Clinical Policy Title: Laparoscopic prostatectomy

Clinical Policy Number: 13.03.05

Effective Date: October 1, 2017
Initial Review Date: September 21, 2017
Most Recent Review Date: October 19, 2017
Next Review Date: October 2018

Policy contains:
- Benign prostatic hyperplasia.
- Prostate cancer.
- Laparoscopic prostatectomy.

Related policies:
- CP# 05.02.02 Brachytherapy for localized prostate cancer
- CP# 13.02.03 Management of benign prostatic hyperplasia
- CP# 18.03.01 Robotic-assisted surgery

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’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 Select Health of South Carolina 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. Select Health of South Carolina’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. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of laparoscopic prostatectomy (or laparoscopic radical prostatectomy [LRP]) to be clinically proven and, therefore, medically necessary for the following indications when performed by a surgeon experienced in laparoscopic urological procedures:

- Curative treatment for clinically localized prostate cancer that can be completely excised surgically with or without pelvic lymph node dissection in members who have no serious comorbidities that would contraindicate surgery (American Urological Association [AUA], 2017; National Comprehensive Cancer Network [NCCN], 2017).
- Palliative treatment of benign prostatic hyperplasia (BPH) in members who are appropriate candidates for simple open prostatectomy and have one or more of the following (AUA, 2014):
  - Moderate-to-severe lower urinary tract symptoms (LUTS) or significant symptoms unresolved by other means.
  - Acute urinary retention.
Renal insufficiency secondary to BPH.
- Recurrent urinary tract infections.
- Bladder stones or gross hematuria due to BPH. See CP# 13.02.03 Management of benign prostatic hyperplasia.

Limitations:

Relative contraindications to laparoscopic prostatectomy include those that may complicate organ dissection, including, but not limited to (Tanaka, 2009):
- Previous abdominal or perineal surgery.
- Prior radiation to the prostate.
- Morbid obesity.
- Large prostate size (e.g., > 100 g).

Robotic assistance added to laparoscopic prostatectomy is not medically necessary and not separately reimbursable. See CP# 18.03.01 Robotic-assisted surgery.

Alternative covered services:

- Pharmacologic drug classes (e.g., alpha-adrenergic antagonists (alpha-blockers), 5-alpha-reductase inhibitors (5-ARIs), anticholinergics, and phytotherapeutics).
- Watchful waiting and active surveillance.
- For localized prostate cancer:
  - Surgery: open radical prostatectomy.
  - Radiation therapy (e.g., external beam radiation therapy [EBRT] and brachytherapy).
  - Hormonal manipulation.
- For BPH. See CP# 13.02.03 Management of benign prostatic hyperplasia:
  - Surgery: transurethral resection of the prostate (TURP); transurethral incision of the prostate (TUIP); simple open prostatectomy.
  - Minimally invasive treatment: transurethral electrical vaporization of the prostate (TUEVP, TUVP, or TVP); transurethral vapor resection (TUVRP); transurethral microwave thermotherapy (TUMT); transurethral needle ablation (TUNA); or radiofrequency needle ablation (RFNA).
  - Laser therapy: contact laser ablation of the prostate (CLAP); holmium laser ablation, enucleation, or resection (HoLAP, HoLEP, HoLRP); noncontact visual ablation (VLAP); photoselective vaporization of the prostate; laser vaporization and laser ablation/coagulation; stents (e.g., UroLume® endourethral prosthesis).

Background
Male LUTS are responsible for considerable morbidity and disability, particularly among older men (Parsons, 2010). The most common cause of LUTS is BPH, the incidence and prevalence of which are increasing rapidly as the U.S. population ages. BPH is caused by the abnormal growth of benign prostate cells that enlarges the prostate gland, resulting in increased frequency of urination, hesitancy, nocturia, urgency, and weak urinary stream.

Prostate cancer is the second most common cancer in American men (American Cancer Society [ACS], 2017). About one in seven men will be diagnosed with prostate cancer during his lifetime, and the ACS estimates 161,360 new cases of prostate cancer in the United States in 2017. Despite its prevalence, the natural history of the disease is heterogeneous and not well understood. Most prostate cancers are diagnosed at an early stage as a result of prostate-specific antigen (PSA) screening and are asymptomatic at the time of diagnosis. When cancer is confined to the prostate gland, treatment is often curative as survival often exceeds five years; treatment is rarely curative for cancers extending beyond the prostate gland (National Cancer Institute [NCI], 2017).

