Clinical Policy Title: Penile implant after prostate cancer surgery

Clinical Policy Number: CCP.1338

Effective Date: October 1, 2017
Initial Review Date: September 21, 2017
Most Recent Review Date: October 2, 2018
Next Review Date: October 2019

Related policies:

CCP.1117 Brachytherapy for localized prostate cancer
CCP.1141 Immunotherapies for prostate cancer and acute lymphoblastic leukemia
CCP.1244 Management of benign prostate hyperplasia

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

Coverage policy

AmeriHealth Caritas considers the use of penile implants following prostate cancer surgery to be clinically proven, and, therefore, medically necessary, when all of the following criteria are met:

- Members are males age 18 and over.
- The history and physical exam of the member documents sexual dysfunction.
- Medical therapies such as testosterone; replacement therapy using topical creams, patches, or intramuscular injections; or phosphodiesterase 5 inhibitors have been tried and failed.

Replacement of a penile implant is considered clinically proven, and, therefore, medically necessary, when all the following criteria are met:

- The device malfunctions, breaks, or becomes infected.
Medical necessity criteria continue to be met.
Replacement is not part of the manufacturer warranty (Burnett, 2018; Levine, 2016; Bella, 2015; Hatzimouratidis, 2010; Montague, 2007).

Limitations:

All other uses of penile implants after prostate cancer are considered investigational/experimental, and therefore not medically necessary.

Alternative covered services:

- Counseling.
- Pellets (suppositories) placed in the penis.
- Prescription drugs for erectile dysfunction.
- Vacuum erection devices.
- Vascular reconstruction surgery.

Background

Radical prostatectomy is one treatment option for prostate cancer. Many males undergoing this procedure will experience some erectile dysfunction after surgery, due to the delicate nature of nerves, muscles, and blood vessels that control erections, which are weakened by surgery. The surgery is associated with a number of side effects, among them impotence (> 50 percent of patients), ejaculatory dysfunction (100 percent), and orgasmic dysfunction (50 percent) (McCullough, 2005).

A total of 138,000 prostatectomy procedures were performed in the United States in 2010; 54 percent were on individuals age 65 and older, and 46 percent were on individuals age 45 to 64 (CDC, 2016). Early in the century, the procedure was performed more frequently, rising 74 percent from 2000 to 2008 (Anderson, 2013). In 2012, the U.S. Preventive Services Task Force recommended watchful waiting in some cases that otherwise would result in radical prostatectomy. As a result, the number of such procedures in the United States fell by 16.2 percent from 2012 to 2016 (Halpern, 2017).

A meta-analysis of impotence rates for males after radical prostatectomy showed ranges for 12 months (10 to 46 percent), and 24 months (6 to 37 percent). A significantly higher (Odds Ratio = 2.84) potency rate after robotic-assisted, compared to retropubic, radical prostatectomy has been observed, while an insignificantly higher (Odds Ratio = 1.89) rate was documented for robotic-assisted, versus laparoscopic, radical prostatectomy (Ficarra, 2012).

Oral phosphodiesterase 5 inhibitors, which re-oxygenate erectile tissue and avoid eventual neuropraxia, are considered the first line treatment for erectile dysfunction after prostate surgery. Appropriate counselling on intracavernous treatment should be considered for patients who do not properly respond.
to these inhibitors. Penile prosthesis implants are considered a third-line treatment for males with erectile dysfunction after prostatectomy (Capogrosso, 2016).

There are three basic kinds of penile implants: semi-rigid (malleable) implant, two-piece inflatable implant, and three-piece inflatable implant. Inflatable implants are a pair of tubes placed into the penis, connected to a pump in the scrotum; the pump is squeezed to obtain an erection. Malleable implants are a pair of bendable rods placed inside the penis; the penis, and thus the rods, is manually moved into a suitable position before sex (Bergman, 2015).

Penile prostheses can also be used for men with Peyronie’s disease, corporal fibrosis due to infection, trauma, prior prosthesis explantation, priapism, and men who have undergone construction of a neophallus (Levine, 2016). A registry at Johns Hopkins Hospital found that, of men with penile prosthesis implantation, 45 percent had undergone prostatectomy (Segal, 2014).

A review of the medical literature indicates higher infection rates after penile prosthesis revision in a clinically uninfected patient than a first-time implantation. Combining infection-retardant coated components, vigorous washout, proper preparation of skin incision site, use of perioperative antibiotics, and avoiding contact between the patient's skin and the implant will reduce infections (Hinds, 2012).

**Searches**

AmeriHealth Caritas 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 3, 2018. Search terms were: “prostate surgery,” “prostatectomy,” “penile implant,” “penile prostheses,” “erectile dysfunction,” and “impotence.”

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**
The U.S. Center for Medicare & Medicaid Services has a longstanding National Coverage Determination on Diagnosis and Treatment of Impotence, which serves as the basis for the coverage policy section of this report. The initial guideline for erectile dysfunction from the American Urological Association, first published in 2005 and updated in 2007, considers penile implants as one of five treatments for the condition (Montague, 2007). The Association’s 2018 guideline lists a number of treatment options for the disease, and includes penile implant; patients considering this option should be counseled about what it entails, along with risks and benefits (Burnett, 2018). The Canadian Urological Association also has a guideline on erectile dysfunction, declaring surgery to be “an important option for men refractory to medical management” (Bella, 2015).

