Photoselective Vaporization of the Prostate (PVP)

[For the list of services and procedures that need preauthorization, please refer to www.mcs.com.pr, go to “Proveedores”, and click “Políticas Médicas”.]

Medical Policy: MP-SU-01-08
Original Effective Date: April 28, 2008
Revised: July 16, 2019
Next Revision: July, 2020

This policy applies to products subscribed by the following corporations, MCS Life Insurance Company (Commercial), and MCS Advantage, Inc. (Classicare) and Medical Card System, Inc., provider’s contract; unless specific contract limitations, exclusions or exceptions apply. Please refer to the member’s benefit certification language for benefit availability. Managed care guidelines related to referral authorization, and precertification of inpatient hospitalization, home health, home infusion and hospice services apply subject to the aforementioned exceptions.

DESCRIPTION

Benign prostatic hyperplasia (BPH) refers to proliferation of glandular epithelial tissue, smooth muscle, and connective tissue within the transition zone of the prostate. It becomes increasingly common as men age. BPH can lead to lower urinary tract symptoms (LUTS), such as urinary urgency, hesitancy, or frequency, and dysuria. Men with clinically significant LUTS attributable to BPH can be treated medically with one or more classes of drugs. Those who do not find adequate relief with medical treatment may benefit from surgical resection or ablation of prostate tissue around the urethra to enlarge the urethral channel.

Photoselective vaporization (PVP) is an alternative minimally invasive treatment that uses laser energy to vaporize prostate tissue, similar to plasma vaporization. The general procedure is similar to that of traditional (monopolar) TURP and saline usually is used as an irrigation solution. Photoselective vaporization (PVP, GreenLight laser) of the prostate is based upon the concept of selective photothermolysis (i.e., selective thermal confinement of light-induced damage). Selected wavelengths of laser light are targeted to different constituents of the tissue to ablate the prostate tissue. The KTP (potassium-titanyl-phosphate) laser (e.g., GreenLight laser) uses a wavelength of 532 nm, which is near the peak absorption of blood. A disadvantage of the KTP laser is coagulative necrosis (not vaporization) in poorly vascularized tissues.

PVP can be performed under local/regional anesthesia as an outpatient procedure, and an office-based procedure has been described. The Physician typically perform these type of procedure in the hospital and observe the patient for one day. The main disadvantage of PVP is that it takes more time than TURP, but, like other non-TURP procedures, blood loss is less. In many instances, less prostatic tissue is removed with PVP compared with TURP.

The GreenLight Laser System (American Medical Systems [formerly manufactured by Laserscope, Inc.]) is a KTP laser used for photoselective vaporization, among many other indications. According to the U.S. Food and Drug Administration (FDA), when used at 532 nm, it is intended to hemostatically vaporize prostate tissue of men with BPH. The FDA also indicates that; the device is not intended to treat prostate cancer.
COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate member certificate and subscriber agreement contract for applicable diagnostic imaging, DME, laboratory, machine tests, benefits and coverage.

INDICATIONS
Medical Card System, Inc., (MCS) will consider the use of Photoselective Vaporization of the Prostate (PVP) as medically necessary, for Both the Commercial & Classicare Lines of Business (LOB), under the following clinical scenario:

1. Treatment for patients with BPH who have clinically documented obstructive and voiding symptoms and no clinical signs of prostate cancer.

2. As a treatment modality for patients with bladder neck obstruction secondary to Benign Prostatic Hyperplasia (BPH), evidenced by All of the following:
   a. Duration of BPH 3 months or longer;
   b. American Urology Association (AUA) symptom score greater than 9 (moderate to severe); &
   c. Peak Urinary Flow Rate less than 10 mL/sec, which is more suggestive of an obstructed state.

CONTRAINDICATIONS
1. Active urine infection.
2. PVP should not be used in patients with:
   a. Carcinoma of the prostate.
   b. Desire for future fertility.
   c. Inability to receive endoscopic treatment.
   d. Intolerance to anesthesia.

LIMITATIONS
1. Urodynamics and Post-void Residual Volume examinations should be used as appropriate, e.g., patients with suspected neurologic disease or those who have failed prostate surgery.
2. The use of these devices must be prescribed and administered under the personal supervision of a qualified and trained physician, after appropriate urological evaluation of the patient.

