ROBOTIC–ASSISTED SURGERY

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INSTRUCTIONS FOR USE
This protocol provides assistance in interpreting UnitedHealthcare benefit plans. When deciding
coverage, the enrollee specific document must be referenced. The terms of an enrollee's document
(e.g., Certificate of Coverage (COC) or Evidence of Coverage (EOC) may differ greatly. In the event
of a conflict, the enrollee's specific benefit document supersedes this protocol. All reviewers must first
identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage
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do not constitute the practice of medicine or medical advice.

COMMERCIAL, MEDICARE & MEDICAID COVERAGE RATIONALE

Robotic-assisted surgery may be used in the following:
• Cardiovascular
• Gastroenterology
• Gynecology
• Neurosurgery
• Ophthalmology
• Otolaryngology (ear-nose-throat [ENT])
• Orthopedic
• Radiosurgery/radiotherapy
• Surgical oncology
• Urology (e.g., prostatectomy)
This list may not be all inclusive.

**Additional Information**
Robotic-assisted surgery is considered equivalent to, but not superior to, a standard minimally invasive surgical approach, where the standard minimally invasive surgical approach is itself supported by clinical evidence. It is a method of performing the procedure and not a separate service, therefore Health Plan of Nevada/Sierra Health and Life does not provide additional payment regardless of the instruments or techniques utilized in the procedure.

Medicare does not have a National Coverage Determination or a Local Coverage Determination for Nevada for Robotic-Assisted Surgery. (Accessed July 2017)

**For Medicare and Medicaid Determinations Related to States Outside of Nevada:**
Please review Local Coverage Determinations that apply to other states outside of Nevada. [http://www.cms.hhs.gov/mcd/search](http://www.cms.hhs.gov/mcd/search)

**Important Note:** Please also review local carrier Web sites in addition to the Medicare Coverage database on the Centers for Medicare and Medicaid Services’ Website.

**BENEFIT CONSIDERATIONS**

For purposes of benefit administration, robotic-assisted surgery is considered equivalent to but not superior to non-robotic surgery. It is considered to be integral to the procedure and not a separate service. The member-specific document should always be reviewed for applicable benefits, limitations, and/or exclusions.

**BACKGROUND**

This policy describes the clinical use of robotic technology for minimally invasive and endoscopic procedures in cardiac, general, gastrointestinal, gynecologic, orthopedic, pediatric, thoracic and urological surgeries. Robotic-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. Robotic-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 (Hayes 2008).

**CLINICAL EVIDENCE**

**General and Gastrointestinal Surgery**
Since the FDA approved the da Vinci surgical system for applications in general laparoscopic surgery in 2000 virtually all gastrointestinal operations have been accomplished using robotic techniques (Ayav 2004; Ballantyne 2007; Bodner 2005; Cadiere 2001a; Corcione 2005; D'Annibale 2006; Giulianotti 2003; Ruurda 2005; Talamini 2003). Randomized controlled trials (RCTs), nonrandomized comparative studies and case series have documented the feasibility, safety and short-term efficacy of
robotic cholecystectomy, fundoplication, Heller myotomy, gastric bypass, pancreatectomy, gastrectomy, colectomy, rectopexy, and splenectomy. The procedures were accomplished with low rates of conversion to laparoscopic operations, mortality, and morbidity. When comparison groups were available, the analysis showed that robotic-assisted operations required more time than the laparoscopic operations, although for robotic-assisted cholecystectomy and fundoplication, this difference disappeared in 10 to 20 operations. Only laparoscopic gastric bypass surgeries were completed faster when a robotic surgical system was used particularly in patients with the highest BMI. Further experience is needed to understand the long-term advantages and disadvantages of the totally robotic approach. Specific patient advantages were not identified for robotic-assisted operations compared with laparoscopic operations, except for a decreased esophageal perforation rate during telerobotic Heller myotomy. Robotic surgical systems offer distinct advantages to surgeons and may facilitate an increase in the number of surgeons performing advanced laparoscopic gastrointestinal operations.

**Cholecystectomy**

A literature search revealed one RCT and four nonrandomized controlled studies that compared robotic-assisted laparoscopic cholecystectomy (n=10 to 26) and conventional laparoscopic cholecystectomy. Three studies used the Zeus system (Zhou 2006; Kornprat 2006; Nio 2004) and two used the da Vinci system (Heemskerk 2005; Ruurda 2003). While blood loss, intraoperative complications and length of hospital stay were similar, all studies reported either an increase in the total operating time or at least in the set-up phase for robotic-assisted laparoscopic cholecystectomy. Kornprat et al. (2006) concluded that due to the time loss in several phases of surgery there is no incremental benefit in using the robot in laparoscopic cholecystectomy. Zhou et al. (2006) reported that the rate of operative error was less with the robotic system (10% versus 25%). Long-term follow-up was only available from an uncontrolled case series involving the first 23 robotic-assisted laparoscopic cholecystectomies performed at one institution. At a median follow-up of 33 months Bodner et al. (2005b) found that results after robotic-assisted laparoscopic cholecystectomy were excellent and comparable to those for conventional laparoscopic cholecystectomy.

In a systematic review comparing robot assistants with human assistants for laparoscopic cholecystectomy, Cochrane included five randomized clinical trials including 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. 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 (Gurusamy 2009).

**Fundoplication**

A literature search revealed six small RCTs, and one nonrandomized controlled study comparing robotic-assisted laparoscopic fundoplication (n=9 to 25) to conventional laparoscopic fundoplication in
patients with gastro-esophageal reflux disease (Cadiere 2001b; Melvin 2002; Morino 2006; Nakadi 2006; Draaisma 2006; Mueller-Stich 2007; Heemskerk 2007a). These studies reported no significant differences in morbidity, complications, hospital lengths of stay, and short-term clinical, endoscopic and functional outcomes between robotic-assisted and conventional laparoscopic fundoplication. Four RCT and the nonrandomized controlled study reported longer operative times with the robotic procedure and concluded that, although robot-assisted surgery appears safe, this approach offers no obvious benefits over the standard laparoscopic approach but is associated with higher costs. Only one study (Mueller-Stich 2007) reported shorter operating times when the robot was used. The experience level of the surgical team was not reported.

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.

**Heller Myotomy**

Horgan et al. (2005) retrospectively compared perioperative data and short-term follow-up data from 59 achalasia patients who underwent robotic assisted Heller myotomy to 62 patients who were treated with standard laparoscopic Heller myotomy at three institutions. Operative time was significantly shorter for the standard laparoscopic approach in the first half of the experience. However, in the last 30 cases there was no difference in operative time between the groups. This study suggests that robotic-assisted myotomy is safer than standard laparoscopic procedure because it decreased the incidence of esophageal perforation from 16% to 0%, even in patients who had previous treatment. The authors concluded that additional randomized controlled studies with long-term follow-up are necessary to confirm these results.

