

Clinical Policy Title: Robotic assisted surgery

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Effective Date:	March 1, 2014
Initial Review Date:	September 18, 2013
Most Recent Review Date:	October 1, 2019
Next Review Date:	February 2021

Policy contains:

- DaVinci surgical system.
- Robotic -assisted surgery.
- ZEUS robotic system.

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory. The plan benefits and/or state and federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory are providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

Robotic assistance in surgery is investigational and, therefore, not medically necessary.

Limitations:

Robotic assistance is not separately reimbursable from the primary surgical procedure.

Alternative covered services:

Surgeon consultation for approved standard or minimally invasive surgery without the assistance of robotic technology.

Background

Robotic assisted surgery has become increasingly common in the United States and in the world, rising from 80,000 to 500,000 procedures annually between 2007 and 2013. By 2015, a total of 1.5 million procedures had been performed worldwide (Vaidya, 2015). The new technology has rapidly expanded. In 2010, 9.5 percent of hysterectomies in U.S. hospitals were performed using robotic technology, up from just 0.5 percent three years earlier. In hospitals that introduced robotic surgery for hysterectomy, 22.4 percent of

the procedures were performed using a robot three years after the first such procedure was performed (Wright, 2013).

The use of computer assistance allows the surgeon to take advantage of the miniaturization possible that leads to smaller incisions, less pain and somewhat reduced hospitalization time. The robotic assistance devices allow the surgeon to operate from a console with three dimensional viewing. Computer technology translates surgeons' hand motions into precise manipulation of surgical instruments inserted into the patients' bodies through cannulas. This allows the surgeon to operate remotely. Much of the original work on robot assisted surgery was performed through grants by the U.S. military looking for ways to operate remotely on soldiers injured on the battlefield. The greatest use of robotics occurs within hospitals where the surgeon is in close proximity to the patient but taking advantage of miniaturization of the incision.

The most commonly used model of robotic assisted surgery is the daVinci[®] system, made by Intuitive Surgical. It is often used for prostatectomies, hysterectomies, bypass surgeries, and removing cancerous tissue (Carlson, 2016). The U.S. Food and Drug Administration approved the device in December, 2009 (U.S. Food and Drug Administration, 2009). Another popular model is the ZEUS Robotic Surgical System (also owned by Intuitive Surgical), which had been approved in October, 2001 (U.S. Food and Drug Administration, 2001).

The Consensus document from the Society for American Gastrointestinal and Endoscopic Surgeons lists four elements of advantages for robotic surgeries (Herron, 2008):

- Superior visualization, including 3-dimensional imaging of the operative field.
- Stabilization of instruments within the surgical field.
- Mechanical advantages over traditional laparoscopy.
- Improved ergonomics for the operating surgeon.

The Society further indicates the optimal use of robotics for intra-abdominal surgery is where the procedure is in a defined space within the abdomen and in which fine dissection and micro-suturing is needed.

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.
- The Cochrane library.

We conducted searches on August 13, 2019. Search terms were "robotic systems", "robotic surgery," and "da Vinci surgery."

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- Guidelines based on systematic reviews.
- Economic analyses, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes sometimes referred to as efficiency studies which also rank near the top of evidence hierarchies.

Findings

On March 14, 2013, American College of Obstetricians and Gynecologists president James T. Breeden MD issued a statement on the College's web site. Breeden stated that "studies have shown that adding this expensive technology for routine surgical care does not improve patient outcomes. . . 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." Breeden cited "aggressive direct-to-consumer marketing of the latest medical technologies may mislead the public into believing that they are the best choice" (American College of Obstetricians and Gynecologists, 2013). A 2015 opinion of the College stated that adopting new surgeries should be based on what is best for the patient plus evidence-based medicine, and noted that well-designed randomized controlled trials and prospective trials are needed to determine which patients benefit from, or are considered risks for, robot-assisted surgery (American College of Obstetricians and Gynecologists, 2015).

In March 2016, Project Hope Senior Fellow and former Health Care Financing Administration director Gail Wilensky PhD published a peer-reviewed journal article echoing these conclusions. Evidence of effective outcomes of robotic surgery patients compared to laparoscopy patients is "considerably less compelling," she wrote. Wilensky also focused on the cost of robotic surgery. The purchase price of a single machine is around \$2 million, and thus the average incremental cost of robotic surgery compared to laparoscopy is about \$3,000 to \$6,000 per patient. She did acknowledge that the greatest efficacy has been found in those procedures that are most difficult to reach with a laparoscope, such as prostatectomy and some head and neck surgeries; but concluded that "there is no indication that these robotic procedures are likely to become more cost-effective over time" (Wilensky, 2016).

