Clinical Policy Title: Robotic Assisted Surgery

Clinical Policy Number: 18.03.01

Effective Date: March 1, 2014
Initial Review Date: September 18, 2013
Most Recent Review Date: September 21, 2016
Next Review Date: September, 2017

Policy contains:
- Robotic assisted surgery.
- DaVinci surgical system.
- ZEUS robotic system.

Related Policies:

CP# 12.03.04 - Radiofrequency (RF) Ablation of Uterine Fibroids

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

Coverage Policy

AmeriHealth Caritas Pennsylvania considers the use of robotic assistance in surgery to be investigational and, therefore, not medically necessary.

Limitations:

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

Alternative Covered Services:

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

Background
Robotic assisted surgery has become increasingly common in the United States and in the world, rising from 80,000 to 500,000 procedures between 2007 and 2013. The new technology has rapidly expanded. In 2010, 9.5% of hysterectomies in U.S. hospitals were performed using robotic technology, up from just 0.5% three years earlier. In hospitals that introduced robotic surgery for hysterectomy, 22.4% of the procedures were performed using a robot three years later (Wright, 2013).

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

Perhaps the most commonly used model of robotic assisted surgery is the daVinci® system, made by Intuitive Surgical. It is often used for prostatectomies, hysterectomies, bypass surgeries, and removing cancerous tissue (Carlson, 2016). The U.S. Food and Drug Administration approved the device in 2000. Another common model is the ZEUS Robotic Surgical System (also owned by Intuitive Surgical).

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

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

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

The application of robotic assisted surgery is now found in the following fields. The majority of these procedures are performed without the use of such computer assistance:

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Procedures</th>
<th>Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiology</td>
<td>• Ablation of aberrant conduction systems.  &lt;br&gt;• Interventional cardiac procedures.</td>
<td>• 3-D cardiac mapping.</td>
</tr>
<tr>
<td>Cardiothoracic surgery</td>
<td>• Atrial septal defect closure.  &lt;br&gt;• Endoscopic coronary artery bypass.</td>
<td>• MIDCAB.  &lt;br&gt;• Valve repair or replacement.</td>
</tr>
<tr>
<td>General surgery</td>
<td>• Bariatric surgery.  &lt;br&gt;• Cholecystectomy.  &lt;br&gt;• Colectomy.  &lt;br&gt;• Gastrectomy.</td>
<td>• Incisional hernia repair.  &lt;br&gt;• Nissan fundoplication.  &lt;br&gt;• Pancreatectomy.  &lt;br&gt;• Rectopexy.</td>
</tr>
</tbody>
</table>
The large number of procedures for which robotic assistance has been used further indicates the technology is in its infancy, with efforts to find optimal outcomes for patients. Most of the above listed procedures have been performed a small number of times and have not been subjected to randomized controlled clinical trials.

**Methods**

**Searches**

AmeriHealth Caritas Pennsylvania searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on August 18, 2016. Search terms were “robotic systems”, “robotic assisted surgery,” and “da Vinci surgery.”

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

**Findings**
Researchers have assessed a variety of outcomes of robotically-assisted surgery. Those measures (typically in studies comparing robotic surgery to laparoscopic surgery) include length of stay, blood loss, anesthesia required, recovery time, time in the operating room, complications, and costs.

Because many procedures using robotic technology having been performed, the literature contains a large number of controlled trials (along with meta-analyses and systematic reviews). While some researchers conclude that robotic surgery is superior to traditional laparotomy or laparoscopy, a number of others strongly believe that the superiority of robotic surgery is unproven.

On March 14, 2013, American College of Obstetrics and Gynecology (ACOG) president James T. Breeden MD issued a statement on the College’s web site. Breeden stated that “studies have shown that adding this expensive technology for routine surgical care does not improve patient outcomes. . . there is no good data proving that robotic hysterectomy is even as good as – let alone better – than existing, and far less costly, minimally invasive alternatives.” Breeden cited “aggressive direct-to-consumer marketing of the latest medical technologies may mislead the public into believing that they are the best choice.”

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

Both Breeden and Wilensky cited a large 2013 *JAMA* study published by Columbia University researchers covering 264,758 women undergoing hysterectomy in 441 hospitals between 2007 and 2010. The study found similar rates of complications, long lengths of stay, transfusions, and nursing home discharges for the two groups, but also cited concern over the higher average costs associated with robotic surgery, especially as the percent of hysterectomies performed with a robot soared (Wright, 2013).

