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**INLAND EMPIRE HEALTH PLAN**

**IEHP UM Subcommittee Authorization Guidelines**

***Robotically Assisted Surgery (RAS)***

**Policy:**

IEHP does not provide separate or additional reimbursement for the use of robotic surgical systems (e.g. da Vinci® Surgical System, ZEUS™ Robotic Surgical System). Reimbursement of surgical services will be based on the payment for the primary surgical procedure performed. The type of instruments, technique, or approach used in a procedure is a matter of choice of the surgeon performing the procedure, including use of robotic surgical systems.

**Medicare:** “Medicare has not issued a national or local coverage determination for robotic surgery.”<sup>1</sup> Therefore, IEHP does not consider robotic assisted surgery a separately covered Medicare benefit. Neither National Coverage Determination (NCD) nor Local Coverage Determination (LCD) articles are currently available for robotically assisted laparoscopic surgeries.<sup>2, 3</sup>

**Medi-Cal:** This procedure is not a covered benefit. No TAR or Medi-Services reservation required.<sup>4</sup>

**Additional Sources:**

*Apollo (2016):* For robot assisted radical prostatectomy, Apollo authors state: “Technical expertise required. Coverage is not recommended unless the procedure is performed in an institution that has high volume of each of these prostatectomy procedures and one or more surgeons who have been specifically credentialed to perform [robot assisted radical prostatectomy] and [laser radical prostatectomy] in addition to the conventional open radical retropubic prostatectomy procedure for prostate cancer and who will be the operating surgeon for the procedure.”<sup>5</sup> For robotic assisted cardiac surgery, Apollo authors state: “Medicare and some health plans will cover otherwise indicated cardiac/vascular surgery using a computerized robotic system. Additional reimbursement is not provided for the use of this technology by most health plans.”<sup>1</sup> Furthermore, they cite the National Institute for Health and Care Excellence to say: “ ‘Current evidence on the safety and efficacy of totally endoscopic robotically assisted coronary artery bypass grafting does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.’ ”<sup>1</sup>

*InterQual (2014):* InterQual lists “Robotic-Assisted Radical Prostatectomy” as a subset of “Prostatectomy: Radical” which is an appropriate procedure for “the inpatient setting based on InterQual Procedures.” No additional references to RAS or its synonyms were found.<sup>6</sup>

10801 Sixth St, Rancho Cucamonga, CA 91730  
Tel (909) 890-2000 Fax (909) 890-2003  
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*ECRI (2014)*: ECRI notes that coverage of RAS is at the discretion of the local Medicare carriers—as there is no national coverage determination for RAS. Furthermore, ECRI’s search of 11 representative private, third-party payers found that “payers with coverage policies that specifically address robotically assisted surgery typically consider use of the robot to be an integral part of the primary surgical procedure and not separately reimbursable.”<sup>7</sup>

### **Coverage by Other Health Plans:**

*Aetna (2016)*: There is no mention of coverage for use of robotic technique within their policies.<sup>8</sup>

*Anthem Blue Cross/Blue Shield (2015)*: “Anthem does not allow separate or additional reimbursement for the use of robotic surgical systems unless provider, state, federal, or CMS contracts and/or requirements indicate otherwise. Surgical techniques requiring use of robotic surgical systems will be considered integral to surgical services and not a separate service. Reimbursement will be based on the payment for the primary surgical procedure(s).”<sup>9</sup>

*Cigna (2016)*: “Cigna does not provide additional reimbursement based upon the type of instruments, technique or approach used in a procedure. Such matters are left to the discretion of the surgeon. Additional professional or technical reimbursement will not be made when a surgical procedure is performed using robotic assistance. [...] Reimbursement for procedures in which a robotic surgical system is used will be based on the contracted rate or usual and customary fee or maximum reimbursable charge for the base procedure. Separate reimbursement is not allowed for the robotic surgical technique. Reimbursement for the base procedure may be subject to medical necessity review.”<sup>10</sup>

*Health Net (2015)*: “Health Net does not provide additional reimbursement for the use of robotic surgical devices (e.g. da Vinci Surgical System, ZEUS Robotic Surgical System). The type of instruments, technique or approach used in a procedure is a matter of choice of the surgeon. [...] Additional professional or technical reimbursement will not be made when a surgical procedure is performed using robotic assistance. Reimbursement for procedures in which a robotic surgical system is used will be based on the contracted rate or usual and customary fee for the base procedure. Separate reimbursement is not allowed for the robotic surgical technique. Reimbursement for the base procedure may be subject to medical necessity review. [...] This policy includes any type of robotically assisted surgery such as prostate, cardiac, gastrointestinal, urology and gynecological etc.”<sup>11</sup>

*UnitedHealthcare, Oxford Health Plans (2016)*: “Oxford considers code S2900,[...] to be a technique integral to the primary surgical procedure and not a separately reimbursed service. When a surgical procedure is performed using code S2900, reimbursement will be considered included as part of the primary surgical procedure.”<sup>12</sup>

### **Background:**

Robotic surgical systems (such as da Vinci® Surgical System, ZEUS™ Robotic Surgical System) are utilized in an increasing number of surgical procedures where conventional laparoscopy is already well-accepted, and usage is increasing rapidly worldwide. Use of these

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systems has many theoretical, and a few proven benefits over conventional laparoscopy in many types of procedures, however more clinical trials are needed to investigate additional benefits.