Both Breeden and Wilensky cited a large 2013 *JAMA* study published by Columbia University researchers covering 264,758 women undergoing laparoscopic hysterectomy, with or without robotic assistance, in 441 hospitals between 2007 and 2010. The study found similar rates between groups for complications, percent of hospital stays over two days, transfusions, and nursing home discharges, but also cited concern over the higher average costs associated with robotic surgery, especially as the percent of hysterectomies performed with a robot soared (Wright, 2013).

Meta-analyses, systematic reviews, and other large-scale studies failed to establish a consistent pattern of improved long-term efficacy of robotic surgery compared to open surgery and laparoscopy, especially in light of the additional cost. These analyses include:

- <u>Cholecystectomy for benign diseases</u>. A systematic review/meta-analysis of 26 studies (only five randomized and controlled) including 4,004 subjects compared results of laparoscopic (n = 2,171) and robot-assisted (n = 1,833) cholecystectomy. No significant differences were observed between groups for intraoperative/postoperative complications, readmission rate, average hospital stay, estimated blood loss, and conversion rates. Robotic-assisted procedures had longer operative time (average 12 minutes), and a higher rate of incisional hernia; the authors concluded robotic gallbladder surgery was no more effective or safe, and laparoscopy is preferred due to lower cost (Han, 2018).
- <u>Cholecystectomy</u>. A review of 13 studies (n = 1,010) who underwent laparoscopic cholecystectomy with robotics for benign gallbladder disease found outcomes similar to laparoscopic procedures without using robotics, in terms of postoperative complications, increased operative time, and and incidence of port site hernia (Migliore, 2018).
- <u>Surgery for upper tract urothelial carcinoma</u>. A total of 3,801 persons undergoing surgery for upper tract urothelial carcinoma by open surgery (n = 1,862), laparoscopy (n = 1,624), or robotic surgery (n = 315) determined robotic surgery was associated with shorter hospital length of stay (P < .001), but highest in-hospital charges (P < .001). There were no differences between groups in readmission rates, overall survival, or cancer-specific survival (Clements, 2018).
- <u>Total hip arthroplasty</u>. In a systematic review/meta-analysis of 1,516 patients undergoing total hip arthroplasty, a comparison was made between 522 robotic-assisted procedures and 994 with conventional surgical methods. Subjects in the robotic category had (insignificantly) longer surgical time, lower complication rates (*P* < .0001), better cup placement, stem placement and global offset, and more heterotopic ossifications. Functional scores, limb length discrepancy, and rates of revision and stress shielding were similar (Chen, 2018).
- <u>Colorectal surgery</u>. A review of colorectal surgery compared 14,770 laparoscopic patients and 1,477 robotic-assisted patients. Robotic-assisted patients had significantly lower conversion rates to laparotomy (2.4 versus 3.4 percent, *P* = .04) and lower length of stay (4.5 versus 5.1 days, *P* < .0001) (Harr, 2018).
- <u>Colorectal cancer surgery</u>. A meta-analysis of 24 studies (only two randomly controlled) with 3,318 patients undergoing colorectal cancer surgery compared the laparoscopic (n = 1,852) and robotic (n = 1,466) approaches. Robotic-assisted patients had lower conversion rates, estimated blood loss, and average hospital stay, while operation times, complication rates, oncological accuracy of resection, and total costs were similar (Zhang, 2016).

