

Subject: Robotically Assisted Surgery		Original Effective Date: 4/2/14
Policy Number: MCR-161 <i>This MCR replaces the following MCR's that have been archived: 90, 98, 99, 100, 101 & 102</i>	Revision Date(s): <i>This MCR is no longer scheduled for revisions.</i>	
Review Date: 4/2/14, 12/16/15, 6/15/16, 9/19/17, 3/8/18, 6/19/19, 4/23/20. 4/5/21, 6/29/21		
MCPC Approval Date: 3/8/18, 6/19/19, 4/23/20, 4/5/21		

Contents

DISCLAIMER	1
Description of Procedure/Service/Pharmaceutical.....	1
Recommendation	2
Continuation of Therapy	3
Coverage Exclusions.....	3
Summary of Medical Evidence.....	3
Coding Information.....	3
Resource References.....	4
REVIEW/REVISION HISTORY	6

DISCLAIMER

This Molina Clinical Review (MCR) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Review (MCR) document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL²⁹⁻³¹

Robotically 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. Robotically 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.

The proposed major advantages of robot-assisted over conventional laparoscopy are:

- Enhanced visualization: 3D versus two-dimensional (2D) imaging of the operative field.
- Mechanical improvements: A fulcrum effect is created when rigid conventional instruments pass through the incision, leading to inversion of movement from the surgeon's hand to the working end of the instrument. Robotic instruments have seven degrees of freedom, similar to the human arm and hand, while rigid conventional instruments have four degrees of freedom.
- Stabilization of instruments within the surgical field: Small movements by the surgeon are amplified (including errors or hand tremor) using conventional laparoscopy procedures.
- Improved ergonomics for the operating surgeon: The surgeon can be seated with telerobotic systems limiting pain, numbness or fatigue in their arms, wrists, or shoulders as compared to performing conventional laparoscopic procedures.

The limitations of robotic surgery may include:

- Additional required surgical training for this technique
- Increased costs and operating room time
- Bulkiness of the devices
- Instrumentation limitations (e.g., lack of a robotic suction and irrigation device, size, cost)
- Lack of tactile feedback
- Risk of mechanical failure
- Limited number of energy sources (e.g., less than with conventional laparoscopy)
- Surgical limitations (Not designed for abdominal surgery involving more than one quadrant; the device needs to be re-docked and repositioned to change quadrants).

FDA Indications: Robotic surgical systems are approved by the FDA as a 510 (k), Class II devices. The da Vinci® Surgical System (Intuitive Surgical Inc.) has received FDA 510(k) premarket approval. Since its original approval in 1997, numerous modifications have been made to the system and its accessories, resulting in multiple subsequent 510(k) approvals. ^{2 28}

RECOMMENDATION ^{3 4-23}

- ❑ Robotically assisted surgery may NOT be authorized separately in adults and children for any indication because it is considered equivalent to but not superior to a standard minimally invasive surgical approach.
 - This includes any type of robotically assisted surgery for any indication such as: abdominal, bariatric, cardiac, general surgery, gynecological, gastrointestinal, orthopedic, otolaryngology, prostate, spinal, thoracic, and urology.

- ❑ 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 because it is considered to be integral to the procedure and not a separate service. ³

CONTINUATION OF THERAPY

N/A

COVERAGE EXCLUSIONS

Robotically assisted surgery for any indication may not be authorized because it is considered equivalent to but not superior to a standard minimally invasive surgical approach.

SUMMARY OF MEDICAL EVIDENCE ⁴⁻²⁴

There is insufficient evidence from large well-designed randomized-control or prospective cohort/comparison studies comparing robotically assisted procedures with conventional procedures. 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. Well-designed long term studies are needed to determine whether robotically assisted procedures are safer, more effective and provide greater benefits than conventional procedures.

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
	N/A

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

ICD-10	Description: [For dates of service on or after 10/01/2015]
8E090CZ	Robotic Assisted procedure head neck region open
8E0W0CZ	Robotic Assisted procedure trunk region open
8E0Y0CZ	Robotic Assisted procedure lower extremity open approach
8E0W4CZ	Robotic Assisted procedure trunk region Perq Endo
8EO93CZ	Robotic Assisted procedure head neck region Perq
8EOW3CZ	Robotic Assisted procedure trunk region Perq
8EOY3CZ	Robotic Assisted procedure lower extremity Perq