**Bariatric Surgery**

Mohr et al. (2005) conducted a retrospective case study comparing the first 10 patients who underwent a totally robotic laparoscopic Roux-en Y gastric bypass to a retrospective sample of 10 patients who had undergone laparoscopic Roux-en Y gastric bypass surgery. The median surgical times were significantly lower for the robotic procedures. Researchers from the same institution also conducted a RCT to compare a single surgeon's results using the da Vinci system (n=25) with those using traditional laparoscopic Roux-en Y gastric bypass surgery (n=25) when the techniques were learned simultaneously. The mean operating time was again significantly shorter for the robotic procedures. The largest difference was in patients with a BMI >43 kg/m² (Sanchez 2005). The authors concluded that these studies demonstrated the feasibility, safety, and potential superiority of robotic laparoscopic Roux-en Y gastric bypass. In addition, the learning curve may be significantly shorter with the robotic procedure. Further experience is needed to understand the long-term advantages and disadvantages of the totally robotic approach.
Sudan et al. (2007) evaluated the safety, feasibility and reproducibility of robotic-assisted biliopancreatic diversion with duodenal switch (BPD/DS) in 47 patients with a mean body mass index (BMI) of 45 kg/m². The operating time decreased for the last 10 procedures. Three patients underwent conversion to open surgery, and four patients experienced postoperative leaks with no mortality. No control group was available in this study.

**Gastrectomy**

Patriti et al. (2008) enrolled thirteen patients with gastric cancer (n=6 stage I, n=6 stage II and n=1 stage III) in a prospective study to assess feasibility and safety of the Da Vinci surgical system in total and partial gastrectomy with extended lymph node dissection. Outcome measures were conversion rate, intra- and postoperative morbidity and mortality, operative time, blood loss, number of lymph nodes harvested and macroscopic and microscopic evaluation of resection margins. Eight distal, four total, and one proximal laparoscopic gastrectomies were completed without conversion. Extended lymph node dissection, and esophagojejunal and esophagogastric anastomoses were successfully carried out using the da Vinci System. Mean operative time was 286 +/- 32.6 min and blood loss was 103 +/- 87.5 ml. Mean number of nodes retrieved was 28.1 +/- 8.3 and all resection margins were negative. There was no mortality. Trocar bleeding requiring laparoscopy was the only major complication encountered. No recurrence occurred during a mean follow-up time of 12.2 +/- 4.5 months. Robot-assisted laparoscopic lymph node dissection and esophageal anastomosis are feasible and safe; however, longer follow-up time and randomized studies are needed to evaluate long-term outcome and clinical advantages of this new technology.

Kakeji et al. (2006) compared the da Vinci and the Zeus system with the aim of evaluating operative feasibility and technical efficacy in distal gastrectomy. During laparoscopic gastrectomy, the da Vinci System (n = 2) had a shorter total operative time and less blood loss compared with the Zeus System (n = 3). Giulianotti (2003) retrospectively compared 21 patients receiving robotic-assisted gastrectomy (either total or subtotal) with 91 patients receiving conventional open gastrectomy. Mean operative times were longer for both robotic groups with little difference in length of stay.

**Pancreatectomy**

Giulianotti (2003) retrospectively compared 13 patients receiving robotic-assisted pancreatic surgery (pancreatoduodenectomy and left pancreatectomy) with 67 patients receiving open pancreatic surgery. Mean operative times were longer for robotic surgery but length of stay was similar in both groups. Complication rate was 31% in both groups.

**Colectomy**

Four nonrandomized studies including a total of 96 robotic-assisted colectomies demonstrated the feasibility and safety of this approach. The studies reported longer operating room time primarily due to the longer set-up time for the robot and higher costs associated with the use of the robotic surgical system. No significant differences were observed between the robotic-assisted and conventional laparoscopic colectomy in terms of conversion to open surgery, intraoperative complications, recovery of bowel function and postoperative hospital stay (Rawlings 2007; D'Annibale 2004; Delaney 2003; Woeste 2005).
Rectopecty
Heemskerk et al. (2007b) compared the outcomes of their first 14 cases of robot-assisted laparoscopic rectopecty with 19 patients who underwent conventional laparoscopic rectopecty in the same period. They found that robot-assisted approach did not show more complications. However, the average operating time was 39 minutes longer, and robotic surgery had a higher cost.

Splenectomy
Bodner et al. (2005c) compared an initial series of six robotic-assisted splenectomies with a series of six conventional laparoscopic procedures performed by a single surgeon. Overall operating time was longer for the robotic group. No complications occurred. There were no open conversions. The median postoperative hospital stay was similar in both groups. The authors concluded that the da Vinci, robotic system offered, at this stage, no relevant benefit and thus was not justified.

Incisional Hernia Repair
Tayar et al. (2007) conducted a pilot study including 11 robotic-assisted (da Vinci) laparoscopic incisional hernia repairs and concluded that this technique is feasible and may not be associated with chronic postoperative pain.

Professional Societies
Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)
In a consensus document on robotic surgery, SAGES states that, with present technology, robotic surgery is best suited to procedures limited to one quadrant of the abdomen that present challenging access: specifically those requiring fine dissection, micro-suturing or reconstruction. Procedures addressed include cholecystectomy, Heller myotomy, paraesophageal hernia repair, gastric bypass, gastric resection for neoplasm, biliary reconstructive surgery, transhiatal esophagectomy, transthoracic esophageal surgery, distal pancreatectomy with splenic preservation, selected colorectal procedures and solid organ surgery, such as adrenalectomy. Robotic surgery may hold promise for pancreatic head resection and hepatectomy, but experience to date is limited. In resections for neoplasm, robotic surgery may help to enhance the completeness of lymph node dissection (SAGES 2007).

Gynecology
Hysterectomy
A controlled study conducted by Payne and Dauterive (2008) retrospectively compared outcomes of 100 women who underwent laparoscopic hysterectomy and 100 who underwent robotically assisted hysterectomy. Mean patient age was 43 years and there were no significant differences between the robotic and laparoscopic groups in mean age, mean body mass index, mean uterine weight, or ethnic origin. Approximately half of the women underwent hysterectomy for myomas, and other indications included endometriosis, ovarian cysts, dysmenorrhea, and dyspareunia. Mean skin-to-skin operative time was 119 minutes for the robotic group versus 92 minutes for the laparoscopic group, a significant difference; however, this result seems to reflect a learning-curve effect, since the mean skin-to-skin operative time was 99 minutes for the last 50 robotic procedures. Exploratory laparotomy or conversion to laparotomy was necessary for 20 (20%) Laparoscopic Group patients versus 4 (4%) Robotic Group patients. Robotically assisted surgery was also associated with statistically significant decreases in mean blood loss (61 versus 113 mL) and mean hospital length of stay (1.1 versus 1.6 days).
Magrina et al. (2008) performed a case-matched controlled trial to evaluate robotically assisted radical hysterectomy (n=27) versus laparoscopic hysterectomy (n=31) and versus open abdominal hysterectomy (n=35) for cervical or uterine cancer. Patients were matched based on age, body mass index, cancer type, and cancer stage. Mean operating time was significantly longer for the Laparoscopic Group (220 versus 190 minutes for the Robotic Group, and 167 minutes for the Open Group). In contrast, estimated mean blood loss was greater for the Open Group (444 versus 133 mL for the Robotic Group, and 208 mL for the Laparoscopic Group). Likewise, mean hospital stay was longer for the Open Group (3.6 versus 1.7 days for the Robotic Group, and 2.4 days for the Laparoscopic Group). Compared with the Laparoscopic Group, the Robotic Group had significantly lower mean blood loss and mean hospital stays. There were no significant differences between the treatment groups in complications, and none of the robotic or laparoscopic procedures required conversion to open surgery. At a mean of 31 months follow-up, no patients had recurrence of cervical cancer.

A nonrandomized controlled study by Nezhat et al. (2008) prospectively evaluated robotically assisted hysterectomy (n=13) versus laparoscopic hysterectomy (n=30) for women who had early cervical cancer. Mean patient age was 55 years for the robotic group versus 47 years for the laparoscopic group, but there were no significant differences between the groups in age, tumor histology, tumor stage, nodal status, or lymphovascular space involvement. With regard to outcomes, no significant differences were seen between the robotic group and the laparoscopic group in operative time, blood loss, complications, or hospital stays, and no procedures required conversion to laparotomy. After a mean follow-up of 12 months for the robotic group and 29 months for the laparoscopic group, no patients had cancer recurrence.