- <u>Colorectal cancer surgery</u>. A systematic review/meta-analysis of 73 studies (n = 169,236), six of which were randomized and controlled, showed robotic surgery, compared to conventional laparoscopic surgery, to be significantly better in conversion to open surgery, all-cause mortality, shorter average hospital stay, time to oral diet (all *P* < .001), and lesser intraoperative blood loss (P < .01), despite having longer average operative time (*P* < 0.001). However, authors pointed to the need for more adequately powered randomized controlled trials before drawing firm conclusion (Ng, 2019).
- <u>Resection of liver tumors</u>. A non-systematic review of many articles on hepatectomy in resection of liver tumors supported laparoscopic surgery over open surgery, but determined that evidence comparing laparoscopic surgery to robotic-assisted surgery was unclear, leaving laparoscopy as the best option (Rodrigues, 2017).
- <u>Hepatectomy for liver neoplasms</u>. A meta-analysis of 17 studies assessed outcomes for patients undergoing hepatectomy for liver cancers: 902 were laparoscopic procedures and 487 were robotic-assisted procedures. Robotic-assisted procedures had more estimated blood loss, longer operative time, and longer time to first nutritional intake (*P* < .05). Robotic-assisted procedures were also more costly, while no significant differences were observed in length of stay, conversion rate during the operation, complications, and mortality (Hu, 2017).
- <u>Rectal cancer surgery</u>. A meta-analysis of seven studies (n = 1,074) reviewed outcomes for patients with rectal cancer, either by open surgery or robotic-assisted surgery. Robotic-assisted subjects had significantly superior outcomes for mean estimated blood loss (*P* < .00001), shorter hospital stay (*P* = .003), lower intraoperative transfusion requirements (*P* = .05), shorter time to flatus passage (*P* < .00001), and shorter time to resume a normal diet (*P* = .04). However, robotic-assisted subjects had a longer average operative time, and no differences were observed between groups in surgery-related complications, oncologic clearance, disease-free survival, and overall survival (Liao, 2016).
- <u>Thoracic surgery for lung resection</u>. A systematic review of 20 articles compared two techniques (robotic-assisted and video-assisted) for lung resection. The robotic-assisted group had longer average operative time and higher costs, but lower rates of prolonged air leak and average length of stay. No difference was observed for rate of conversion to thoracotomy (Agzarian, 2016).
- Lobectomy for lung cancer. A meta-analysis of 14 studies (n = 7,438) compared robotic-assisted (n = 3,239) and video-assisted (n = 4,199) approaches to radical lung cancer resection. Robotic-assisted subjects showed significantly lower 30 day mortality (0.7 versus 1.1 percent, P =.045) and conversion rate to open surgery (10.3 versus 11.9 percent, P <.001). No differences were observed between groups in postoperative complications, operation time, hospital stay, days to tube removal, retrieved lymph node, and retrieved lymph node station (Liang, 2017).
- <u>Lung cancer surgery</u>. A systematic review and meta-analysis of thoracic surgery for patients with lung cancer included five articles (n = 2,433) of robotic surgery and open surgery. The robotic group

had significantly lower perioperative morbidity and mortality rates (P < .01 for morbidity, P = .007 for mortality) (Zhang, 2015).

- <u>Coronary artery bypass surgery</u>. A systematic review of 44 studies compared outcomes for roboticassisted coronary artery bypass graft and endoscopic coronary artery bypass surgeries. Authors concluded that despite lower perioperative mortality for the robotic group (1.0 percent versus 1.7 percent); evidence is limited by lack of randomized controlled trials and standard definitions of techniques and complications (Cao, 2016).
- <u>Hysterectomy</u>. A meta-analysis by researchers at the Geisel School of Medicine at Dartmouth College found no difference in complications, length of stay, operating time, conversions to laparotomy, and blood loss between robotic versus laparoscopic hysterectomies, leading to the conclusion that robotic surgery's role in benign gynecological surgery "remains unclear" (Albright, 2016).
- <u>Gynecological surgery</u>. A Cochrane review of 12 randomized controlled trials (n = 1,016) compared outcomes for robotic surgery versus both open and laparoscopic surgery, for benign and malignant gynecologic procedures. Eight studies involved hysterectomy, and three studies addressed sacrocolpopexy No judgement could be made for malignancies, due to lack of survival data. For benign conditions, data quality was limited, but did suggest intraoperative and postoperative complication rates were comparable between robotic and conventional laparoscopic surgery (Lawrie, 2019).
- <u>Tongue reduction</u>. In patients affected by sleep apnea undergoing tongue reduction, failure rates of trans-oral robotic surgery and coblation tongue surgery were not significantly different (34.4 percent and 38.5 percent). However, complication rates were significantly higher in the robotic-assisted group (21.3 percent versus 8.4 percent) (Camaroto, 2016).
- <u>Various procedures</u>. A large meta-analysis (99 articles, n = 14,448) comparing outcomes for robotic versus minimally invasive surgery for various types of procedures documented robotic groups had reduced blood loss, and a lower transfusion rate. However, robotic groups had similar average length of stay and 30-day complication rates, and a higher average operative time. The report noted that many studies suffered from high risk of bias and inadequate statistical power (Tan, 2016).
- <u>Sacrocolpopexy</u>. Systematic review/meta-analysis of sacrocolpopexy (treating prolapse of the apical segment of the vagina) compared results for patients undergoing laparoscopy versus open surgery versus robotic. In nine studies of 1,157 subjects, no difference was found in anatomical outcomes, mortality, average length of stay, and postoperative quality of life. However, the robotic-assisted subjects experienced higher postoperative pain and longer operating times (DeGouveia, 2016).

