of robotic radical prostatectomy compared with laparoscopic radical prostatectomy in the treatment of localised prostate cancer. Evidence was considered from randomised controlled trials (RCTs) and

non-randomised comparative studies of men with clinically localized prostate cancer (cT1 or cT2); outcome measures included adverse events, cancer related, functional, patient driven and descriptors of care. Two reviewers abstracted data and assessed the risk of bias of the included studies. The searches identified 2722 potentially relevant titles and abstracts, from which 914 reports were selected for full-text eligibility screening. Of these, data were included from 19,064 patients across one RCT and 57 non-randomised comparative studies, with very few studies considered at low risk of bias. The review concluded that robotic prostatectomy had lower perioperative morbidity and a reduced risk of a positive surgical margin compared with laparoscopic prostatectomy although there was considerable uncertainty. Robotic prostatectomy will always be more costly to the NHS because of the fixed capital and maintenance charges for the robotic system. The authors modeling showed that this excess cost can be reduced if capital costs of equipment are minimized and by maintaining a high case volume for each robotic system of at least 100-150 procedures per year. This finding was primarily driven by a difference in positive margin rate. There is a need for further research to establish how positive margin rates impact on long-term outcomes. [27]

Albadine et al. conducted a retrospective study (2012) detailing differences in positive surgical margin among open retropubic radical prostatectomy, laparoscopic radical prostatectomy, and robotic-assisted laparoscopic radical prostatectomy. 99 cases were reviewed and 6 (5%) were reinterpreted as having negative margins. Ninety-three cases were, therefore, included, corresponding to 37 retropubic radical prostatectomies, 19 laparoscopic radical prostatectomies, and 37 robotic-assisted laparoscopic radical prostatectomies. The relationship of positive surgical margin characteristics to clinicopathologic parameters and biochemical recurrence was assessed. The most commonly found positive surgical margin site was the apex/distal third in all groups (62% retropubic prostatectomies, 79% laparoscopic prostatectomies, 60% robotic-assisted prostatectomies). Total linear length of positive surgical margin sites was significantly correlated with preoperative prostate-specific antigen, preoperative prostate-specific antigen density, pT stage, and tumor volume ($P \leq .001$). We found no significant differences among the 3 groups with respect to total linear length, number of foci, laterality, or location of positive surgical margin. The rate of biochemical recurrence was also comparable in the 3 groups. On univariate analyses, biochemical recurrence was significantly associated with preoperative prostate-specific antigen values, preoperative prostate-specific antigen density, Gleason score, number of positive surgical margins, and total linear length of positive surgical margin ($P \leq .02$). Only preoperative prostate-specific antigen density and number of positive surgical margin foci were statistically significant ($P \leq .03$) independent predictors of biochemical recurrence. The authors found no significant difference in positive surgical margin characteristics or biochemical recurrence among the 3 radical prostatectomy modalities. Preoperative prostate-specific antigen density and number of positive surgical margin foci were the only independent predictors of biochemical recurrence. [15]

A systematic review was conducted by Xylinas et al. (2010) evaluating seventy-five research publications that met eligibility criteria.[9] Two randomized-control trials (RCTs), six propsective cohort, 11 retrospective cohort, and 56 case series were the study design of the trials included. The two RCTs compared technical modifications of RALP with each other rather than comparing RALP to open or laparoscopic prostatectomy. Both studies, focused on the effectiveness of the so-called Rocco stitch and the relative advantages and disadvantages of an extra- versus intraperitoneal approach. Overall, the published literature provided level 2, 3, and 4 evidence in 2.7% (n = 2), 24.0% (n = 18), and 73.3% (n = 55) of studies, respectively. The median sample

size was 120 patients (interquartile range: 55–300), with only 12.0% of studies reporting on >500 patients and only three studies (3.9%) including 1000 patients. The vast majority of studies (96%) originated from a single center and did not report their source of funding (97.3%). Twelve authors co-wrote 72% (54 of 75) of the published studies. The authors concluded that that laparoscopic prostatectomy and RALP were associated with lower blood loss and transfusion rates but rapid and widespread adoption of RALP is not supported by high-quality evidence that would be suitable to demonstrate relative superiority over the alternative surgical techniques it has replaced.