Results of the available studies provide preliminary evidence that robotically assisted hysterectomy provides significant clinical benefits compared with open abdominal hysterectomy; however, the benefits that robotically assisted hysterectomy provides may be essentially identical to those provided by laparoscopic hysterectomy. Additional well-designed studies are needed to compare robotically assisted hysterectomy with laparoscopic hysterectomy and with vaginal hysterectomy to determine whether one of these procedures provides greater benefits to patients (Hayes 2008d).

**Cancer Staging**

Bell et al. (2008) compared hysterectomy and lymphadenectomy completed via robotic assistance, laparotomy and laparoscopy for endometrial cancer staging with respect to operative and peri-operative outcomes, complications, adequacy of staging and cost. One hundred and ten patients underwent hysterectomy with bilateral salpingo-oophorectomy, pelvic and para-aortic lymphadenectomy for endometrial cancer staging. All cases were performed by a single surgeon, at a single institution (40 robotic, 40 laparotomy, and 30 laparoscopic) and were retrospectively reviewed to compare demographics and peri-operative variables including, operative time, estimated blood loss, lymph node count, hospital stay, complications and return to normal activity. Patients undergoing robotic assisted hysterectomy and staging experienced longer operative time than the laparotomy cohort with no difference in comparison to the laparoscopic cohort. Estimated blood loss was significantly reduced for the robotic cohort in comparison to the laparotomy cohort and comparable to laparoscopic cohort. The complication rate was lowest in the robotic cohort (7.5%) relative to the laparotomy (27.5%) and laparoscopic cohorts (20%). Average return to normal activity for the robotic patients was significantly shorter than those undergoing laparotomy and those undergoing laparoscopy. Lymph node retrieval did not differ between the 3 groups.
Reynolds et al. (2005) demonstrated the feasibility of integrating robot-assisted technology in the performance of laparoscopic staging of gynecologic malignancies in seven patients in a retrospective case series analysis. Boggess (2007) compared 13 robotic-assisted radical hysterectomies with bilateral pelvic lymph node dissection with 48 historic abdominal radical hysterectomies. There were significantly more lymph nodes recovered robotically than abdominally, and no increase in operative time. Patients in the robotic group had less blood loss, no need for transfusions or intra-venous pain medication and shorter lengths of stay. In the same article Boggess also compared 43 patients with endometrial cancer staged robotically to 101 patients staged laparoscopically and found again favorable outcomes in the robotic cohort. Sert and Abeler (2007) performed a pilot case-control study to evaluate the feasibility and efficacy of robotic-assisted laparoscopic radical hysterectomy and bilateral pelvic lymph node dissection in 15 patients with early-stage cervical carcinoma in comparison to conventional laparoscopic surgery. Median operation time and hospital stay were shorter in the robotic group and there was less bleeding. The histopathological results concerning the number of lymph nodes, the parametrial tissue and vaginal cuff size were similar in both groups. Although these initial results suggest that robotic surgery for gynecologic cancer has potential advantages including increased lymph node retrieval for optimal staging, these benefits have not yet been established in a prospective randomized study. So far no long-term oncological outcomes have been reported for robotic-assisted surgery. Overall, robotically assisted hysterectomy is still in the early stage of development.

Sacral colpopexy
Geller et al. (2008) conducted a retrospective cohort study comparing robotic sacrocolpopexy (n=73) with abdominal sacrocolpopexy (n=105) for vaginal vault prolapse. The primary outcome was vaginal vault support on 6-week postoperative pelvic organ prolapse quantification (POP-Q) system examination. Secondary outcomes included blood loss, operative time, length of stay, blood transfusion, pulmonary embolus, gastrointestinal or genitourinary tract injury, ileus, bowel obstruction, postoperative fever, pneumonia, wound infection and urinary retention. Robotic sacrocolpopexy demonstrated similar short-term vaginal vault support compared with abdominal sacrocolpopexy, with longer operative time, less blood loss and shorter length of stay. There were no differences in other secondary outcomes. Long-term data are needed to assess the durability of this new minimally invasive procedure.

Elliott et al. (2006) performed 30 robotic-assisted sacrocolpopexy procedures. Twelve months follow-up data were available for 21 patients. Recurrent grade 3 rectocele developed in one patient, one had recurrent vault prolapse and two had vaginal extrusion of mesh. All patients were satisfied with the outcome. Daneshgari et al. (2006) attempted robotic-assisted sacrocolpopexy in 15 women with advanced pelvic organ prolapse. One patient required conversion to laparoscopic sacrocolpopexy, one to an open procedure and one to transvaginal repair. Seven patients had concurrent placement of a mid-urethral sling and one patient had a concurrent Burch colposuspension. Since both studies had no comparison group no conclusions regarding safety and efficacy compared to conventional laparoscopic surgery can be drawn.

Repair of Vesicovaginal Fistula
Sundaram et al. (2006) reported the initial experience with robotic repair of vesicovaginal fistula in 5 patients. Fistula repair was successful in all cases. At 6 months of follow-up, these patients continued to void normally without any recurrence of the vesicovaginal fistula. While the early experience
utilizing robotic repairs in urogynecology is encouraging, long-term data from controlled studies are needed to confirm these findings and establish longevity of the repair.

**Tubal Anastomosis**

One institution published several case series with overlapping patient populations. The most recent publication by Rodgers et al. (2007) reported outcomes of a retrospective case-control study that compared tubal anastomosis by robotic system (n=26) with outpatient minilaparotomy (n=41). The robotic technique required significantly prolonged surgical and anesthesia times over outpatient minilaparotomy and was associated with higher costs. Return to normal activity was shorter with the robotic technique. In an earlier study from the same institution Golderberg and Falcone (2003) compared outcomes of laparoscopic microsurgical tubal anastomosis procedures performed with (n=10) or without (n=15) robotic assistance and concluded that robotic assistance increased operative times without an appreciable improvement in patient recovery or clinical outcomes.

**Myomectomy**

In a retrospective matched control study, Nezhat et al. (2009) compared robotic-assisted laparoscopic myomectomy (RALM) (n=15) to standard laparoscopic myomectomy (LM) (n=35). The two groups were matched by age, body mass index, parity, previous abdominopelvic surgery, size, number and location of myomas. Mean surgical time for the RALM was 234 minutes (range 140-445) compared with 203 minutes (range 95-330) for standard LMs. Blood loss, hospitalization time and postoperative complications were not significantly different. The RALM required a significant prolonged surgical time over LM. The authors concluded that RALM does not offer any major advantage over standard laparoscopic myomectomy.

Advincula et al. (2004) attempted 35 robot-assisted laparoscopic myomectomies with a conversion rate of 8.6%. This study demonstrated the feasibility and safety of robotically-assisted myomectomy but did not report long-term clinical outcomes in comparison to conventional procedures. In 2007, Bocca et al. reported the first case of an uncomplicated full term pregnancy after laparoscopic myomectomy with the assistance of the da Vinci robotic system. Overall, robot-assisted laparoscopic myomectomy is a promising new technique that may overcome many of the surgical limitations of conventional laparoscopy. However, more studies are needed to establish indications and outcome of the technique according to the number, size and location of fibroids.