Meta-analyses and systematic reviews have failed to establish a pattern of improved long-term efficacy of this procedure. In addition to the seminal Columbia research, the following were published in the first half of 2016:

- A meta-analysis by researchers at the Geisel School of Medicine at Dartmouth College found no difference in complications, length of stay, operating time, conversions to laparotomy, and blood loss between robotic vs. laparoscopic hysterectomies, leading to the conclusion that robotic surgery’s role in benign gynecological surgery “remains unclear” (Albright, 2016).
• In patients affected by sleep apnea undergoing tongue reduction, failure rates of trans-oral robotic surgery and coblation tongue surgery were not significantly different (34.4% and 38.5%). However, complication rates were significantly higher in the robotic group (21.3% vs. 8.4%) (Camaroto, 2016).

• A large Meta-analysis (99 articles, 14,448 patients) comparing outcomes for robotic vs. minimally invasive surgery for various types of procedures documented robotic groups had reduced blood loss, and a lower transfusion rate. However, robotic groups had similar LOS and 30 day complication rates, and a higher average operative time. The report noted that many studies suffered from high risk of bias and inadequate statistical power (Tan, 2016).

• A meta-analysis of sacrocolpopexy (treating prolapse of the apical segment of the vagina) compared results for patients undergoing laparoscopy vs. open surgery vs. robotic. In 9 studies of 1157 subjects, no difference was found in anatomical outcomes, mortality, LOS, and post-operative quality of life, but the robotic subjects experienced higher post-op pain and longer operating times (DeBouveia, 2016).

• In a review of 24 studies on radical prostatectomy (laparoscopy vs. robotic), the robotic subjects had less blood loss and a lower transfusion rate, along with better functional outcomes – but there was no difference in perioperative and oncological outcomes (Huang, 2016).

• An analysis of 18 studies of 4878 patients undergoing thyroidectomy, comparing the conventional (open) approach vs. endoscopic vs. robotic documented a similar risk of post-operative complications, but a longer operative time (mean difference 43.5 minutes) for robotic-assisted surgery procedures than conventional surgery (Kandil, 2016).

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

Policy Updates:

Ten (10) new peer-reviewed references have been added to this policy, eight (8) of which were published in 2016. Of these three (3) have been added to the Summary of Clinical Evidence section. There are also an additional three (3) references added to the Clinical Guidelines/Other section, two (2) of which were published in 2016.

The Findings section has been expanded. Discussion of the 2013 statement by ACOG President James T. Breeden MD that concluded robotic surgery doesn’t improve patient outcomes has been included, as did the 2016 journal article by Gail Wilensky PhD, which also presented analysis of incremental costs of using
robotic surgery instead of laparoscopic surgery. A summary of a seminal article in *JAMA* covering over 264,000 women undergoing hysterectomy, plus recent meta analyses and cost analyses of robotic surgery are now included in the policy.

