Robotic-Assisted Surgery

Medical Policy

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Description

This policy describes the clinical use of robotic technology for minimally invasive and endoscopic surgical procedures in urology, gynecology, general and gastrointestinal, thoracic and pediatric surgery. Robotic surgery systems use motion scaling, a process that allows the translation of the operator's natural hand movements into extremely exact, micro-movements of a robotic arm, to facilitate precise surgical instrument manipulation. The goal of robotic-assisted surgery is to reduce the morbidity associated with conventional open procedures and to enhance the complexity of surgical techniques in endoscopic minimally invasive procedures.

The following robotic systems are currently used in clinical surgical practice worldwide:

- da Vinci® Surgical System (Intuitive Surgical Inc, Sunnyvale, CA)
- ZEUS® Surgical System and HERMES® Control System (Intuitive Surgical Inc, Sunnyvale, CA)
- AESOP® Endoscope Positioner (Automatic Endoscopic System for Optimal Positioning) (Intuitive Surgical Inc, Sunnyvale, CA), a voice-controlled endoscope with 7 degrees of freedom.
- ROBODOC® and NeuroMate(Integrated Surgical Systems Inc, Sacramento, CA)
Policy

Robotic-assisted surgery is considered equivalent to but not superior to non-robotic surgery or a standard surgical approach. Robotic-assisted surgery is considered **not medically necessary**. When a surgical procedure is performed using robotic-assisted technique, additional professional or technical reimbursement will not be made for the robotic-assisted technique. Payment will be based on the reimbursement for the standard surgical procedure(s). Any additional charges for the robotic assisted surgery will be bundled into the standard surgical procedure. Modifier -22 is not appropriate if the sole purpose for the modifier is due to the use of robotic-assisted technique.

The medical necessity and thus the appropriateness of additional reimbursement for robotic-assisted gastrointestinal and general surgical procedures including but not limited to cholecystectomy, fundoplication, Heller myotomy, bariatric surgery, gastrectomy, pancreatectomy, colectomy, rectopexy, splenectomy, and hernia repair has not been established.

The medical necessity and thus the appropriateness of additional reimbursement for robotic-assisted gynecological procedures including but not limited to hysterectomy, cancer staging, sacrocolpopexy, repair of vesicovaginal fistula, tubal anastomosis, and myomectomy has not been established.

The medical necessity and thus the appropriateness of additional reimbursement for robotic-assisted urological procedures including but not limited to pyeloplasty, ureteral reimplantation, partial and radical nephrectomy, cystectomy or cystoprostatectomy, donor nephrectomy, and adrenalectomy has not been established. The medical necessity and thus the appropriateness of additional reimbursement for robotic-assisted radical prostatectomy as a form of laparoscopic radical prostatectomy for the treatment of localized prostate cancer has not been established.

The medical necessity and thus the appropriateness of additional reimbursement for robotic-assisted thoracic procedures including but not limited to lobectomy, thymectomy, thymectomy, transhiatal esophagectomy, mediastinal mass resection, resection of neurogenic tumor, and repair of gastro-esophageal reflux has not been established.
The medical necessity and thus the appropriateness of additional reimbursement for robotic-assisted pediatric procedures including but not limited to fundoplication, heminephrectomy, pyeloplasty, patent ductus arteriosus closure, and vascular ring repair has not been established.

For information about the use of robotic-assisted cardiac surgery, refer to the Medical Policy 7.01.62 entitled, 'Minimally Invasive Coronary Artery Bypass Graft Surgery.

For information about the use of robotic-assisted orthopedic surgery refer to the policy entitled 'Medical Policy 7.01.96 Computer-assisted Musculoskeletal Surgical Navigational Orthopedic Procedure.

Rationale

Minimally invasive surgical (MIS) procedures are generally performed through smaller access ports, into body cavities such as the abdomen and the thorax, or into body spaces such as the anterior cervical triangle of the neck or the acetabulum of the hip. The use of MIS techniques has allowed patients to benefit from reduced rates of infection, fewer blood transfusions, less pain, shorter hospital stays, better cosmesis and quicker recovery. (Langenburg et al., 2003)

Standard MIS instruments, such as those used in laparoscopic and thoracoscopic procedures, limit the complexity of surgical tasks that can be performed. MIS instruments are long, straight effectors, manipulated through fixed entrance sites, with limited degrees of freedom. (Cadiere et al., 2001) Additionally, surgeons often experience muscle fatigue due to poor ergonomic positioning over extended periods of time. As a result, to increase the complexity of tasks performed within a body cavity and improve overall ergonomics, a computer interface can be employed between the surgeon and the patient, which establishes the basis for robotic surgery. (Langenburg et al., 2003)

Robotic-assisted techniques typically use a 'semi-active robot,' which requires input from the operator to perform a procedure. The robot provides assistance in aligning the surgical tools or in preventing movement outside a predetermined surgical field. Robotic surgical systems that have been approved by the U.S. Food and Drug Administration (FDA) are semi-active robotics called 'master-slave telemanipulators (MSTs).’ They include the da Vinci Surgical System and the ZEUS Robotic Surgical System (Intuitive Surgical Inc, Sunnyvale, CA). However, the manufacturers of the da Vinci and ZEUS systems have merged and now only the da Vinci® system is actively marketed. Both systems have an endoscopic camera arm and robotic arms capable of powered movement of surgical tools when guided by a surgeon's hand movements. The surgeon sits at a console with a three-dimensional view of the operative field and grips master control handles. Moving the 'master' (surgeon) causes the 'slave' (surgical instrument) to duplicate the movement in an operative field. Adding a wrist-like joint near the end of the instruments allow seven degrees of freedom (eg, right-left; up-down; in-out; rotate left-right;
angle left-right; angle up-down; and grip on-off). Robotic systems may modify the surgeon’s input by removing tremors or by reducing the scale of motion, which allows larger hand movements to control much finer actions under a magnified endoscopic view. Additionally, visualization of the magnified surgical field can be controlled by robotic assistance. In the AESOP system, a voice-controlled robotic arm controls the endoscope, and thereby eliminates the need for an assistant and improves the stability of the image. (Guyton, 2002)