**Professional Societies**

**Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)**

In a consensus document on robotic surgery, SAGES states that robotic surgery has shown promise in hysterectomy for both benign and malignant disease, as well as myomectomy (SAGES 2007).

**American College of Obstetricians and Gynecologists (ACOG)**

The field of robotic surgery is developing rapidly and its use in gynecologic conditions has expanded. Robotic surgery is used in hysterectomies, sacrocolpopexies, myomectomies, adnexal surgeries and staging of malignancies. Although there has been quick acceptance of robotic surgery for gynecological conditions, its use is not currently supported by high-quality patient outcomes, safety or cost data. The majority of studies are retrospective, observational, and non-comparative. applications of this technology (ACOG 2015, Reaffirmed 2017).
Pediatric Surgery

Pediatric surgeons are using robotic surgical systems to assist in a wide variety of pediatric laparoscopic, general, and reconstructive surgical procedures including fundoplication, heminephrectomy, patent ductus arteriosus closure, pyeloplasty, and vascular ring repair. The evidence describing robotic surgery for pediatric applications come primarily from single-center, uncontrolled case series, and small nonrandomized controlled studies that compared robotic surgery with conventional laparoscopic surgery or open surgery. The literature searches did not identify any RCTs. Sample sizes were small, including 15 to 100 patients. Lack of standard procedure protocols, a wide range of surgical experience, differences in outcome definitions, and the extent of robotic assistance per procedure hindered a direct comparison between studies (Hayes 2008b).

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.

Robotic surgery is safe for children, but evidence that it offers better clinical outcomes than conventional open or laparoscopic techniques is lacking. A total of eight case series and five studies comparing robotic surgery with open or conventional laparoscopic surgery were reviewed. A few small studies that focused on rare complex surgical procedures also were reviewed. None of the studies was randomized, and some were retrospective. Overall, results demonstrated that routine robotically-assisted procedures were feasible and safe when performed by surgeons experienced with the technique; however, robotic surgery did not provide superior outcomes, compared with traditional laparoscopic and open surgery. The advantages of robotic systems have best been demonstrated in complex procedures that involve areas that are difficult to access and in procedures in which dissection of delicate, vulnerable, anatomic structures is required (van Haasteren 2009).

Lehnert et al. (2006) prospectively compared the outcomes of 10 patients who had robotic-assisted fundoplication with the outcomes of 10 patients who had conventional laparoscopic surgery. The mean age of the children was 12 years. No conversion to an open operation was necessary, and there were no intraoperative and no postoperative complications up to 14 months after surgery. Total operative time was similar in both groups. In the robotic-assisted group, time for setup was significantly longer but dissection of the hiatal region as the most challenging operative step was accomplished 34% faster in the robotic-assisted group. The authors concluded that the potential benefit in operating time is counterbalanced by the increased complexity of setting up the robotic system.
Lee et al. (2006) retrospectively compared 33 patients who had robotic-assisted laparoscopic pyeloplasty for ureteropelvic junction obstruction with 33 patients who had open surgery. The mean age was 8 years. Mean operative time was significantly less for open surgery. Estimated blood loss was less, length of stay shorter and total narcotic requirements were significantly less in the robotic group. All patients in the open surgery group and 31 in the robotic group had either resolution of hydronephrosis, improvement in drainage, or relief of symptoms.

Franco et al. (2007) compared 15 robotic-assisted pyeloplasties to 12 conventional laparoscopic procedures and found that both procedures produced similar outcomes in pediatric patients. Overall operative times did not vary significantly between the two procedures. The authors concluded that there appeared to be no quantifiable benefits between the two procedures.

In summary, the published evidence is limited to short follow-up time, lack of randomization, different surgical indications, possible differences in robotic surgical technique and systems, potential differences in training. At this time, too little evidence of too low quality is available to determine whether robotic-assisted pediatric surgery is as safe and effective as unassisted laparoscopic surgery or open surgery and whether it provides additional benefits. Further long-term studies are needed to confirm the usefulness of robotics in minimally invasive pediatric surgery.

Definitive patient selection criteria have not been established for robotic-assisted surgery in children. Criteria have to be established for each procedure.

Professional Societies
Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)
In a consensus document on robotic surgery, SAGES states that over 50 different types of abdominal and thoracic procedures have been performed in pediatric patients. Neonates and infants have also undergone robotic procedures safely and with excellent results. In particular, robotic surgery may present advantages for the Kasai procedure, choledochal cyst repair and thoracic tumor excision. It may also be beneficial in abdominal and thoracic procedures requiring reconstruction. The major limitation is the size of the robotic instruments in relation to the pediatric patient (SAGES 2007).

Thoracic Surgery
Thymectomy
Cakar et al. (2007) retrospectively compared surgical and neurologic outcomes of 10 open access thymectomies for myasthenia gravis to outcomes of 9 robotic-assisted thymectomies. Operating times were significantly shorter with the open approach while hospital stay was shorter after robotic-assisted surgery. Authors concluded that the results of this small series favor the robotic approach for extended thymectomy for myasthenia gravis in respect of both surgical and early neurologic outcome. However, prospective randomized trials with longer follow-up periods are required to prove a general validity. Rea et al. (2006) reported outcomes of 33 myasthenia gravis patients who underwent robotic thoracoscopic thymectomy using the da Vinci system. At a mean follow-up of 23.4 months for the first 24 patients the global benefit rate of 91.7%. This study did not include a control group.

Esophageal Tumors
The safety and feasibility of robotic-assisted thoracoscopic esophagectomy including lymph node dissection was evaluated in 3 small (n=6 to 21) uncontrolled studies (Bodne 2005; Kernstine, 2007;
van Hillegersberg 2006). The potential of the da Vinci system, especially for oncologic indications, remains to be proven in future clinical trials.

**Lobectomy**

Park et al. (2006) demonstrated feasibility and safety of robot assistance for video-assisted thoracic surgical lobectomy in 34 patients. Four (12%) patients required conversion to thoracotomy. The authors concluded that the utility and advantages of robotic assistance for video-assisted thoracic surgical lobectomy require further refinement and study of the technique.

In summary, various different thoracoscopic procedures have been shown to be feasible and safe when performed with the robot. Randomized trials with long-term follow-up are required to establish long-term safety and efficacy in comparison to open or conventional endoscopic surgery.

**Urology**

**Pyeloplasty**

Although robotic-assisted procedures may theoretically be more advantageous than conventional laparoscopic ones, few studies have shown clear superiority of robotic-assisted laparoscopic pyeloplasty (RAP) over conventional laparoscopic pyeloplasty (CLP) for ureteropelvic junction obstruction (UPJO). Braga et al. (2009) conducted a systematic review and meta-analysis of eight studies that evaluated the effect of RAP versus CLP for patients with UPJO, focusing on operative time, length of hospital stay, postoperative complications and success rate. Meta-analysis of extractable data showed that RAP was associated with a 10-min operative time reduction and significantly shorter hospital stay compared with CLP. There were no differences between the approaches with regard to complication rates and success.

Nguan et al. (2007) performed 32 dismembered laparoscopic pyeloplasties using three different robotic surgical systems (AESOP=6, Zeus=5; da Vinci =21). The authors found pyeloplasties performed using the da Vinci robotic system resulted in decreased anastomotic and operating times. However, the set-up time was longer for the da Vinci system compared to AESOP.