**Summary of Clinical Evidence**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albright (2016)</td>
<td><strong>Key Points:</strong></td>
</tr>
<tr>
<td>Complications in</td>
<td>• 41 complications among 326 patients</td>
</tr>
<tr>
<td>hysterectomy,</td>
<td>• No significant differences in rates of class 1-2-3-4 complications</td>
</tr>
<tr>
<td>laparoscopic vs.</td>
<td>• No significant differences in mean length of stay, operating time, conversions to</td>
</tr>
<tr>
<td>robotic</td>
<td>laparotomy, or blood loss</td>
</tr>
<tr>
<td></td>
<td>Concludes the role of robotic surgery in benign gynecology “remains unclear”</td>
</tr>
<tr>
<td>Tan (2016)</td>
<td><strong>Key Points:</strong></td>
</tr>
<tr>
<td>Outcomes, robotic vs. minimally invasive surgery</td>
<td>• 99 studies, 14,448 subjects, variety of procedures</td>
</tr>
<tr>
<td></td>
<td>• Robotic subjects had less blood loss, lower transfusion rate</td>
</tr>
<tr>
<td></td>
<td>• Robotic subjects had similar LOS and 30 day complication rates</td>
</tr>
<tr>
<td></td>
<td>• Robotic subjects had longer operative time</td>
</tr>
<tr>
<td></td>
<td>Many studies had high risk of bias or inadequate statistical power</td>
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<tr>
<td>Fonseka (2015)</td>
<td><strong>Key Points:</strong></td>
</tr>
<tr>
<td>Comparing methods of cystectomy</td>
<td>• 24 studies, 2104 cases</td>
</tr>
<tr>
<td></td>
<td>• Robot assisted vs laparoscopic vs. open cystectomy</td>
</tr>
<tr>
<td></td>
<td>• Robot assisted had outcomes superior to open</td>
</tr>
<tr>
<td></td>
<td>• Robot = longer operative time vs. laparoscopic, same LOS, blood loss, complications</td>
</tr>
<tr>
<td>Lang (2015)</td>
<td><strong>Key Points:</strong></td>
</tr>
<tr>
<td>Thyroidectomy via robotic and non-robotic assisted methods</td>
<td>• 10 studies, 2205 cases (differentiated thyroid carcinoma)</td>
</tr>
<tr>
<td></td>
<td>• Open vs. robotic-assisted thyroidectomy</td>
</tr>
<tr>
<td></td>
<td>• Robotic resulted in fewer central lymph nodes, less-complete thyroid resections, otherwise similar outcomes</td>
</tr>
<tr>
<td>Cundy (2014)</td>
<td><strong>Key Points:</strong></td>
</tr>
<tr>
<td>Pyeloplasty in children</td>
<td>• 12 studies, 679 participants</td>
</tr>
<tr>
<td></td>
<td>• Open vs. laparoscopic vs. robotic-assisted pyeloplasty</td>
</tr>
<tr>
<td></td>
<td>• Robotic had shorter LOS, lower anesthesia required, lower blood loss</td>
</tr>
<tr>
<td></td>
<td>• Robotic had higher cost, longer operating time</td>
</tr>
<tr>
<td>Robertson (2013)</td>
<td><strong>Key Points:</strong></td>
</tr>
<tr>
<td>Treatment of localized prostate cancer</td>
<td>• Meta-analysis of 58 studies (only 1 RCT) of 19,064 men with prostate surgery</td>
</tr>
<tr>
<td></td>
<td>• Fewer significant complications with robotic (0.4%) vs. laparoscopic (2.9%)</td>
</tr>
</tbody>
</table>
Lower incidence residual tumor invading margins of resected tissue by robot.

Close (2013)
Treatment of localized prostate cancer

Key Points:
- Meta-analysis of patients with prostate cancer for up to 10 years.
- Higher cost of robotic prostatectomy may be offset by lower risk of early harms and positive margin, if > 150 cases are performed each year.*

Wright (2013)
Benign gynecology surgery

Key Points:
- 441 U.S. hospitals, 264,758 procedures, 2007-2010, robotic vs. laparoscopic
- Similar rates of complications, LOS > 2 days, transfusions, discharge to nursing home
- Average additional costs of robotic patients was $2189

Glossary

da Vinci robotic surgical system — A device featuring a magnified 3D high definition vision system and tiny instruments that bend and rotate. Surgeons operate remotely in a console, using several small incisions.

Laparoscopic surgery — Surgery that utilizes a laparoscope with a video camera and surgical instruments inserted through small incisions. (Gale Encyclopedia of Medicine. ©2008 The Gale Group, Inc).

Minimally invasive surgery — Surgery done with only a small incision or no incision at all, such as through a cannula with a laparoscope or endoscope (Dorland's Medical Dictionary for Health Consumers).

Robotic assisted surgeries — The performance of operative procedures with the assistance of robotic technology. It allows great precision and is used for remote-control, minimally invasive procedures. Current systems consist of computer-controlled electromechanical devices that work in response to controls manipulated by the surgeon.

ZEUS robotic surgical system — A medical robot used in minimally assisted surgery, using three arms (voice-activated endoscope, and two to mimic the surgeon’s movements for incisions and extractions).

References

Professional society guidelines/other:


**Peer-reviewed references**


**Clinical trials**
Searched clinicaltrials.gov on August 18, 2016, using “robotic assisted surgery” and “robotic surgery.” 55 Open Studies, four (4) relevant.


**Centers for Medicare & Medicaid Services (CMS) national coverage determination**
No NCDs found as of the writing of this policy.

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

**Commonly submitted codes**

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

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2900</td>
<td>Surgical techniques requiring use of robotic surgical system (list separately in addition to code for primary procedure)</td>
<td>NOT FOR USE WITH MEDICARE CLAIMS</td>
</tr>
<tr>
<td>ICD-10 Code</td>
<td>Description</td>
<td>Comment</td>
</tr>
<tr>
<td>-------------</td>
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<tr>
<td>55866</td>
<td>Laparoscopy, surgical prostatectomy, retropubic, radical; including nerve sparing, includes robotic experience when performed</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Level II</th>
<th>Description</th>
<th>Comment</th>
</tr>
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<tbody>
<tr>
<td>N/A</td>
<td></td>
<td></td>
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</tbody>
</table>