8EO94CZ	Robotic Assisted procedure head neck region Perq Endo
8EO98CZ	Robotic Assisted procedure H&N Nat/Art opening Endo
8EOW8CZ	Robotic Assisted procedure trunk Nat/Art opening Endo
8EOY4CZ	Robotic Assisted procedure lower extremity Endo approach
8EO97CZ	Robotic Assisted procedure head neck Nat/Art opening
8EO9XCZ	Robotic Assisted procedure of head neck region
8EOW7CZ	Robotic Assisted procedure trunk region Nat/Art opening
8EOWXCZ	Robotic Assisted procedure trunk region
8EOYXCZ	Robotic Assisted procedure lower extremity

RESOURCE REFERENCES

Government Agency

- Centers for Medicare & Medicaid Services (CMS) [website]. Medicare Coverage Database. National Coverage Documents [search: robot; robotic; robotically assisted]. Accessed at: <https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>
- Center for Devices and Radiological Health (CDRH). 510(k) Premarket Notification Database [search: da Vinci]. Product code NAY. 510(k) Number K050802. Updated Nov 1, 2013. Food and Drug Administration (FDA) [website]. Available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>.
- American Medical Association. Current Procedural Terminology (CPT®) © 2019 Professional Edition.

Peer Reviewed Literature

- Maeso, Reza M, Mayol JA et al. Efficacy of the da Vinci surgical system in abdominal surgery compared with that of laparoscopy. Systematic review and meta-analysis. *Annals of Surgery* August 2010;252(2):254-262.
- Reza M, Maeso S, Blasco et al. Meta-analysis of observational studies on the safety and effectiveness of robotic gynecological surgery. *British Journal of Surgery* 2010;97(12):1772-1783.
- Xylinas E, Durand X, Taille A and Ploussard G. Robot-assisted Extraperitoneal Laparoscopic Radical Prostatectomy-A Review of the Current Literature. *European Neurological Review* 2010;5(1):15-8.
- Wright JD, Ananth CV, Lewin SN et al. Robotically assisted vs laparoscopic hysterectomy among women with benign gynecologic disease. *JAMA*. 2013 Feb 20;309(7):689-98. doi: 10.1001/jama.2013.186.
- Cochrane Database Syst Rev. Robotic surgery for benign gynaecological disease. 2012 Feb 15;2:CD008978. doi: 10.1002/14651858.CD008978.pub2.
- Albadine R, Hyndman ME et al. Characteristics of positive surgical margins in robotic-assisted radical prostatectomy, open retropubic radical prostatectomy, and laparoscopic radical prostatectomy: a comparative histopathologic study from a single academic center. *Hum Pathol*. 2012 Feb;43(2):254-60. Epub 2011 Aug 4.
- Herron D, Marohn M et al. The SAGES-MIRA Robotic Surgery Consensus Group. A Consensus Document on Robotic Surgery. 2007. Accessed at: <http://www.sages.org/publications/guidelines/consensus-document-robotic-surgery/>
- Merseberger AS, Herrmann TRW et al. European Association of Urology Guidelines for Robotic- and Single-Site Surgery in Urology. March 2013. Accessed at: www.uroweb.org
- Shi G, Lu D, Liu Z, Liu D, Zhou X. Robotic assisted surgery for gynaecological cancer. *Cochrane Database of Systematic Reviews* 2012, Issue 1. Art. No.: CD008640. DOI: 10.1002/14651858.CD008640.pub2