- <u>Prostatectomy</u>. A Cochrane review of two randomized controlled trials (n = 446) assessed performance of open, laparoscopic, and robotic-assisted methods of prostatectomy. No differences were observed in urinary and sexual quality of life, or in overall surgical or serious postoperative complications. (Ilic, 2017).
- Radical prostatectomy for prostate cancer. A systematic review/meta-analysis of 78 studies on radical prostatectomy for men with cancer showed robotic surgery patients had a longer operative time (P < .001) than those undergoing retropubic surgery. Those in the robotic-assisted group had less intraoperative blood loss (P < .001), lower blood transfusion rates (P < .001), less time to remove catheters (P < .001), shorter hospital stays (P < .001), lower positive surgical margin rates (P < .04), fewer positive lymph nodes (P < .001), fewer complications (P < .001), lower readmission rates (P = .03), and higher three- and 12-month recovery rates (P = .02 and P = .005) (Tang, 2017).
- <u>Prostatectomy</u>. In a review of 24 studies on radical prostatectomy (laparoscopy versus robotic), the robotic-assisted subjects had less blood loss and a lower transfusion rate, along with better functional outcomes but there was no difference in perioperative and oncological outcomes (Huang, 2016).
- <u>Prostatectomy</u>. A meta-analysis of 58 reports (n = 19,064) compared results of robotic and laparoscopic prostatectomy. Robotic prostatectomy had a lower risk of major intra-operative harms (0.4 percent versus 2.9 percent) and lower rate of surgical margins positive for cancer (17.6 percent versus 23.6 percent). No difference was observed between groups in the proportion of men with urinary incontinence at 12 months (Robertson, 2013).
- <u>Pyeloplasty</u>. A meta-analysis of 12 observational studies compared 679 pyeloplasty procedures, with 384 done robotically assisted, 131 by laparoscopy, and 164 by open surgery. Robotic-assisted procedures had significantly lower length of stay, (borderline) significantly lower amounts of blood loss, (borderline) significantly longer operating time, and significantly higher total cost compared to open procedures (Cundy, 2014).
- <u>Cystectomy</u>. A systematic review and meta-analysis of radical cystectomy compared the robotic with the open surgical approach. Four randomized trials (n = 239) were included. No significant differences were observed in 30 90 day postoperative and overall grade 3 5 complications, along with average length of stay and health-related quality of life (Lauridsen, 2017).
- <u>Cystectomy</u>. A systematic review/meta-analysis of 24 articles (n = 2,104) compared cystectomy using open radical, laparoscopic radical, and robot-assisted radical methods. Robot-assisted patients had a longer operative time versus laparoscopy with no statistical difference between length of stay and estimated blood loss. Robot-assisted patients had a significantly shorter length of stay, reduced estimated blood loss, lower complication rate, and longer operative time compared to open surgery. There were no significant differences regarding lymph node yield and positive surgical margins (Fonseka, 2015).

- <u>Cystectomy for bladder cancer</u>. A Cochrane study of five randomized trials (n = 541) compared outcomes after robotically assisted surgery and open surgery. The two groups were similar after five years in terms of time to recurrence, major complications, quality of life, and positive margin rates. Robotic surgery had substantially fewer transfusions and slightly shorter hospital stays (Rai, 2019).
- <u>Bariatric surgery</u>. A systematic review/meta-analysis found no significant differences between bariatric surgery performed by robots or laparoscopy, covering postoperative complications, major complications, average length of stay, reoperation, conversion, and mortality. Anastomotic leak rates were lower in the robotic group. Hospital costs were higher in the robotic group (Li, 2016).
- <u>Roux-en-Y gastric bypass</u>. A systematic review/meta-analysis of 19 studies of patients with morbid obesity (n = 276,732) compared outcomes after open, laparoscopic, and robotic gastric bypass procedures. The two less invasive procedures were superior to the open approach for 30-day mortality complications, surgical site infections, and pulmonary complications. No differences between laparoscopic and robotic outcomes were cited (Aiolfi, 2019).
- <u>Pancreatectomy</u>. A meta-analysis of seven nonrandomized trials (n = 568) compared pancreatectomy by robotic and laparoscopic surgery. Robotic surgery was associated with longer operating time, but also lower estimated blood loss, higher spleen-preservation rate, and shorter hospital stays. No differences were detected between the two groups in rates of transfusion, conversion to open surgery, complications, and pancreatic fistula, along with intensive care stay, costs, and 30-day mortality (Zhou, 2016).
- <u>Myomectomy</u>. A systematic review/meta-analysis compared outcomes of robotic, laparoscopic, and open surgical techniques in 17 studies (n = 2,027) of removal of uterine myomas. In the nine studies comparing robotic and open surgeries, robotic procedures had higher operative time, but lower estimated blood loss, need for transfusion, complications, and length of stay. In the eight studies comparing robotic and laparoscopic surgery, no significant differences were found (lavazzo, 2016).
- <u>Thyroidectomy</u>. An analysis of 18 studies of 4,878 patients undergoing thyroidectomy, comparing the conventional (open) approach versus endoscopic versus robotic documented a similar risk of post-operative complications, but a longer operative time (mean difference 43.5 minutes) for robotic-assisted surgery procedures than conventional surgery (Kandil, 2016).
- <u>Thyroidectomy</u>. A systematic review/meta-analysis of 10 studies of thyroidectomy (n = 2,205) compared 752 patients whose surgery used the robotic technique and 1,453 who had open thyroidectomy. Patients with robotic surgery had significantly fewer average central lymph nodes