Schwentner et al. (2007) presented 5-year results of robotically assisted laparoscopic pyeloplasty (RALP) in 92 patients with pelvi-ureteric junction obstruction (PUJO) using the daVinci system. Mean follow-up was 39.1 months; PUJO was successfully resolved in 89 patients (96.7%) while three required additional procedures. Hemorrhage into the collecting system and urine extravasation, occurring early after surgery, were the causes of failure. The mean (range) operative duration, including the set-up of the robot was 108.34 (72-215) min; the mean duration of docking and surgery significantly decreased with experience. The authors found RALP using the daVinci system safe and effective, achieving similar long-term success rates to open surgery. There were no cases of late complications, corroborating the accuracy of robot-assisted intracorporeal suturing and the subsequent quality of the pelvi-ureteric anastomosis. Moreover, the robotic approach was easy and quick to learn for both the surgical and the technical staff. The authors therefore concluded that RALP is a preferred technique to treat PUJO.

**Partial and Radical Nephrectomy**

Hayes identified 5 nonrandomized controlled studies that compared robotically assisted and laparoscopic nephrectomy procedures. Results of these studies provide preliminary evidence that the...
benefits of robotically assisted nephrectomy are equal but not superior to the benefits of laparoscopic nephrectomy. The largest controlled study found that, compared with laparoscopic partial nephrectomy (PN), robotically assisted PN was associated with statistically significant reductions in average procedure time and average hospital length of stay (HLOS); however, the other 4 controlled studies did not confirm these findings except for a statistically significant decrease in HLOS in a single study. Moreover, one of the smaller controlled studies found that average operation time was longer for robotically assisted complete kidney removal. Further studies with long-term patient monitoring are needed to compare robotically assisted nephrectomy with open surgery and to confirm that robotically assisted and laparoscopic nephrectomy provide comparable benefits (Hayes 2009).

Benway et al. (2009) compared robot assisted partial nephrectomy versus laparoscopic partial nephrectomy for renal tumors. 118 consecutive laparoscopic partial nephrectomies and 129 consecutive robot assisted partial nephrectomies performed at 3 academic centers were evaluated using a retrospective chart review. The authors concluded that robot assisted partial nephrectomy provided equivalent early oncological outcomes and comparable morbidity to a traditional laparoscopic approach. Moreover robot assisted partial nephrectomy appears to offer the advantages of decreased hospital stay as well as significantly less intraoperative blood loss and shorter warm ischemia time, the latter of which may help to provide maximal preservation of renal reserve. In addition, operative parameters for robot assisted partial nephrectomy appear to be less affected by tumor complexity compared to laparoscopic partial nephrectomy.

Nazemi et al. (2006) evaluated the perioperative outcomes using a contemporary cohort of 57 patients undergoing radical nephrectomy by 4 different methods (open=18; robotic=6; laparoscopy with hand assistance =21; laparoscopy without hand assistance =12) performed by the same surgeon. While the estimated median blood loss, postoperative narcotic use for pain control, and hospital stay were significantly higher in the open surgery method, the median operative time was significantly shorter compared to the robotic method. Operating room costs were significantly higher in the robotic and laparoscopic groups; however, there was no significant difference in total hospital costs between the 4 groups. A larger cohort and longer follow up are needed to validate these findings and establish oncological outcomes.

**Cystectomy or Cystoprostatectomy with Urinary Diversion**

No RCTs were found. The available literature pertaining to robotic assisted radical cystectomy or cystoprostatectomy consists primarily of small uncontrolled pilot studies and case series. Four small studies (n=7 to 33) provided a comparison to the standard open procedure (Pruthi and Wallen 2007; Wang 2007; Rhee 2006; Galich 2006). In these studies urinary diversion was performed extracorporeally. The mean operating time was longer for robotic cases but decreased with increased experience of the team. Estimated blood loss, transfusion requirements were less for robotic procedures and time to bowel movement, time to resumption of a regular diet and the hospital stay were shorter. Complication rates were comparable. The authors concluded that robotic-assisted radical cystectomy appears to offer some operative and perioperative benefits compared with the open approach without compromising pathological measures of early oncological efficacy, such as lymph node yield and margin status. As their experience increases, they expect to continue to refine the surgical technique and decrease operative time. Larger, randomized studies with long-term follow-up are required to establish oncological equivalence.
Radical Prostatectomy

In a meta-analysis of observational studies, Parsons et al. (2008) compared outcomes of radical retropubic, laparoscopic and robotic-assisted prostatectomy for the treatment of localized prostate cancer. The primary outcomes were operative blood loss, perioperative transfusion, surgical margin status, postoperative urinary incontinence and postoperative erectile dysfunction. Based on established similarities in surgical principles, the investigators combined laparoscopic and robotic-assisted data into a single group. Nineteen studies (n = 3893 patients) met inclusion criteria for this analysis. Compared with those undergoing retropubic prostatectomy, patients undergoing laparoscopic or robotic-assisted prostatectomy experienced less operative blood loss and were 77% less likely to receive a perioperative transfusion. There was no significant difference in overall risk of positive surgical margin. There were also no significant differences in 1-year urinary continence and 1-year erectile function; however, these outcomes were measured using nonvalidated instruments. Further comparative studies using consistent, validated outcomes measures are needed to further assess postoperative urinary continence and potency.

Nine studies, involving 423 patients who underwent robot-assisted LRP, were identified in the literature search; six of these studies involved at least 20 patients and were selected for detailed review. Study design was prospective in seven of the studies, while two studies appeared to be retrospective. Study populations were small in eight studies (1-120 patients) and moderate in one study (300 patients), and appeared to overlap between two studies conducted in Europe and among three studies conducted at one U.S. site. Although all studies were case reports or case series, four studies provided comparison between robot-assisted LRP and standard LRP or open prostatectomy. In the prospective comparisons, treatment randomization was planned but was not accepted by patients; thus, mode of treatment was based on patient preference. The retrospective study compared outcomes of 60 robot-assisted prostatectomy procedures (after a learning curve of 45 procedures) with outcomes of 60 conventional open prostatectomy procedures performed by the same surgeon. Among all reviewed studies, reporting of operative, pathologic, and functional variables was inconsistent, and follow-up was inadequate to determine long-term tumor control or functional outcome with respect to urinary control and sexual potency.

All studies utilized the da Vinci Surgical System for robot-assisted LRP. Data from these studies suggest that, although operating time for robotic LRP may be relatively long among the initial procedures undertaken, it is likely to decrease to approximately 4 hours or less and compare favorably with average operating time for standard LRP after the initial learning curve, and to decrease further thereafter and be similar to average operating time for open prostatectomy. Conversion to open prostatectomy was rarely required in these studies, and most procedures were considered technically successful. Data from the comparative studies indicate that robotic-assisted LRP may be associated with significantly less blood loss and fewer serious complications than standard LRP or open prostatectomy. Additionally, compared with open prostatectomy, robotic-assisted surgery appears to lead to significantly shorter hospitalization in most patients and significantly less postoperative pain. Although incomplete, preliminary data suggest that return to full continence and preoperative level of sexual function may occur earlier after robotic LRP than after standard LRP or open prostatectomy.

Krambeck et al. (2009) assessed the perioperative complications and early oncological results in a comparative study matching open radical retropubic (RRP) and robot-assisted radical prostatectomy (RARP) groups. The investigators identified 294 patients undergoing RARP for clinically localized...
Robotic-assisted surgery for prostate cancer. A comparison RRP group of 588 patients from the same period was matched 2:1 for surgical year, age, preoperative prostate-specific antigen level, clinical stage and biopsy Gleason grade. The authors concluded that there was no significant difference in overall early complication, long-term continence or potency rates between the RARP and RRP techniques. Furthermore, early oncological outcomes were similar.