Hayes, Cochrane, UpToDate

Hayes has several reports on the topic of robotic surgery for various indications. These reports outline that robotic surgery has potential but unproven benefit. Some published evidence suggests that safety and impact on health outcomes are at least comparable to standard treatment/testing. However, substantial uncertainty remains about safety and/or impact on health outcomes because of poor-quality studies, sparse data, conflicting study results, and/or other concerns. [3][4][5][6][7]

Cochrane

A *Cochrane* review (2012) was conducted to assess the effectiveness and safety of robot-assisted surgery in the treatment of benign gynecological disease. Selection criteria included all randomised controlled trials (RCTs) comparing robotic surgery for benign gynecological disease to laparoscopic or open surgical procedures. RCTs comparing different types of robotic assistants were also included. Two review authors independently screened studies for inclusion. The domains assessed for risk of bias were allocation concealment, blinding, incomplete outcome data and selective outcome reporting. Odds ratios (OR) were used for reporting dichotomous data with 95% confidence intervals (CI), whilst mean differences (MD) were determined for continuous data. Statistical heterogeneity was assessed using the $I(2)$ statistic. The main results involved two trials and included 158 participants. Since one included trial was published in conference proceedings, limited usable data were available for further analysis. The only analysis in this trial showed comparable rates of conversions to open surgery between the robotic group and the laparoscopic group (OR 1.41, 95% CI 0.22 to 9.01; $P = 0.72$). One RCT showed longer operation time (MD 66.00, 95% CI 40.93 to 91.07; $P < 0.00001$), higher cost (MD 1936.00, 95% CI 445.69 to 3426.31; $P = 0.01$) in the robotic group compared with the laparoscopic group. Also, both studies reported that robotic and laparoscopic surgery seemed comparable regarding intraoperative outcome, complications, length of hospital stay and quality of life. The authors concluded that currently, the limited evidence showed that robotic surgery did not benefit women with benign gynaecological disease in effectiveness or in safety. Further well-designed RCTs with complete reported data are required to confirm or refute this conclusion. [14]

Another Cochrane review (2012) was performed to evaluate the evidence for and against robotic assisted surgery in gynecological cancer. Selection criteria included all randomised controlled trials (RCTs) comparing robotic assisted surgery for gynecological cancer to laparoscopic or open surgical procedures as well as RCTs comparing different types of robotic assistants. No RCTs were identified, therefore data collection and analysis could not be performed. No studies were found that met the inclusion criteria. Controlled clinical trials (CCTs)

are summarized and analyzed, but are not discussed in the main body of the review as they present a high risk of bias. The authors concluded that Well-designed RCTs are required as only low quality evidence from CCTs is available. These studies support the use of robotic assisted surgery for endometrial cancer and cervical cancer, but these findings present a high risk of bias. [18]

A Cochrane review (2009) compared robot assistants with human assistants for laparoscopic cholecystectomy. Five randomized clinical trials were included of 453 patients: 159 to the robot assistant group and 165 to the human assistant group (one trial report including 129 patients was a conference abstract and did not state the number of patients in each group). There was no statistically significant difference between the two groups for morbidity, conversion to open cholecystectomy, total operating time, or hospital stay. The instrument set-up time was significantly lower in the human assistant group. In one trial, about one sixth of the laparoscopic cholecystectomies in which robot assistant was used, required temporary use of a human assistant. The review does not identify a requirement for human assistants in the other three published trials. In two of the three trials, which reported surgeons' preference, the surgeons preferred a robot assistant to a human assistant. The authors concluded that although robot-assisted laparoscopic cholecystectomy appears safe, there are no significant advantages over human-assisted laparoscopic cholecystectomy. Further randomized trials with low risk of bias (systematic errors) and low risk of play of chance (random errors) are needed. [29]

UpToDate

There are several reports on robotic surgery for various indications. These reports outline that in benign gynecological disease there is no high quality evidence that robot-assisted laparoscopy is superior to laparotomy or conventional laparoscopy. [21] Robot-assisted laparoscopic hysterectomy is more costly than conventional laparoscopic surgery and outcomes appear comparable to conventional laparoscopic or vaginal hysterectomy. Comparative studies have found that complication rates are similar for conventional and robotic-assisted laparoscopic hysterectomy. [22] Robot-assisted laparoscopic endometrial carcinoma staging was compared with conventional laparoscopy and laparotomy and the advantages of robotic procedures were mainly in comparison with laparotomy. [23] There are no randomized trials that compare open versus minimally invasive radical prostatectomy. Comparative studies of efficacy and side effects have yielded conflicting results, which appear to reflect differences in case selection and tumor characteristics and lack of long term follow-up. [24] For cardiac valve surgery there are no randomized comparisons of conventional and alternative approaches to valve surgery with regard to clinical outcomes, postoperative complications, and cost. While the results for isolated minimal access aortic valve surgery have been uniformly encouraging, the results for minimally invasive, port access mitral valve surgery have been more controversial with mixed results in early studies. [25] There is limited experience with totally endoscopic coronary artery bypass graft (CABG) with cardiopulmonary bypass using a robotically enhanced telemanipulation system in patients with single or double vessel disease. [26]