The 2015 International Consultation on Sexual Medicine performed a systematic review and created a guideline on penile prostheses. Despite limited level 1 and 2 evidence, the group recommended a prosthesis be considered for erectile dysfunction not responding to less invasive methods including oral treatment with phosphodiesterase 5 inhibitors, vacuum erection device, and intracorporal injection therapy. Patients must be informed of potential benefits and risks, including mechanical failure, infection, shortening of the penis, change in penis sensation or configuration, and injury to local structures (Levine, 2016). The European Association of Urology concluded that penile implant be considered as a third-line therapy after other, less invasive therapies have failed (Hatzimouratidis, 2015).

A 2015 review of rehabilitation of men with erectile dysfunction after radical prostatectomy failed to conclude which type of treatment was optimal and did not list penile implant surgery as one option (Gandablia, 2015). This review exemplifies the ongoing relative paucity of good-quality data to evaluate the efficacy of penile implant surgery. A literature review indicates that robotic surgery in radical prostatectomy and nerve-sparing techniques have helped reduce the incidence of post-operative erectile dysfunction, and that any consideration of penile implant must be preceded by proper patient counseling of risks and benefits (Capogrosso, 2016).

Almost no head-to-head comparisons between types of erectile dysfunction treatment are available. One study of 54 men who underwent nerve-sparing radical prostatectomy and presented with erectile dysfunction six months after surgery were assigned to receive a phosphodiesterase 5 inhibitor (tadalafil) or undergo a penile implant. The degree of change (improvement) after two years in the International Index of Erectile Function was significantly greater in the penile prosthesis group (20.4 versus 8.1, $P < .001$), although improvements for both treatments were considered significant (Megas, 2013).

Over time, the three-component device has become the most often used type of penile implant. A recent multi-institutional study of 353 implants by the Italian Society of Andrology, a national registry launched in December 2014, observed that 288 were three-component devices, compared to just 45 non-hydraulic devices and 20 two-component devices (Pescatori, 2016).

A systematic review of 22 studies compared outcomes for penoscrotal and infrapubic incisions, each a surgical technique for three-piece inflatable penile prosthesis. The infrapubic approach is faster, but
other measures showed no difference between the two groups. No cases of glans hypoesthesia after placement are reported; the peri-prosthetic infection rate was below 3.3 percent, and patient satisfaction exceeded 80 percent (Palmisano, 2018).

An early prospective cohort study of 331 men who underwent penile prosthesis surgery and were followed for 10 years identified a number of adverse events, including mechanical failure of the prosthesis (seven percent); wound infection, most of which were abscesses requiring surgical removal of the prosthesis (six); pain over one week (six); swelling over one month (five); and temporary hematoma pains (five) (Chiang, 2000).

A systematic review summarized the outcomes of penile prostheses after surgical implant, for men who failed to improve using more conservative measures. Three-piece penile prostheses had mechanical survival of 81 – 94 percent, 68 – 89 percent, and 57 – 76 percent after five, 10, and 15 years, respectively. Infection rates range from 1 – 2 percent and 2 – 3 percent for low- and high-risk populations after five and 10 years. Patient and partner satisfaction for low- and high-risk groups are essentially similar, ranging from 92 – 100 percent and 91 – 95 percent after five and ten years. Two-piece and malleable devices are associated with slightly higher mechanical reliability and decreased patient satisfaction (Trost, 2013a). Similar survival data for inflatable penile prosthesis — 96 percent at five years and 60 percent at 15 years — have been reported elsewhere (Henry, 2012).

High levels of patient satisfaction are linked with decreased preoperative expectations, favorable female partner sexual function, body mass index < 30, absence of Peyronie’s disease, and no prior prostatectomy. Elevated dissatisfaction levels are linked with perceived or actual loss of penile length; decreased glandular engorgement; altered erectile or ejaculatory sensation; pain; diminished cosmetic outcome; difficulty with device function; partner dissatisfaction; and perception of unnatural sensation, complications, and extent of alternative treatments offered (Trost, 2013b).

Revision procedures are sometimes required for surgically-implanted penile prostheses. Of 186 patients requiring revision procedures, 65 percent experienced mechanical failure, and 19 percent experienced combined erosion or infection. A total of 93 percent of cases were successfully revised, resulting in functioning penile prostheses (Henry, 2012).

A comparison was made of 180 men who received penile implants, who were divided into those who had had radical prostatectomy (n = 84) and those who had diabetic and metabolic syndrome (n = 96). No difference was observed after 12 months between the groups according to the International Index of Erectile Function-5 (21.0 and 20.4, \(P = .65\)). The Erectile Dysfunction Inventory of Treatment Satisfaction comparison was also similar (73.9 and 71.1, \(P = .55\)) (Antonini, 2016).