In a comparative study by Rozet et al. (2007), 133 consecutive patients who underwent extraperitoneal robot assisted radical prostatectomy were compared to 133 match-paired patients treated with a pure extraperitoneal laparoscopic approach. The 2 groups of patients were statistically similar and matched for age, body mass index, previous abdominopelvic surgery, American Society of Anesthesiologists score, prostate specific antigen level, pathological stage and Gleason score. Conversion from robotic assisted laparoscopic prostatectomy to laparoscopic radical prostatectomy was necessary in 4 cases. None of the laparoscopic radical prostatectomy cases required conversion to an open technique. The transfusion rate was 3% and 9.8% for laparoscopic radical prostatectomy and robotic assisted laparoscopic prostatectomy, respectively (p = 0.03). The percentage of major complications was 6.0% vs. 6.8%, respectively (p = 0.80). The overall positive margin rate was 15.8% vs. 19.5% for laparoscopic radical prostatectomy and robotic assisted laparoscopic prostatectomy, respectively (p = 0.43). The authors concluded that laparoscopic extraperitoneal radical prostatectomy is equivalent to the robotic assisted laparoscopic prostatectomy in the hands of skilled laparoscopic urological surgeons with respect to operative time, operative blood loss, hospital stay, length of bladder catheterization and positive margin rate.

As a treatment for prostate cancer, the purpose of prostatectomy is to achieve long-term tumor control. Since long-term follow-up data are not available, no statement can be made regarding how effective robotic-assisted LRP is or how it compares with alternative techniques in achieving this. However, findings indicate that the risk for recurrent or metastatic prostate cancer may be similar for robot-assisted LRP, standard LRP, and open prostatectomy. Data are not available regarding how robotic LRP may compare with radiotherapy or experimental approaches for clinically localized prostate cancer.

Complications reported for robotic-assisted LRP were similar to those associated with standard prostatectomy procedures, and included intraoperative blood loss, transient ileus, postoperative bleeding or thrombosis, wound dehiscence, urinary retention, urinary incontinence and sexual dysfunction. However, there may be some inherent risks specific to telesurgery systems, such as computer system failure, loss of communication between the surgeon and operating theater, or intraoperative complications that require immediate attention. Because of these potential risks, current procedures include safeguards, such as a patient-side surgeon who can take charge and implement procedures to correct problems that may arise. Additionally, telesurgery robotic systems are designed with certain safeguards, including alarms, override mechanisms, and automatic freezing of movement in the event of a power interruption. Other potential safety concerns involve possible delay or loss of data during transmission, particularly if significant distances are involved or multiple networks are involved.

**Donor Nephrectomy**

Renoult et al. (2006) compared the outcome of 13 robotic-assisted laparoscopic donor nephrectomy with those of 13 previous open live-donor nephrectomies. Robotic-assisted nephrectomies were
associated with very low morbidity among donors, in which both the operative and warm ischemia times were of longer duration, but had no observable adverse effects upon short-term graft function. The largest case series was reported by Horgan et al. (2007) who performed 273 robotic-assisted left donor nephrectomies using a hand-assisted technique and provided prospectively collected outcome data for 214 patients. The series included a group of 61 donors with vascular anomalies. The authors concluded that the robotic-assisted laparoscopic technique is safe and effective, even in the presence of vascular anomalies. The operative time and complications decreased significantly after the first 74 cases. The 1-year recipient survival rate was 100%, and the 1-year graft survival rate was 98%.

Adrenalectomy
A literature search identified a randomized controlled trial (Morino 2004), a nonrandomized controlled trial (Brunaud 2004), and an uncontrolled trial (Winter 2006) that evaluated robotically assisted adrenalectomy. Although the reviewed studies were small (n=20 to 33), all of them involved assessments of relevant operative and postoperative outcomes such as complications, conversion to laparoscopic or open surgical procedures, and length of hospital stay. Robotically assisted surgery did not reduce blood loss, postoperative pain, complications, or length of hospital stay. Moreover, the two controlled studies found that robotically assisted adrenalectomy was associated with statistically significant increases of 47% and 67% in mean operative and total intervention times, respectively. Although the third study found a mean decrease in robotically assisted operative time of 2.9 minutes per procedure over the course of 25 procedures performed by a single physician, this study was uncontrolled. Further controlled studies are needed to determine whether robotically assisted adrenalectomy provides any improvements in clinical outcomes compared with standard laparoscopic adrenalectomy.

Professional Societies
Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)
In a consensus document on robotic surgery, SAGES states that robotic surgery has been shown to offer substantial advantages over conventional minimally invasive surgery in several urological procedures. While the most mature outcomes data are for radical prostatectomy, robotics may also offer advantages for cystectomy, pyeloplasty, nephrectomy (partial, complete and donor) and ureteral reimplantation. Resection of bladder neoplasm may also be approached robotically with a lower incidence of postoperative ileus (SAGES 2007).

American Urological Association (AUA)
In the organization’s BLUS Handbook of Laparoscopic and Robotic Fundamentals, the AUA states that laparoscopic prostatectomy with or without robotic assistance has been shown to be equally effective in producing negative surgical margins as radical prostatectomy via an open incision. Laparoscopic and robotic assisted radical prostatectomy are both associated with low morbidity and an expeditious convalescence. As such, both techniques are accepted as standards of care (AUAn.d.).

Cardiac Surgery
Coronary Artery Bypass Graft (CABG)
In 2005, the National Institute for Health and Clinical Excellence (NICE) issued a guidance document on totally endoscopic robotically assisted coronary artery bypass grafting. NICE concluded that the current evidence on the safety and efficacy of TECABG does not appear adequate for this procedure (NICE 2005).
Kappert et al. (2000) evaluated the da Vinci system to perform MIDCAB or TECAB in 109 CAD patients who had single-vessel or multivessel disease. Operative time was longer for TECAB compared with MIDCAB; differences in other outcomes were not reported. Six patients required median sternotomy due to intraoperative complications. In a 2001 study by the same group, short-term outcomes, including survival and graft patency, were very good for 201 patients with single-vessel disease (Kappert 2001).

Falk et al. (2000) used the da Vinci system for CABG performed via median sternotomy (n=12), MIDCAB (n=32), and TECAB (n=22). In the TECAB group there were four conversions to mini-thoracotomy. Postoperative angiography demonstrated graft patency in all patients immediately after surgery.

Mohr et al. (2001) reported on robotic-assisted CABG performed with the da Vinci system (n=131). The first 96 procedures were performed as standard CABG with robotic assistance or as MIDCAB. Afterwards, the authors used the da Vinci system to perform TECAB on 35 patients; of these, 8 were performed on a beating heart. Surgical times were much higher for the endoscopic procedures than for the MIDCAB procedures, and the rate of conversion to mini-thoracotomy or sternotomy was 18.5% for patients undergoing TECAB. The authors noted that the learning curve for total endoscopic CABG was steep, despite previous training on animals and cadavers and the initial use of robotic surgery for the MIDCAB procedures.

Argenziano et al. (2006) conducted a multicenter study of the safety and efficacy of the da Vinci system for TECAB surgery. Ninety-eight patients requiring single-vessel LAD revascularization were enrolled at 12 centers. Thirteen patients (13%) were excluded intraoperatively (e.g., failed femoral cannulation, inadequate working space). Of the 85 patients who underwent TECAB, five were converted to open techniques and one patient required reintervention of the target vessel on the first postoperative day for graft occlusion. Three month angiographic data on 76 patients revealed anastomotic occlusion in two cases and significant anastomotic stenosis in four others. Overall freedom from reintervention or angiographic failure was 91%. No medium or long-term follow-up data were reported.