Treatment:

Treatment of BPH focuses on reducing symptom severity. Symptoms typically appear slowly and progress gradually over time, and treatment options progress from watchful waiting to medical management, and finally to surgical intervention. Surgery is generally reserved for failed medical therapy or a desire to discontinue medical therapy. TURP is the accepted surgical treatment for relieving bladder outlet obstruction secondary to BPH, but is associated with significant morbidity (e.g., bleeding, blood transfusion) and prolonged hospital stay. Most minimally invasive alternatives apply heat from lasers, microwaves, radiofrequency, high-intensity ultrasound waves, and high-voltage electrical energy to ablate the hyperplastic lesion. Simple open prostatectomy (enucleation of the hyperplastic adenoma within the prostate) is an option for patients with very large prostates or for whom minimally invasive procedures are contraindicated (American Urological Association [AUA], 2014).

Standard therapies for prostate cancer include open surgery, various forms of radiation therapy (e.g., EBRT and interstitial implantation of radioisotopes), hormonal manipulation, and active surveillance or watchful waiting (NCI, 2017). The most commonly applied curative treatment is radical prostatectomy usually with pelvic lymphadenectomy for patients with cancer confined to the prostate gland (American Joint Committee on Cancer [AJCC] Cancer Staging Stage I or II) who are in good health and elect surgical intervention (Edge, 2010).

Conventional open, radical prostatectomy incorporates open retropubic or perineal access and is associated with substantial morbidity, the most common being urinary incontinence, urethral stricture, and impotence, as well as morbidity associated with general anesthesia and major surgery (ACS, 2017). It can be difficult to perform after a TURP.
Nerve-sparing and minimally invasive laparoscopic approaches, along with robotic assistance, represent advances in prostatectomy. Laparoscopic approaches apply several small incisions for intra-abdominal access.

**Searches**

Select Health of South Carolina 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 (CMS).

We conducted searches on August 10, 2017. Search terms were: “Prostatectomy (MeSH),” “Laparoscopy (MeSH),” and “Prostatic Hyperplasia (MeSH),” and the free text terms “radical prostatectomy” and “laparoscopic prostatectomy.”

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**

We found four systematic reviews, including one economic analysis, and three evidence-based guidelines for this policy. For treating localized prostate cancer, the evidence for LRP consists of non-randomized observational studies and limited direct comparisons from two randomized controlled trials (RCTs) (Allan, 2016; De Carlo, 2014; Robertson, 2013). The data suggest the safety and short-term (less than 12 months) outcomes of LRP, robotic-assisted laparoscopic radical prostatectomy (RALP), and open radical prostatectomy are at least comparable. Laparoscopic approaches are more time-consuming and costly, but are associated with lower blood loss, need for transfusion, catheterization time, hospitalization duration, and complication rates. There remains uncertainty surrounding the long-term effectiveness of the laparoscopic approaches relative to the open procedures. Both NCCN (2017) and AUA (2017) guideline recommendations are consistent with these findings.

The evidence supporting minimally invasive simple prostatectomy (MISP) for treating BPH is far more limited, consisting entirely of non-randomized comparative studies. The advantages and disadvantages
of MISP over open prostatectomy appear similar to those for treating localized prostate cancer (Lucca, 2015). While the AUA recommends TURP for surgical treatment of BPH in most cases, open and laparoscopic simple prostatectomy may be alternatives for treating moderate-to-severe LUTS and significant symptoms unresolved by other means (AUA, 2014).

NCCN (2017), De Carlo (2014), and Robertson (2013) highlighted the importance of surgical proficiency in achieving optimal surgical outcomes, as overall complications and surgical outcomes improve with the level of experience. The existing literature lacks a precise definition of surgical competency for urologic procedures in terms of a minimum number of procedures (Abboudi, 2014), but the AUA has issued guidance for specific training and credentialing in laparoscopic techniques with or without robot assistance to institutions responsible for privileging surgeons (AUA, 2016).