*Robotic surgical procedures* are defined as “surgical procedures performed using a computer that remotely controls surgical instruments attached to mechanical arms designed to perform the tasks of the surgeon.”<sup>13</sup> *Robotically assisted surgery (RAS)* can be defined as surgery performed by an experienced surgeon using a robotic device or devices during the procedure. Robotically assisted laparoscopic surgery generally involves an active, immersive, teleoperated surgery performed by an experienced surgeon and necessary assistants using a surgeon’s console, a surgical cart with several robotic arms and laparoscopic instruments, and an equipment cart.<sup>14</sup> Robotically assisted surgeries can include a variety of devices. Currently, “two active functional robots are available: the robotic camera holder (AESOP) and immersive telerobotic surgical system (da Vinci).”<sup>14</sup>

In 2005, the U.S. Centers for Medicare and Medicaid Services (CMS) introduced the new Healthcare Common Procedure Coding System (HCPCS) coding for “surgical techniques requiring use of robotic surgical systems” with the temporary national code *S2900*—a code to be included with the code for the primary procedure.<sup>15</sup> *S2900* is not listed on the California Department of Health Care Services Medi-Cal Rates online publications.<sup>16</sup> In 2008, CMS introduced new ICD-9-CM coding for robotic assisted procedures with the subcategory 17.4, which includes “use of a computer console with (3-D) imaging, software, camera(s), visualization and instrumentation *combined* with the use of robotic arms, device(s), or system(s) at the time of the procedure.”<sup>17</sup> ICD-10-PCS continues allowance for coding of robotic assisted procedures with the use of the sixth character coding position which codes for “method.”<sup>18</sup> At present, only one Current Procedural Terminology (CPT) code exists which includes robotic assistance within the primary procedure: 55866—“Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed.”<sup>19</sup>

The U.S. Food and Drug Administration (FDA) has cleared robotically-assisted surgical devices for “use by trained physicians in an operating room environment for laparoscopic surgical procedures in general surgery[,] cardiac, colorectal, gynecologic, head and neck, thoracic, and urological surgical procedures.”<sup>20</sup> Since approval of Intuitive Surgical’s da Vinci® Surgical System in 2000, and subsequent clearances for expanded indications and additional devices, worldwide use has dramatically increased, with as many as 1,900 da Vinci Surgical Systems installed in U.S hospitals by late 2013, and as many as 3,477 robotic units in use worldwide in late 2014.<sup>21,7,14</sup> Additionally, from 2012 to 2013, procedural volume grew by 16% (from 450,000 procedures in 2012 to 523,000 procedures in 2013). FDA approval for three robotic devices—da Vinci S®, Si®, and/or Xi® systems—exists for the following procedures: radical prostatectomy, partial nephrectomy, Pyeloplasty, hysterectomy, myomectomy, sacrocolpopexy, endometriosis resection, mitral valve repair, internal mammary artery mobilization, cardiac tissue ablation, cholecystectomy, colon resection, gastric bypass, Transoral robotic surgery for throat cancer, and thyroidectomy.<sup>7</sup>

Robotically assisted laparoscopic surgery theoretically “has all of the advantages of minimally invasive surgery [including] less postoperative pain, smaller and possibly more cosmetically appealing incisions, shorter hospital stay, shorter recovery time, and faster return to work.” In

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addition to these, robotically assisted laparoscopic surgery offers: three dimensional imaging of the surgical field, mechanical improvement through increased degrees of freedom for surgical instruments, improved ergonomics, and stabilization of instruments. These benefits are tempered by several limitations of RAS, including: necessity for additional surgical training, increased device costs and operating room time, bulkiness of the surgical devices, instrumentation limitations (e.g. lack of a robotic suction and irrigation device; energy source limitations), lack of tactile feedback for the surgeon, risk of mechanical device failure, and inability to operate in more than two abdominal quadrants at a time.<sup>14</sup>

Many observational studies, clinical trials, and meta-analyses have evaluated the benefits and drawbacks of robotically assisted laparoscopic surgery (RAS) compared to conventional laparoscopic surgery (CLS). Differences between these two procedures vary with the underlying primary surgery (e.g. cholecystectomy, prostatectomy, etc.). Additionally, professional guidelines have been developed by several professional organizations regarding these procedures.