Katz et al. (2006) assessed a hybrid approach which integrates TECAB surgery in conjunction with percutaneous coronary intervention (PCI) as this technique may become a viable treatment option for patients with multi-vessel CAD. A total of 27 patients requiring double vessel revascularization were treated at 7 centers. Eleven patients underwent PCI before surgery, 12 patients underwent PCI after surgery, and 4 patients underwent simultaneous surgical and percutaneous intervention. Three-month angiographic follow-up demonstrated an overall left internal mammary artery (LIMA) anastomotic patency of 96.3% and PCI vessel patency of 66.7%. There were no deaths or strokes. One patient experienced a perioperative myocardial infarction. Eight of 27 patients (29.6%) required reintervention, 1 LIMA anastomotic stenosis (3.7%), 3 after bare metal stent (30%), and 4 after drug-eluting stent placement (23.5%).

Evidence from primarily uncontrolled studies suggests that robotically assisted coronary artery bypass grafting (CABG) procedures are feasible and relatively safe in the short term in patients with single-vessel coronary artery disease (CAD). However, there are insufficient data to evaluate the long-term outcome of robotic surgery or to conclude that such procedures provide outcomes comparable to those
achieved with conventional open CABG or other minimally invasive procedures (Hayes 2008a).

**Valve Repair or Replacement**

Chitwood et al. (2008) report the largest single-center robotic mitral valve repair experience (n=300) using the daVinci Surgical System. All operations were done with 3- to 4-cm right intercostal access, transthoracic aortic occlusion, and peripheral cardiopulmonary bypass. There were 2 (0.7%) 30-day mortalities and 6 (2.0%) late mortalities. No sternotomy conversions or mitral valve replacements were required. Immediate postrepair echocardiograms showed the following degrees of mitral regurgitation: none/trivial, 294 (98%); mild, 3 (1.0%); moderate, 3 (1.0%); and severe, 0 (0.0%). Complications included 2 (0.7%) strokes, 2 transient ischemic attacks, 3 (1.0%) myocardial infarctions, and 7 (2.3%) reoperations for bleeding. The mean hospital stay was 5.2 +/- 4.2 (standard deviation) days. Sixteen (5.3%) patients required a reoperation. Mean postoperative echocardiographic follow-up at 815 +/- 459 (standard deviation) days demonstrated the following degrees of mitral regurgitation: none/trivial, 192 (68.8%); mild, 66 (23.6%); moderate, 15 (5.4%); and severe, 6 (2.2%). Five-year Kaplan-Meier survival was 96.6% +/- 1.5%, with 93.8% +/- 1.6% freedom from reoperation. The authors concluded that robotic mitral valve repair is safe and is associated with good midterm durability; however, they noted that further long-term follow-up is necessary.

Nifong et al. (2005) enrolled 112 patients who had mitral valve repair with robotic assistance in a phase II multicenter trial. All the patients had moderate to severe mitral valve regurgitation. There were no operative deaths, strokes or device-related complications. Ninety-two percent of patients (103 of 112) achieved mitral valve competence postoperatively. Nine patients had grade 2 mitral regurgitation necessitating reoperation in 6 patients.

Tatooles et al. (2004) performed 25 mitral valve repairs using the da Vinci system as part of a multicenter phase II study. There were no incisional conversions, deaths, strokes, or reoperations for bleeding. Five patients experienced postoperative atrial fibrillation, and two ultimately required mitral valve replacements for recurrent mitral valve insufficiency.

Woo and Nacke (2006) enrolled 64 patients and assigned them to a study group based on the request of the referring physician or the patient. One study group (n=25 patients) had right chest minimally invasive mitral valve repair with robotic assistance using the da Vinci Surgical System, and the other study group (n=39 patients) had sternotomy. While cross-clamp and bypass times were longer for patients in the minimally invasive group, the mean ICU stay and duration of postoperative hospitalization were shorter.

Folliguet et al. (2006) compared 25 mitral valve repair procedures using the da Vinci System (group one) to 25 retrospectively matched repair procedures using medial sternotomy (group two). Valve repair was successful in all patients and there were no deaths. One patient in group one was converted to an extended thoracotomy due to bleeding on the left atrial appendage. Ninety-two percent (23 of 25 in each study group) achieved mitral valve competence postoperatively. Postoperative echocardiography showed mitral regurgitation in two patients in each group.

Murphy et al. (2007) conducted a multicenter retrospective review of 201 patients who underwent lateral "ports only" endoscopic robotic valve surgery. One hundred eighty-six (92.5%) were scheduled for a repair procedure and 15 (7.5%) were scheduled for replacement. The repair was accomplished in
179 of 186 (96.2%) of patients. Eight patients (4.3%) required a conversion to sternotomy incision. One hundred seventy-nine patients (96.2%) had regurgitation grade of 0 to 1 after repair.

The reviewed evidence had several limitations including lack of randomization, short follow-up time, mixed patient population (mitral valve repair and replacement). Only surrogate outcome measures (e.g., operative time, length of ICU stay, length of hospital stay, and mitral valve competence) were reported. No study reported patient functioning, quality of life, and long-term surgical repair survival. Further studies are needed to assess the durability of robotically assisted cardiac valve replacement and to determine whether the safety and efficacy of this procedure equals or exceeds that of other approaches to valve replacement, including conventional open replacement surgery and less invasive methods such as minithoracotomy and port-access techniques (Hayes 2008c; Hayes 2007a).

**Atrial Septal Defect (ASD) Closure**

The evidence on the efficacy and safety of robotically assisted surgery to treat ASD is limited to 4 small case series (n=7 to 22).

Argenziano et al. (2003) published their single-institution experience drawn from two trials submitted to the FDA on the efficacy and safety of the da Vinci system in the closure of ASDs. Although a total of 22 adult patients were enrolled, 5 were excluded intraoperatively because of anatomical obstacles (n=4) or allergic reaction (n=1). The study population consisted of 17 patients (12 patients with ostium-secundum ASD and 5 with PFO). Sixteen of 17 (94.1%) operations were successful. One (5.9%) patient had a recurrent defect that was repaired with a patch via mini-thoracotomy.

A follow-up study by Morgan et al. (2004) compared quality of life (QOL) outcomes in the same patient group as above (n=16; excluding the patient with a recurrent defect) with those for a group of patients who underwent the same operation by traditional mini-thoracotomy (n=17) or sternotomy (n=17) in the same institution. Superiority of QOL was statistically significant in robotic surgery recipients compared with those undergoing mini-thoracotomy or sternotomy in 6 of 8 categories of the SF-36. There was a strong trend toward improvement in general health in the robotic surgery group. There was no significant difference in ICU length of stay (LOS), hospital LOS, or in the time until return to work among the 3 groups. Despite the positive aspects associated with robotic surgery, the inherent deficiencies in study design and sample size make it difficult to draw conclusions based upon these data.

In a series of 17 consecutive patients with ostium secundum ASD (n=14) or patent foramen ovale (n=3) who had either suturing (n=15) or patch (n=2) closure of their defect using the da Vinci system, Bonaros et al. (2006) found a statistically significant learning curves for total operative time, CPB, and aortic occlusion time. The learning curves were steep, such that, according to the authors, experience with more than 10 procedures was necessary to more than halve the procedure time. No such decreases in intubation time, ICU LOS, or total hospital LOS were observed in these cases, and the duration of CPB was not correlated with any of these 3 parameters. In 2004, the same group also published data on their initial experience in implementing robotically assisted totally endoscopic repair of ASD. They recommended a stepwise approach, first gaining experience with traditional minimally invasive techniques (mini-thoracotomy), adapting to peripheral CPB, and gaining experience with other more established robotically assisted surgeries first.
Wimmer-Greinecker et al. (2003) used the da Vinci system to repair ASD defects in 10 consecutive adult patients. Two operations had to be converted to mini-thoracotomies due to failure of the endoaortic balloon clamp. Satisfactory results were reported for the other 8 patients.