retrieved during neck dissection (4.7 versus 5.5, P < .001) and higher pre-ablation stimulated thyroglobulin level (3.6 versus 2.0 ng/mL, P = .033) (Lang, 2015).

- <u>Thyroidectomy</u>. A systematic review/meta-analysis of nine studies (n = 2,881) of thyroidectomy compared 1,122 robotic procedures with open and laparoscopic approaches. Robotic surgery patients had greater cosmetic satisfaction, longer operative time (versus open surgery), and shorter operative time than laparoscopic approaches. Robotic surgery had similar risks to other approaches (Jackson, 2014).
- <u>Gastrectomy</u>. A meta-analysis comparing laparoscopic and robotic gastrectomy for stomach cancer included eight studies (n = 1,875). Robotic patients had significantly longer operative time, lower estimated blood loss, and a longer average distal margin, each P <.05. No significant differences were observed between the groups for complications, hospital stay, proximal margin, and harvested lymph nodes (Shen, 2014).
- <u>Endometrial cancer surgery</u>. A review (Ind, 2017) compared robotic with standard laparoscopy for treatment of endometrial cancer. Thirty-six papers including 33 retrospective studies, two matched case-control studies, and one randomized controlled study were used in the meta-analysis.
 Information from a further seven registry/database studies were assessed descriptively. There were no differences in the duration of surgery but an average of 0.46 days fewer spent in the hospital were observed in the robotic arm than with standard laparoscopy. A robotic approach had less blood loss (57.74 milliliters), less conversions to laparotomy (relative risk, and less overall complications (0.82). The authors cited the robotic approach for treatment of endometrial cancer has favorable clinical outcomes.

Some articles have analyzed additional costs for treating patients with robotic assisted surgery. As mentioned, average incremental costs per procedure are estimated at \$3,000 to \$6,000 (Wilensky, 2016). Trials of sacrocolpopexy, in addition to finding robotic procedures had longer time in the operating room and caused more pain than laparoscopic surgery, calculated that average cost per patients was nearly twice as high for robotic surgery when cost of purchase and maintenance was factored in, i.e. \$19,616 versus \$11,573 (Callewaert, 2016). A study of 10,347 U.S. women diagnosed with uterine cancer from who underwent hysterectomies from 2008-2012 found that robotic surgery had higher median charges than laparoscopic surgery, i.e. \$38,161 versus \$31,476 (Zakhari, 2015). A systematic review of 13 studies of surgery for localized prostate cancer support the cost effectiveness of radical prostatectomy over other approaches (including robotic-assisted surgery), based on limited evidence (Becerra, 2016).

Policy Updates:

A total of two guideline/other and five peer-reviewed references were added to, and five guidelines/other removed from this policy in August, 2019.

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Centers for Medicare & Medicaid Services National Coverage Determination

No National Coverage Determinations found as of the writing of this policy.

Local Coverage Determinations

No Local Coverage Determinations found as of the writing of this policy.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

CPT Code	Description	Comment
S2900	Surgical techniques requiring use of robotic surgical system (list separately in addition to code for primary procedure)	NOT FOR USE WITH MEDICARE CLAIMS

ICD-10 Code	Description	Comment
	Diagnoses not specified	

HCPCS Level II	Description	Comment
N/A		

Appendix

No additional information was identified for this section during the writing of this policy.