According to a Washington State Health Care Authority 2012 summary assessment for RAS, “Guidelines addressing the use of robotic technology across procedures are mixed.” All professional recommendations that they found, with a few exceptions, “are based primarily on whether the procedure is recommended for the indication rather than the specific use of robotic technology. In other words, in all other guidelines if the laparoscopic procedure is recommended, then robotic is also included.”<sup>3</sup>

### General surgical and gastrointestinal procedures:

*Cholecystectomy:* A Cochrane Review in 2012 compared RAS and CLS for cholecystectomy noted that RAS “did not seem to offer any significant advantages over human assisted laparoscopic cholecystectomy;” and that “further well-designed randomized trials with low risk of [...] errors are needed.”<sup>22</sup>

*Distal pancreatectomy:* Zhou, et al. (2016), conducted a meta-analysis of 568 patients enrolled in seven non-randomized clinical trials comparing laparoscopic distal pancreatectomy (CLS) to robotic-assisted distal pancreatectomy (RAS) and found “[RAS] to be associated with longer operating time, lower estimated blood loss, a higher spleen-preservation rate, and shorter hospital stay.” Additionally, “no significant difference in transfusion, conversion to open surgery, R0 resection rate, lymph nodes harvested, overall complications, severe complications, pancreatic fistula, severe pancreatic fistula, ICU stay, total cost, and 30-day mortality between the two groups” were found. Of note, currently “there is no consensus on whether laparoscopic or robotic-assisted distal pancreatectomy is more beneficial to the patient.”<sup>23</sup>

*Colectomy and rectal resection:* Lorenzon, et al. (2016), conducted a meta-analysis of 2772 colorectal resections (1652 laparoscopic; 1120 robotic-assisted) documented in 22, mostly observational (three of 22 were randomized trials), studies. Dividing the studies into three categories—(1) right-sided colectomies, (2) left-sided colectomies, and (3) pelvic resections—they evaluated for differences between laparoscopic (CLS) and robotic-assisted (RAS) in the following variables: operating time, blood loss, bowel function recovery, time to oral intake,

lymph node harvest, hospital stay, costs, and morbidity rate variables. They found operating time to be significantly shorter for left-sided or pelvic CLS resections compared to left-sided or pelvic RAS resections, respectively, and blood loss variables to be significantly better for pelvic CLS resections compared to pelvic RAS resections. Overall (combining the three groups), they found significantly different costs and operating time in favor of CLS, and significantly different morbidity rate in favor of RAS. However, when the researchers focused their analysis on only randomized trials these findings could not be confirmed.<sup>24</sup>

Gynecologic procedures:

Chen, Li, and Du (2016) conducted a meta-analysis comparing CLS and RAS for treatment of advanced stage endometriosis and found a higher average operating time of approximately 74 minutes, and no significant differences in blood loss, complication rates, and hospital stay.<sup>25</sup>

A Cochrane Review in 2014 compared RAS and CLS for gynecologic procedures involving benign and malignant gynecological diseases and found RAS to be on average 42 minutes longer than CLS, but associated with an on average seven-hour reduction in hospital stay. However, the authors noted that more data is needed to understand the differences in postoperative pain and intraoperative or postoperative complication rates between RAS and CLS.<sup>26</sup>

Urologic procedures:

*Prostatectomy for prostate cancer:* Tewari, et al. (2012), conducted a meta-analysis of predominantly observational studies comparing the complication rates and positive surgical margin rates of open retropubic, CLS, and RAS radical prostatectomy for prostate cancer, and found RAS to have fewer positive margin rates than CLS. Intraoperative and perioperative complication rates were also significantly lower for RAS compared to CLS for radical prostatectomy.<sup>27</sup> Robertson, et al. (2013), conducted a similar meta-analysis comparing open radical prostatectomy and robot-assisted and standard laparoscopic techniques, and found RAS prostatectomy to be associated with a lower risk of major intra-operative harms and a lower rate of surgical margins positive for cancer, compared to CLS, with other outcome measures—biochemical cancer recurrence at 12 months, urinary incontinence at 12 months, conversion to open surgery, blood transfusion, bladder neck contracture, infection, ileus, and deep vein thrombosis—being not significantly different.<sup>28</sup>

*Pyeloplasty for pelviureteric junction obstruction:* Two recent meta-analyses comparing robotic versus conventional laparoscopic Pyeloplasty for ureteropelvic junction obstruction did not find any “statistically significant differences in success rate or complication rate,” and found mixed results regarding hospital stay and operative time reduction.<sup>29</sup> Wang, et al. (2013) found an 18.76-minute reduction in suturing time for RAS and a 0.75-day decrease in mean length of hospital stay for RAS compared with CLS.<sup>30</sup> Whereas, Autorino, et al. (2014), found a 27.9-minute reduction in operating time for RAS, and no difference in hospital stay compared to CLS.<sup>31</sup>

*Radical and partial nephrectomy for kidney cancer:* Choi, et al. (2015), conducted a meta-analysis of 2240 patients participating in observational studies comparing rates of several perioperative outcomes for robotic partial nephrectomy (RAS) versus laparoscopic partial

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nephrectomy (CLS) for renal cancer. Significant findings included a lower conversion rate to open surgery and radical nephrectomy, a shorter warm ischemia time, a more favorable change in estimated glomerular filtration rate, and a shorter length of stay for RAS compared to CLS. Other measured outcome rates—change of serum creatinine, operative time, estimated blood loss, and positive surgical margins—were not significantly different between RAS and CLS.<sup>32</sup>

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