Torracca et al. (2002) reported successful results using the da Vinci system in 7 patients with no major intraoperative or postoperative complications.

Overall, the existing evidence base is insufficient to recommend widespread adoption of robotically assisted ASD repair. There is no solid indication of effectiveness compared with traditional surgery; and among the few patients studied there were a number of intraoperative conversions and complications. Additional, well-designed clinical trials are needed to derive more evidence on this technology before definitive conclusions can be drawn (Hayes 2007b).

**Patent Ductus Arteriosus (PDA) Closure**

Le Bret et al. (2002) compared a robotically assisted technique using the ZEUS and AESOP systems in 56 children with PDA. In this study, 28 procedures were performed with videothoracoscopic technique, and 28 were performed with the robotic systems. Operative room time and surgical procedure time for the robotically assisted technique were approximately double that required for the thoracoscopic approach. There were no intraoperative complications, and there were no differences between the two groups in length of time in ICU or hospital length of stay.

Suematsu et al. (2005) reported their initial experience with totally endoscopic robotic-assisted PDA closure (n=9) and vascular ring division (n=6) in children. One patient with vascular ring was converted to thoracotomy because of dense adhesions due to previous surgery. Precise and easy surgical maneuver was possible with the articulated surgical instruments and three-dimensional visualization in 14 patients. Intraoperative transesophageal echocardiography confirmed no persistent shunt in all PDA patients. No laryngeal nerve injury and hemorrhage were noted.

**Professional Societies**

American College of Cardiology/American Heart Association (ACC/AHA)
The ACC/AHA states that robotic CABG has several potential clinical advantages but is still in the developmental stage (Eagle 2004).

The ACC/AHA guidelines for the management of patients with valvular heart disease state that the standard approach for mitral valve replacement or complex repair is use of a median sternotomy with cardiopulmonary bypass; however, many alternative incisions are now used, including partial sternotomy and small right thoracotomy access, strategies described as minimally invasive. Video-assisted and robotic-assisted mitral valve surgery are becoming more feasible, and standard outcomes have been described for small numbers of selected patients undergoing surgery at centers that specialize in these alternative surgical strategies. However, these procedures are not included in current treatment recommendations (Bonow 2006; updated 2008).

**Orthopedic Surgery**

Schulz et al. (2007) reported the results of total hip arthroplasty using the Robodoc surgical assistant system. 143 total hip replacements (128 patients) were performed using the Robodoc system. Complete follow-up was possible in 97 hips at a mean follow-up period of 3.8 years. The authors
concluded that robotic-assisted total hip arthroplasty achieves equal results as compared to a manual technique. However, there was a high number of technical complications directly or indirectly related to the robot.

In a randomized comparative trial, Honl et al. (2003) compared robotic-assisted and traditional open total hip replacement (THR) in 154 patients with a 24-month follow-up period. Although robotic-assisted technology offered advantages in terms of preoperative planning and high accuracy of the intraoperative procedure (limb-length equality and varus-valgus stem orientation), there were several disadvantages: high revision rates, muscle damage leading to higher dislocation rates, high rates of nerve damage, and longer operative durations. Patients treated with robotic assistance had better Mayo clinical scores and Harris Hip Scores (HHS) at 12 months, but by 24 months, there was no difference between robotic-assisted and traditional open surgical patient groups with regard to scores.

Siebert et al. (2002) studied robotic-assisted total knee replacement (TKR) in 69 patients using the CASPAR®. A group of historical controls was used for comparison. Study results suggested that robotic-assisted TKR offered a clear advantage in executing a very precise preoperative plan based on CT scans. Prosthetic components were better aligned in patients who had robotic-assisted TKR surgery compared with the historical controls who had traditional open TKRs. However, robotic assistance required fiducial markers to facilitate orientation, and operating times were longer for the first 70 robotic cases, indicating a steep learning curve.

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.

**Telerobotic Surgery (Telepresence)**

From its inception, the da Vinci Surgical System was engineered to perform telerobotic surgery. In telerobotic surgery, the surgeon is physically and visually separated from the patient, connected only through a three-dimensional video image, which transports the surgeon to a remote operative field. This type of surgery may offer surgical advantages such as improving clinical outcomes for infrequently performed difficult operations and serving as a tool to address the shortage of trained surgeons in medically underserved countries and remote locations. However, the ethical and legal issues of telerobotic surgery remain uncertain and ill defined. The clinician-patient relationship may be disrupted, and the impact of state and international borders on medical licensing and care is unclear (Ballantyne and Moll 2003). Marescaux et al. (2002) described the use of the ZEUS robotic system and a high-speed terrestrial network (ATM) in a laparoscopic cholecystectomy in a case report of 1 patient. In one such case, the patient was located in Strasbourg, France, while the surgeons were based in New York, NY. Study results suggested that remote robot-assisted surgery appears feasible due to an uneventful postoperative course for this sole patient. The patient returned to normal activity within 2 weeks postsurgery.

One of the first telerobotic remote surgical services was designed in Canada. Anvari et al. (2007) created a program in 2003 by which the Zeus system was set up in Hamilton Ontario for the surgeon and the robotic arms were positioned on the patient in North Bay, Ontario - 400 km away. The service
was designed to provide telerobotic surgery and assistance by expert surgeons to local surgeons, and to improve the range and quality of advanced laparoscopic surgeries offered locally. Two surgeons have collaboratively performed 22 remote telepresence surgeries including laparoscopic fundoplications, laparoscopic colon resections, and laparoscopic inguinal hernia repairs. This is currently the largest clinical experience with assisted robotic telepresence surgery.

**Professional Societies**

**Society of American Gastrointestinal Endoscopic Surgeons (SAGES)**

The SAGES guidelines state that remote surgery, at this time, is highly investigational and should not be performed except under IRB approval and by persons thoroughly familiar with the technology. SAGES strongly urge surgeons and hospitals to defer clinical implementation of these modalities until the technology has been validated. It is our opinion that current clinical use of this technology should only be conducted under a protocol reviewed by an institutional committee for the protection of patients and should include the collection of quality assurance and outcomes data. The participants, facilities and telecommunication service vendors involved in these events should coordinate their efforts so that the visual fidelity and telecommunications interface is suitable for the planned activity (SAGES 2004).

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

Approved robotic surgical devices include the da Vinci® Surgical System, the ZEUS® MicroWrist™ Surgical System and the AESOP® Endoscope Positioner. The ZEUS and AESOP products were formerly of Computer Motion Inc., which merged with Intuitive Surgical in 2003.

The FDA has cleared the da Vinci® Surgical System for use in urological surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1 and T2, general thoracoscopic surgical procedures and thoracoscopically assisted cardiomyotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use (except for transoral otolaryngology surgical procedures). See the following website for additional information (use product code NAY).  

The ROBODOC® system was FDA approved on August 6, 2008 for use in total hip arthroplasty procedures. See the following website for additional information.

**Additional Products**

CASPAR® Planning and Robotics, ACROBOT and PROBOT

**APPLICABLE CODES**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined
by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

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