Most studies reported similar outcome measures and included one or more of the following: total operating time, hospital length of stay, degree of postoperative pain, radiographic examinations, rates of conversion to ‘open’ procedures, morbidity and mortality rates, blood loss, time until patient returned to work, adverse events/complications. Except for studies evaluating robotic-assisted cardiac procedures, most follow-up periods were limited to the immediate postoperative period.

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.

Evidence from these studies indicates that many robotic-assisted laparoscopic or endoscopic procedures are relatively safe and feasible and can provide initial favorable clinical outcomes such as reduced blood loss and reduced hospital length of stay in selected patients. However, operating times reported for robotically assisted surgery were often longer than those reported for minimally invasive or conventional open techniques, especially for robotically assisted procedures that were performed endoscopically. Conversion to open procedures was required in some cases, and some patients required reoperation. Moreover, several of the studies describe steep learning curves, even after specific training and cadaver practice with the robotic systems.

Overall, the safety of robotic-assisted surgery was comparable to that of standard treatment modalities and no complications specific to the procedure were reported.

General surgeons have reported that robotics has been most frequently used in cholecystectomies for gallbladder disease and gastric fundoplications for gastroesophageal reflux disease. (1) Other procedures have also been performed and documented in the scientific literature: pyloroplasty, sigmoid colectomy, adrenalectomy, gastroplasty, esophageal myotomy, inguinal hernia repair, lumbar sympathectomy, appendectomy, splenectomy, distal pancreatectomy, varicocele ligation, and rectoplexy.

In a large uncontrolled trial, Talamini et al. (2002) reported on a variety of robotic-assisted general surgical procedures (‘n=211) performed using the da Vinci Surgical System. (15) These included antireflux surgery, cholecystectomy, Heller myotomy, bowel resection, donor nephrectomy, gastric bypass, splenectomy, adrenalectomy, pyloroplasty, panniculotomy, gastrojejunostomy, and colon polypectomy. Early results suggested that robotic-assisted procedures are comparable to conventional laparoscopy in terms of mortality, complications, and hospital length of stay. A small comparative study comparing robotic and traditional laparoscopic colorectal procedures (‘n=6) reported that although blood loss and length of stay were not significantly different between the two procedures, operative time was increased for robotic-assisted surgery. (46) In a prospective, uncontrolled trial, Hildebrandt et al. (2003) evaluated laparoscopic colonic resection in 41 patients and reported no cases of conversion to
open surgery but three postoperative complications. (16) With robotic assistance, a single surgeon was able to complete two thirds of the colorectal resection on his own with no need for a surgical assistant.

Aioni et al. (2002) conducted a comparative trial to evaluate a robotic camera assistant (EndoAssist) for laparoscopic cholecystectomy in 93 patients. Seven required conversion to open surgical operations. The total operating time while using a robotic assistant was less than that required when using a human assistant. Additionally, surgeons demonstrated competency with the use of the robotic assistant within three procedures. A nonrandomized comparative trial evaluated robot-assisted laparoscopic cholecystectomy performed by two surgical trainees. Investigators demonstrated the feasibility of robot-assisted cholecystectomy; however, the procedure required significantly more operating time than conventional laparoscopic cholecystectomy due to slower performed actions. Two large uncontrolled trials (n=193 and n=146) evaluated robotic assistance in abdominal, thoracic, and vascular procedures. Both studies demonstrated feasibility, with low perioperative and postoperative morbidity rates, and low rates of conversion to open procedures. Operative time was not evaluated in these studies.

In one of the few studies with long-term follow-up, Bentas et al. (2003) reported 1-year results after robot-assisted laparoscopic pyeloplasty (n=11). Intraoperatively, no patient experienced complications, and blood loss was negligible. Functional results at 1 year were considered excellent.

**Telerobotic Surgery:** 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. 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.

There is insufficient evidence to conclude that robotic-assisted surgical procedures provide comparable outcomes to conventional open or minimally invasive surgical procedures. The available evidence suggests that certain robotic-assisted surgical procedures, such as cholecystectomy and colonic resection can result in improved clinical outcomes in selected patients. However, operative times for robotically assisted procedures were generally longer than those reported with conventional open surgical techniques, and a steep learning curve was described by a number of investigators. Questions remain with regard to patient selection for robotic-assisted surgery and comparative safety, efficacy, or accuracy of this technology relative to non-robotic-assisted open or minimally invasive orthopedic procedures.
Coding

The HCPCS code listed in this policy is for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the medical policy document.

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

References:


• Heffner T, Hailey D. Computer-enhanced surgical systems ('robotic surgery'). Canadian Coordinating Office for Health Technology Assessment (CCOHTA) 2002. Issues in


  Meehan JJ, Sandler A. Pediatric robotic surgery: A single-institutional review of the first 100 consecutive cases. Surg Endosc. 2007 May 24;


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