3. The treating physician must be present at all times during the treatment.

**CODING INFORMATION**

_CPT® Codes (List may not be all inclusive)_

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>52648</td>
<td>Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)</td>
</tr>
</tbody>
</table>


**ICD-10 Codes (List may not be all inclusive)**

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>D29.1</td>
<td>Benign neoplasm of prostate</td>
</tr>
<tr>
<td>N40.1</td>
<td>Enlarged prostate with lower urinary tract symptoms</td>
</tr>
<tr>
<td>N40.3</td>
<td>Nodular prostate with lower urinary tract symptoms</td>
</tr>
</tbody>
</table>

**REFERENCES**


Intended Use/Indications for Use. Accessed July 2, 2019. Available at URL address:
http://www.bostonscientific.com/content/dam/bostonscientific/uro-wh/portfolio-

Information. Accessed July 2, 2019. Available at URL address:

7. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA) Billing and Coding
for Laser Ablation of the Prostate (A56467). Contractor Name: CGS Administrators, LLC.
Geographical Jurisdiction: Kentucky. Original Effective Date: For services performed on or after
10/01/2015. Revision Effective Date: N/A. Accessed July 2, 2019. Available at URL address:

8. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) for Laser
Ablation of the Prostate (L34090). Contractor Name: CGS Administrators, LLC. Geographical
Jurisdiction: Kentucky. Original Effective Date: For services performed on or after 10/01/2015.
Revision Effective Date: For services performed on or after 04/11/2019. Accessed July 2, 2019.
Available at URL address: https://www.cms.gov/medicare-coverage-database/details/lcd-
details.aspx?LCID=34090&ver=10&CntrcrSelected=228*2&Cntrctr=228&name +=(15102%2c+MAC++Part+B)&s=22&DocType=Active&bc=AggAAAAQBAAAA&

9. Green Light HPS (High Performance System) Laser Prostate Treatment. How is the GreenLight

symptoms in men: management. Clinical guideline [CG97]. Published date: May 2010. Last
updated: June 2015. Accessed July 2, 2019. Available at URL address:
https://www.nice.org.uk/guidance/cg97

2, 2019. Available at URL address: https://www.niddk.nih.gov/health-information/urologic-
diseases/prostate-problems/prostate-enlargement-benign-prostatic-hyperplasia

the prostate for the treatment of benign prostatic hyperplasia. Canadian Urological Association,
address: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2422913/, and at URL address:


POLICY HISTORY

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 28, 2008</td>
<td>Origination of Policy</td>
<td>Yearly review with addition of CPT, HCPCS &amp; ICD9 Codes to policy. The different types of lasers used to perform laser prostatectomy were deleted from the policy.</td>
</tr>
<tr>
<td>August 27, 2009</td>
<td>Revised</td>
<td>Yearly review with addition of CPT, HCPCS &amp; ICD9 Codes to policy. The different types of lasers used to perform laser prostatectomy were deleted from the policy.</td>
</tr>
<tr>
<td>August 26, 2010</td>
<td>Yearly Revision</td>
<td>References updated.</td>
</tr>
<tr>
<td>August 18, 2011</td>
<td>Yearly Revision</td>
<td>References updated.</td>
</tr>
<tr>
<td>August 16, 2012</td>
<td>Yearly Revision</td>
<td>Policy was reviewed and approved by the Medical Card System (MCS) Medical Advisory Committee (MAC) on December 10, 2012.</td>
</tr>
<tr>
<td>February 20, 2013</td>
<td>Revised</td>
<td>References updated. Added new references, numbers 3-6, 8-13, 16, 18-19, &amp; 22-26.</td>
</tr>
<tr>
<td>September 30, 2013</td>
<td>Revised</td>
<td>References updated. Added new references, numbers 3-6, 8-13, 16, 18-19, &amp; 22-26.</td>
</tr>
</tbody>
</table>

To the Description Section:

- Deleted: Benign Prostatic Growth can cause serious difficulty with urination as men age. About 50 percent of men will experience a change in their pattern of urination during their lifetime because of this benign growth. Photo selective vaporization of the prostate (PVP), more often termed Green Light Laser Prostatectomy, is a minimally invasive procedure that results in dramatic improvements in urinary symptoms from benign prostate hypertrophy (BPH). It is usually done as an outpatient procedure in a hospital or surgery center under general or spinal anesthesia. PVP works by using a laser with a green wavelength to vaporize the prostate tissue. The obstructing prostate tissue is effectively removed just as well as
it can be by the conventional standard Transurethral Resection of the Prostate (TURP). PVP is less invasive than TURP because the prostate tissue is selective vaporized rather than cut. When the prostate tissue is cut with an electrical loop in a TURP, the prostate will bleed during the procedure. The laser device is introduced endoscopically through the urethra, allowing direct visualization of and access to the prostate gland during PVP of the prostate, the tissue does not bleed.