**Policy updates:**

None.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tr>
<td><strong>Key points:</strong></td>
<td>Clinicians should inform patients with localized prostate cancer that robotic, laparoscopic, or perineal techniques are associated with less blood loss than retropubic prostatectomy. (Strong recommendation; evidence level: Grade B — based on RCTs with some weaknesses of procedure or generalizability or moderately strong observational studies with consistent findings.)</td>
</tr>
<tr>
<td>AUA (2017) for the AUA/American Society for Radiation Oncology (ASTRO)/Society of Urologic Oncology (SUO) Guideline: Clinically localized prostate cancer</td>
<td><strong>Key points:</strong></td>
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<tr>
<td>NCCN (2017) Guideline: Prostate cancer</td>
<td>• Radical prostatectomy is appropriate for any patient with clinically localized prostate cancer that can be completely excised surgically, who has a life expectancy of at least 10 years, and who has no serious comorbidities that would contraindicate surgery.</td>
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<td>Allan (2016) LRP vs. RALP for localized prostate cancer</td>
<td>• Systematic review and meta-analysis of two RCTs.</td>
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<td>Lucca (2015)</td>
<td>• Significantly higher rate of return of erectile function (relative risk [RR] 1.51, 95% confidence interval [CI] 1.19 to 1.92) and return to continence function (RR 1.14; 95% CI 1.04 to 1.24) with RALP.</td>
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<tr>
<td></td>
<td>• RALP was more efficient at preserving the erectile function and continence vs. LRP.</td>
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<tr>
<td>Citation</td>
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| MISP versus open simple prostatectomy for BPH | - Systematic review of 27 observational studies with 764 total patients.  
- Overall quality: low with high risk of bias.  
- MISP had lower length of hospital stay (weighted mean difference [WMD] -1.6 days, p = 0.02), length of catheter use (WMD -1.3 days, p = 0.04) and estimated blood loss (WMD -187 ml, p = 0.015), but longer operative time (WMD 37.8 min, p < 0.0001).  
- No differences in improvements in peak flow rate, International Prostate Symptom Score, or perioperative complications between procedures; 104 (13.6%) developed a surgical complication.  
- MISP seems a effective and safe as open procedure.  
- Prospective RCTs needed to define the standard surgical treatment for large prostates. |
| AUA (2014) Guideline: Management of BPH | **Key points:**  
- Surgery is recommended for renal insufficiency secondary to BPH, recurrent urinary tract infections (UTIs), bladder stones or gross hematuria due to BPH, and LUTS refractory to other therapies. Bladder diverticulum is not an absolute indication for surgery unless associated with recurrent UTI or progressive bladder dysfunction.  
- TURP remained the benchmark for therapy.  
- Open prostatectomy (retropubic, suprapubic) is an alternative for moderate to severe LUTS and/or significant symptoms.  
- Laparoscopic or robotic prostatectomy is considered investigational but may be an alternative for moderate to severe LUTS and/or significant symptoms. There is insufficient published data on which to base a treatment recommendation.  
- Other surgical options include application of holmium laser ablation, enucleation, and resection of the prostate, photoselective vaporization of the prostate, transurethral incision of the prostate, and transurethral vaporization of the prostate. |
| De Carlo (2014) Retropubic radical prostatectomy (RRP), LRP, and RALP for prostate cancer | **Key points:**  
- Systematic review of 44 comparative studies.  
- Overall quality: low with high risk of bias, incomplete reporting (e.g., lymph node status).  
- Compared to RRP, both laparoscopic approaches were more time-consuming and more costly, but had superior blood loss rates, transfusion rates, catheterization time, hospitalization duration, and complication rates.  
- RALP may have better functional and oncological outcomes.  
- Superiority of any surgical approach not proven in terms of functional and oncologic outcomes, but cost comparison clearly supports RRP.  
- Surgical outcomes depend more on surgical expertise and less on surgical approach. |
| Robertson (2013) Relative effectiveness of RALP v. LRP for localized prostate cancer | **Key points:**  
- Systematic review and mixed treatment comparison meta-analysis of one RCT and 57 non-randomized comparative studies (19,064 total men).  
- Overall quality: low with high risk of bias.  
- Results [odds ratio [OR], 95% credible interval [CrI]]:  
  - RALP had a lower risk of major intra-operative harms such as organ injury (0.4% robotic vs 2.9% laparoscopic; OR 0.16, 95% CrI 0.03 to 0.76) and a lower |
risk of positive surgical margins (17.6% robotic vs 23.6% laparoscopic; OR 0.69, 95% CrI 0.51 to 0.96).
- No difference in the proportion of men with urinary incontinence at 12 months (OR 0.55, 95% CrI 0.09 to 2.84).
- Insufficient data on sexual dysfunction or long-term effectiveness.
- Limited data suggest no difference in surgeon learning rates for each procedure.
- Considerable uncertainty in results.

References

Professional society guidelines/other:


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs identified 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.

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<th>Description</th>
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<td>55866</td>
<td>Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed</td>
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<td>C61.</td>
<td>Malignant neoplasm of prostate</td>
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