A 1998 – 2005 study of 65,558 Medicare patients age 66 and older a found that just 2.3 percent and 0.3 percent (0.8 percent total) who had radical prostatectomy or radiotherapy for prostate cancer eventually had a penile implant for erectile dysfunction. Authors conclude that, given the rates of postsurgical erectile problems, these data constitute an under-utilization of the procedure (Tal, 2011).
Policy updates:

A total of two guidelines/other and two peer-reviewed references were added to this policy in August 2018.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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</thead>
<tbody>
<tr>
<td>Trost (2013a)</td>
<td>Key points:</td>
</tr>
</tbody>
</table>
| Improvements in mechanical survival, infections, and satisfaction with penile implants | • Review of improvements in penile prostheses for men who failed to improve using more conservative measures; most reports included at least 12 months of follow-up.  
  • Recent notable device enhancements include Parylene coating, Bioflex® material, Inhibizone™ antibacterial impregnation, hydrophilic coating, lockout valves, and easy release pump mechanisms.  
  • Three-piece penile prostheses had mechanical survival of 81 – 94 percent (%), 68 – 89%, and 57 – 76% after five, 10, and 15 years, respectively.  
  • Infection rates range from 1 – 2%, and 2 – 3% for low- and high-risk populations.  
  • Patient and partner satisfaction for low- and high-risk groups range from 92% – 100 percent and 91 – 95%.  
  • Two-piece and malleable devices are associated with slightly higher mechanical reliability and decreased patient satisfaction. |
| Megas (2013)  | Key points:                       |
| Outcomes of treating erectile dysfunction with phosphodiesterase 5 versus. penile implant | • Controlled trial of 54 men who underwent nerve-sparing radical prostatectomy and presented with erectile dysfunction six months after surgery; participants were assigned to receive a phosphodiesterase 5 inhibitor (tadalafil) or undergo a penile implant.  
  • Significant reductions using the International Index of Erectile Function were observed in both treatment groups after two years.  
  • The improvement after two years using the International Index of Erectile Function was significantly greater in the penile prosthesis group (20.4 versus 8.1, P < .001). |
| Henry (2012)  | Key points:                       |
| Reasons for and success in revisions, survival of penile prostheses | • Survival data for inflatable penile prosthesis — 96 and 60% (five and 15 years).  
  • Study of four institutions. Inflatable penile implant revisions performed on 214 patients; 186 had complete data; average age, 66 years  
  • 65 percent of patients experienced mechanical failure, and 19 percent experienced combined erosion or infection.  
  • A total of 93% of cases were successfully revised, resulting in functioning penile prostheses. |
<table>
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</thead>
<tbody>
<tr>
<td>Tal (2011)</td>
<td><strong>Key points:</strong></td>
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</table>
| Utilization of penile implants | • A 1998 – 2005 study of 65,558 males covered by Medicare age 66 or older treated with radical prostatectomy (n = 15,811) or radiotherapy (n = 52,747).
• Only 2.3% of men with radical prostatectomy and 0.3 percent with radiotherapy (0.8% total) eventually had a penile implant for erectile dysfunction.
• Men who are younger, African American, or Hispanic, and those who have a radical prostatectomy, are more likely to have a penile implant after prostate cancer treatment.
• Authors conclude that, given the rates of post-surgical erectile problems, these data constitute an under-utilization of the procedure. |

**References**

**Professional society guidelines/other:**


Peer-reviewed references:


**Centers for Medicare & Medicaid Services National Coverage Determinations:**

230.4 Diagnosis and Treatment of Impotence. Effective date long-standing, not posted.

**Local Coverage Determinations:**

No Local Coverage Determinations 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.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>54400</td>
<td>Insertion of penile prosthesis; non-inflatable (semi-rigid)</td>
<td></td>
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<tr>
<td>54401</td>
<td>Insertion of penile prosthesis; inflatable (self-contained)</td>
<td></td>
</tr>
<tr>
<td>54405</td>
<td>Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir</td>
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<tr>
<td>CPT Code</td>
<td>Description</td>
<td>Comments</td>
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<tr>
<td>54406</td>
<td>Removal of all components of a multi-component, inflatable penile prosthesis without replacement of prosthesis</td>
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<tr>
<td>54408</td>
<td>Repair of component(s) of a multi-component, inflatable penile prosthesis</td>
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<tr>
<td>54410</td>
<td>Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session</td>
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<tr>
<td>54412</td>
<td>Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis</td>
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<tr>
<td>54415</td>
<td>Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis</td>
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<td>54416</td>
<td>Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session</td>
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<tr>
<td>54417</td>
<td>Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue</td>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
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<tr>
<td>N52.31</td>
<td>Erectile dysfunction following radical prostatectomy</td>
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<tr>
<td>T83.490A-T83.490S</td>
<td>Other mechanical complication of implanted penile prosthesis</td>
<td></td>
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<tr>
<td>Z85.06</td>
<td>Personal history of malignant neoplasm of prostate</td>
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<thead>
<tr>
<th>HCPCS Level II Code</th>
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<tr>
<td>C1813</td>
<td>Prosthesis, penile, inflatable</td>
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<tr>
<td>C2622</td>
<td>Prosthesis, penile, non-inflatable</td>
<td></td>
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