- Added: Benign prostatic hyperplasia (BPH) is the proliferation of prostate cells and the enlargement of the gland beyond the natural confines of the organ. The enlargement of the gland causes urinary symptoms due to compression of the urethra immediately down from the bladder neck. The standard surgical treatment, transurethral resection of the prostate (TURP), is generally effective but is associated with a risk of certain adverse events, such as incontinence, bleeding, and retrograde ejaculation (ECRI, 2012). Photo selective vaporization of the prostate (PVP), an alternative minimally invasive treatment for BPH, is a non-contact laser vaporization technique for eliminating prostatic tissue constricting the urethra and bladder neck. It employs a high-power Potassium-Titanyl-Phosphate (KTP) laser (60 to 80 watts) alone, compared to earlier KTPs used at low power (30 watts) in a hybrid laser technique with Nd:YAG (neodymium-doped yttrium aluminum garnet; Nd:Y3Al5O12). The KTP laser is a green-colored beam (532 nm) that is absorbed strongly by hemoglobin and therefore penetrates only a few millimeters. This feature of the KTP laser should help to avoid the deep-tissue coagulation side effects seen with other lasers. In addition, this laser is not absorbed appreciably by water and so can be used in a convenient side-firing, noncontact technique with aqueous irrigation. Competing Nd: YAG lasers used for this purpose have side effects caused by deep-tissue coagulation (postsurgical irritation, swelling, and tissue sloughing) (ECRI, 2012). The GreenLight Laser System (American Medical Systems [formerly manufactured by Laserscope, Inc.]) is a KTP laser used for photoselective vaporization, among many other indications. According to the U.S. Food and Drug Administration (FDA), when used at 532 nm, it is intended to hemostatically vaporize prostate tissue of men with BPH. The FDA also indicates that, the device is not intended to treat prostate cancer (ECRI, 2012). In studies of BPH treatments, an important factor to consider is whether patients’ symptoms would have improved without treatment. Previous studies of other therapies have shown that BPH is subject to placebo effects and regression to the mean effects (patients with waxing and waning conditions tend to be enrolled in studies when their symptoms are worst, while post-treatment measurements may be taken when symptoms have subsided independently of treatment). Therefore, studies of new BPH treatments without parallel control groups with no treatment or other treatment as a comparison group will potentially overestimate effectiveness.

To the Indications Section:

- Revised Indications.
- To Indication 2b, added: (moderate to severe).
- To Indication 2c, deleted: Free Peak Uroflow Rate (PUR) less than 15cc/sec when voided volume is more than 125cc.
- Restructured Indication 2c: Peak Urinary Flow Rate less than 10 mL/sec, which is more suggestive of an obstructed state (AUA, 2010).
<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
<th>Referenced Dates</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 21, 2014</td>
<td><strong>Revised</strong>&lt;br&gt;Added Note 1: Urodynamics and Post-void Residual Volume examinations should be used as appropriate, e.g., patients with suspected neurologic disease or those who have failed prostate surgery (CMS L31876, 2011).&lt;br&gt;To the Contraindications/Limitations Section: Added #2 &amp; #3.&lt;br&gt;To the Coding Information: Added new ICD-9 Code 222.2.</td>
<td>November 23, 2014&lt;br&gt;November 23, 2015&lt;br&gt;September 8, 2016</td>
</tr>
<tr>
<td>October 3, 2014</td>
<td><strong>Revised</strong>&lt;br&gt;References updated. Added new references, numbers 7, and 28-32. Deleted the following reference: American Medical Systems (AMS). Green Light™ Laser Therapy: Photoselective Vaporization of the Prostate – 2012 Most Billed Codes.&lt;br&gt;To the Indications Section:&lt;br&gt;Revised and modified Indications opening statement to read as follows: Medical Card System, Inc., (MCS) will consider the use of Photoselective Vaporization of the Prostate (PVP) (e.g., by means of the 120-W GreenLight laser [potassium-titanyl-phosphate laser], holmium laser, not an all-inclusive list) as medically necessary, for both the Commercial &amp; Classicare Lines of Business (LOB), under the following clinical scenario.&lt;br&gt;Deleted the following indication: Treatment for patients with BPH who have clinically documented obstructive and voiding symptoms and no clinical signs of prostate cancer.&lt;br&gt;Revised and modified the following indication: Renal insufficiency secondary to chronic bladder outlet obstruction; to read as follows: As a treatment modality for patients with bladder neck obstruction secondary to Benign Prostatic Hyperplasia (BPH), evidenced by All of the following.&lt;br&gt;Deleted previous Note 1 (i.e., Urodynamics and Post-void Residual Volume examinations should be used as appropriate, e.g., patients with suspected neurologic disease or those who have failed prostate surgery), but moved its content to the new Limitations Section.&lt;br&gt;To the Contraindications Section:&lt;br&gt;Separated from the Limitations Section.&lt;br&gt;Added new contraindication #2: PVP should not be used in patients with: a. Carcinoma of the prostate; b. Desire for future fertility; c. Inability to receive endoscopic treatment; or d. Intolerance to anesthesia.&lt;br&gt;To the Limitations Section:&lt;br&gt;Moved previous Note 1, as new Limitation #1: Urodynamics and Post-void Residual Volume examinations should be used as appropriate, e.g., patients with suspected neurologic disease or those who have failed prostate surgery.&lt;br&gt;To the Coding Information:&lt;br&gt;Added the following ICD-9-CM Codes: 596.0, 599.60 &amp; 599.69.</td>
<td>October 3, 2014&lt;br&gt;November 23, 2015&lt;br&gt;September 8, 2016</td>
</tr>
<tr>
<td>November 23, 2015</td>
<td><strong>Revised</strong>&lt;br&gt;To the coding section:&lt;br&gt;Eliminate ICD-9 codes since they are no longer valid for diagnosis classification.&lt;br&gt;Add new section of ICD-10 codes which are the valid diagnosis classification system since October 1, 2015.</td>
<td>November 23, 2015&lt;br&gt;November 23, 2015&lt;br&gt;September 8, 2016</td>
</tr>
<tr>
<td>September 8, 2016</td>
<td><strong>Revised</strong>&lt;br&gt;To the Description Section:&lt;br&gt;Phrase “in a hybrid laser technique with Nd: YAG (neodymium-doped yttrium aluminum garnet; Nd: Y3Al5O12)” was deleted</td>
<td>November 23, 2015&lt;br&gt;November 23, 2015&lt;br&gt;September 8, 2016</td>
</tr>
</tbody>
</table>
Benign prostatic hyperplasia (BPH) refers to proliferation of glandular epithelial tissue, smooth muscle, and connective tissue within the transition zone of the prostate. It becomes increasingly common as men age. BPH can lead to lower urinary tract symptoms (LUTS), such as urinary urgency, hesitancy, or frequency, and dysuria. Men with clinically significant LUTS attributable to BPH can be treated medically with one or more classes of drugs. Those who do not find adequate relief with medical treatment may benefit from surgical resection or...
ablation of prostate tissue around the urethra to enlarge the urethral channel.

Photoselective vaporization (PVP) is an alternative minimally invasive treatment that uses laser energy to vaporize prostate tissue, similar to plasma vaporization. The general procedure is similar to that of traditional (monopolar) TURP and saline usually is used as an irrigation solution. Photoselective vaporization (PVP, GreenLight laser) of the prostate is based upon the concept of selective photothermolysis (i.e., selective thermal confinement of light-induced damage). Selected wavelengths of laser light are targeted to different constituents of the tissue to ablate the prostate tissue. The KTP (potassium-titanyl-phosphate) laser (e.g., GreenLight laser) uses a wavelength of 532 nm, which is near the peak absorption of blood. A disadvantage of the KTP laser is coagulative necrosis (not vaporization) in poorly vascularized tissues.

PVP can be performed under local/regional anesthesia as an outpatient procedure, and an office-based procedure has been described. The Physician typically perform these type of procedure in the hospital and observe the patient for one day. The main disadvantage of PVP is that it takes more time than TURP, but, like other non-TURP procedures, blood loss is less. In many instances, less prostatic tissue is removed with PVP compared with TURP.

To the References Section:
- The following References were deleted from this Policy: #7, 10, 11, 13, 14, 18, and 21.