13. Rosengart TK, Feldman T, Borger MA, et al.; American Heart Association Council on Cardiovascular Surgery and Anesthesia; American Heart Association Council on Clinical Cardiology; Functional Genomics and Translational Biology Interdisciplinary Working Group; Quality of Care and Outcomes Research Interdisciplinary Working Group. Percutaneous and minimally invasive valve procedures: a scientific statement from the American Heart Association Council on Cardiovascular Surgery and Anesthesia, Council on Clinical Cardiology, Functional Genomics and Translational Biology Interdisciplinary Working Group, and Quality of Care and Outcomes Research Interdisciplinary Working Group. *Circulation*. 2008;117(13):1750-1767. Available at: <http://circ.ahajournals.org/cgi/content/full/117/13/1750>
14. Ramsey C, Pickard R. Systematic review and economic modelling of the relative clinical benefit and cost-effectiveness of laparoscopic surgery and robotic surgery for removal of the prostate in men with localised prostate cancer. *Health Technol Assess*. 2012;16(41):1-313. doi: 10.3310/hta16410.
15. Mi J, Kang Y, Chen X, et al. Whether robot-assisted laparoscopic fundoplication is better for gastroesophageal reflux disease in adults: a systematic review and meta-analysis. *Surg Endosc*. 2010 Jan 29. [Epub ahead of print]
16. Gurusamy KS, Samraj K, Fusai G, Davidson BR. Robot assistant for laparoscopic cholecystectomy. *Cochrane Database Syst Rev*. 2009 Jan 21;(1):CD006578.
17. Alqahtani A, Albassam A, Zamakhshary M, et al. Robot-Assisted Pediatric Surgery: How Far Can We Go? *World J Surg*. 2010 Feb 3. [Epub ahead of print]
18. Cundy TP, Marcus HJ, Clark J, et al. Robot-Assisted Minimally Invasive Surgery for Pediatric Solid Tumors: A Systematic Review of Feasibility and Current Status. *Eur J Pediatr Surg*. 2013 May 17. [Epub ahead of print]
19. Wiedemann D, Bonaros N, Schachner et al. Surgical problems and complex procedures: issues for operative time in robotic totally endoscopic coronary artery bypass grafting. *J Thorac Cardiovasc Surg*. 2012 Mar;143(3):639-647.e2. Epub 2011 Jun 30.
20. Ramzey D, Trento A, Cheng W et al. Three hundred robotic-assisted mitral valve repairs: The Cedars-Sinai experience. *J Thorac Cardiovasc Surg*. 2013 Nov 4. pii: S0022-5223(13)01131-8. doi: 10.1016/j.jtcvs.2013.09.035. [Epub ahead of print]
21. Witjes JA, Comp  rat E, Cowan NC, De Santis M, Gakis G, Lebre  t T, Ribal MJ, Sherif A. Guidelines on muscle-invasive and metastatic bladder cancer. Arnhem (The Netherlands): European Association of Urology (EAU); 2013 Mar. 82 p.
22. Cirocchi R, Boselli C, Santoro A et al. Current status of robotic bariatric surgery: a systematic review. *BMC Surgery*. 2013; 13:53. Accessed at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3826835/>
23. Bailey JG, Hayden JA, Davis PJ, et al. Robotic versus laparoscopic Roux-en-Y gastric bypass (RYGB) in obese adults ages 18 to 65 years: a systematic review and economic analysis. *Surg Endosc*. 2013 Oct 3. [Epub ahead of print]

Professional Society Guidelines

24. American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) 2011 Guideline for Coronary Artery Bypass Graft Surgery: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2011;124:e652-e735. Accessed at: <http://circ.ahajournals.org/content/124/23/e652>
25. American Urological Association: Standard operating practices for urologic robotic surgery. April, 2013.
26. Breedon JT. Statement on Robotic Surgery by ACOG President James T. Breedon, MD [news release]. American Congress of Obstetricians and Gynecologists. March 14, 2013.
27. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). Clinical Practice Guidelines. Accessed at: <https://www.sages.org/publications/guidelines/>

Other Resources

28. Intuitive Surgical. da Vinci® overview. Accessed at: <http://www.intuitivesurgical.com/products/>
29. Hayes a Tract Manager Company. Medical Technology Directory:
 - Pediatric Robotic-Assisted Surgery. Winifred Hayes Inc. Lansdale, PA. July 2, 2010. Updated 2014. Archived 2015.
 - Robotic Assisted Prostatectomy. Winifred Hayes Inc. Lansdale, PA. 2008. Updated 2012. Archived 2013.
 - Comparative Effectiveness Review of Robotically Assisted Hysterectomy. 2018. Updated Oct, 2019.
30. Hayes a TractMananger Company. Medical Technology Brief:
 - Robotically Assisted Mitral Valve Repair Using the da Vinci Surgical System (Intuitive Surgical Inc.). Winifred Hayes Inc. Lansdale, PA. Updated 2015. Archived 2016.
 - Robotically Assisted Atrial Septal Defect Repair Using the da Vinci Surgical System (Intuitive Surgical Inc.). Winifred Hayes Inc. Lansdale, PA. 2010. Updated 2012. Archived 2013.
31. UpToDate: [website]: [website]. Waltham, MA: Walters Kluwer Health; 2021.
 - Paraiso MFR, Falcone T. Robot-assisted laparoscopy.
 - Lyons T. Laparoscopic approach to hysterectomy.
 - Plaxe S. Endometrial carcinoma: Pretreatment evaluation, staging, and surgical treatment.
 - Klein E. Radical prostatectomy for localized prostate cancer.
 - Aldea GS. Minimally invasive aortic and mitral valve surgery.
 - Aldea GS. Minimally invasive coronary artery bypass graft surgery: Definitions and technical issues.
32. Advanced Medical Review (AMR): Policy reviewed by a practicing physician board certified in Surgery General, Surgery Vascular, Surgical Critical Care, Surgery. Jan 21, 2014.

REVIEW/REVISION HISTORY

3/8/18, 6/19/19, 4/23/20, 4/5/21: Policy reviewed, no changes to criteria.