Professional Organizations

The American Congress of Obstetricians and Gynecologists (ACOG) 2013 Statement on Robotic Surgery indicates that robotic surgery for hysterectomies should not be the first, or even second, choice for women

undergoing routine procedures. According to the statement, expertise with robotic hysterectomy is limited and varies widely among both hospitals and surgeons. While there may be some advantages to the use of robotics in complex hysterectomies, especially for cancer operations, studies have shown that adding this expensive technology for routine surgical care does not improve patient outcomes. Consequently, there is no good data proving that robotic hysterectomy is even as good as, let alone better than, existing, and far less costly, minimally invasive alternatives. [8]

The American College of Cardiology Foundation (ACFF)/American Heart Association (AHA) 2011 Guideline for Coronary Artery Bypass Graft Surgery indicates that robotic technology in minimally invasive CABG leads to less traumatic harvesting of the LIMA for minimally invasive direct coronary artery bypass procedures compared with nonrobotic techniques. The ultimate goal of robotic CABG is totally endoscopic CABG, but its use has been limited, at least partly because of a substantial learning curve, cost considerations, and few data demonstrating non-inferior graft patency and outcomes compared with standard CABG. [19]

American Heart Association (AHA): In a 2008 scientific statement concerning percutaneous and minimally invasive valve procedures, the American Heart Association (AHA) concluded that early experience with robotically assisted valve repair indicates that this approach may provide benefits such as reduced pain and surgical trauma, improved cosmesis, and shortened HLOS; however, longer follow-up is needed to evaluate the durability of robotically assisted valve repairs. According to the AHA, this technology has not been adequately evaluated in patients who are older and sicker since the published studies have primarily enrolled younger, healthier patients who do not have significant left ventricular dysfunction. Another concern of the AHA is cost-effectiveness of this technology since the large capital expense for the robotic surgical system may offset cost savings from factors such as shorter hospital length of stay. [20]

American Urological Association: Standard operating practices for ulogogic robotic surgery: These guidelines from 2013 formulate standard operating practices for institutions to use during the process of credentialing of urologists for privileges to perform robotic surgery. [41]

European Association of Urology (EAU): The 2013 Guidelines on Robotic and Single Site Surgery in Urology [17] outline the following recommendations:
- Robotic radical prostatectomy (RP) surgery does not improve oncological outcomes in comparison to open RP and laparoscopic RP; surgical expertise is the crucial factor. Use of the robot is not recommended to improve surgical outcomes.
- There are no comparable long-term data on oncological, safety and functional outcomes for robotic or laparoscopic partial nephrectomy.
- Robotic RP, open RP and laparoscopic RP achieve similar perioperative and oncological pelvic lymph node dissection outcomes so either technique can be used in lymphadenectomy.

EAU Guidelines on muscle-invasive and metastatic bladder cancer state that "Laparoscopic and robot-assisted laparoscopic cystectomy are both management options. However, current data have not sufficiently proven the

advantages or disadvantages for both oncological and functional outcomes of laparoscopic and robotic-assisted laparoscopic cystectomy". [38]

Society of American Gastrointestinal Endoscopic Surgeons (SAGES): A Consensus Document [16] on Robotic Surgery was developed by the Board of Governors of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) on Nov 2007. According to the document, the 3 major impediments to the clinical use of robots are cost, training issues and lack of outcomes data and the primary technical limitation of robotic surgery is the difficulty in performing procedures that extend over a large area, such as multiquadrant abdominal surgery.

- SAGES guidelines for surgical treatment of gastroesophageal reflux disease indicate that "while robotic assistance can be safely and effectively used for fundoplication, its higher cost compared with conventional laparoscopy and similar short-term patient outcomes make it a less than ideal initial choice (Grade B). Nevertheless, further study regarding learning curves and surgeon workload with the robotic technique are needed before stronger recommendations can be made." [35]
- SAGES guidelines for laparoscopic resection of curable colon and rectal cancer state that "While robotic surgery for colon and rectal cancer appears feasible and safe, in the absence of long-term oncologic outcome studies, no clear recommendation can be made." [36]
- SAGES guidelines for the minimally invasive treatment of adrenal pathology Compared with standard laparoscopic techniques, robotic adrenalectomy may offer advantages for large tumors and in morbidly obese patients. However, given the increased cost, longer operative times, and lack of clear patient outcome benefits using this technique, additional higher quality evidence is needed before a firm recommendation can be provided. [37]

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-9	Description (Procedure Codes)
17.4	Robotic assisted procedures
17.41	Open robotic assisted procedure
17.42	Laparoscopic robotic assisted procedure
17.43	Percutaneous robotic assisted procedure

17.44	Endoscopic robotic assisted procedure
17.45	Thoracoscopic robotic assisted procedure
17.49	Other and unspecified robotic assisted procedure

ICD-10	Description
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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