

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:	June 16, 2023
Next Revision:	June, 2024

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) is a histologic diagnosis that refers to proliferation of glandular epithelial tissue, smooth muscle, and connective tissue within the prostatic transition zone. 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 performs this type of procedure in the hospital and observes 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); the treatment must be 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) Urodynamics and Post-void Residual Volume examinations; &
 - c. Peak Urinary Flow Rate less than 10 mL/sec, which is more suggestive of a bladder outlet obstruction (BOO).

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.

DOCUMENTATION REQUIREMENTS

1. The patient's medical record must contain documentation that fully supports the medical necessity for services included within this Medical Policy. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.
2. The medical record/progress notes must document the duration of BPH, AUA symptoms index, and the urodynamics studies and/or post-void residual volume results if performed.
3. Documentation must be available to MCS Medical Consultant Physician upon request.

RATIONALE

Benign prostatic hyperplasia (BPH) increases in prevalence as men age. Urinary symptoms include increased frequency of urination, nocturia, hesitancy, urgency, and weak urinary stream. Treatment includes medical and surgical options. Many men with BPH discontinue medical therapy without seeking surgery due to the perceived invasiveness or potential side effects of the traditional procedures. Some of these men may be amenable to minimally invasive surgical treatments. Photoselective vaporization (PVP) is an alternative minimally invasive treatment that uses laser energy to vaporize prostate tissue, similar to plasma vaporization. According to scientific literature, PVP was comparable to transurethral resection of the prostate TURP in terms of International Prostate Symptom Score (IPSS), peak urinary flow (Qmax), reduction in prostate volume and post-void residual, adverse event incidence, transfusion requirement, and need for reoperation.

MCS considers the photoselective laser vaporization of the prostate (PVP) approach as medically necessary as an alternative technique to the conventional surgical intervention TURP for the treatment of bladder outlet obstruction caused by benign prostate hypertrophy (BPH).

CODING INFORMATION

CPT® Codes (List may not be all inclusive)

CPT® Codes	DESCRIPTION
52648	Laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscope, urethral calibration and/ or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)

Current Procedural Terminology (CPT®) 2023 American Medical Association: Chicago, IL.

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

ICD-10-Codes	DESCRIPTION
D29.1	Benign neoplasm of prostate
N40.1	Benign prostatic hyperplasia with lower urinary tract symptoms
N40.3	Nodular prostate with lower urinary tract symptoms

REFERENCES

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2. Advance Urologic Services (AUS). (2021). Greenlight XPS™ Laser by Boston Scientific. Accessed May 23, 2023. Available at URL address: <https://urologicservices.com/about-aus/american-medical-systems-greenlight-xps/>
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POLICY HISTORY

DATE	ACTION	COMMENT
April 28, 2008	Origination of Policy	
August 27, 2009	Revised	Yearly review with addition of CPT, HCPCS & ICD9 Codes to policy. The different types of lasers used to perform laser prostatectomy were deleted from the policy.
August 26, 2010	Yearly Revision	
August 18, 2011	Yearly Revision	
August 16, 2012	Yearly Revision	References updated.
December 10, 2012	Revised	Policy was reviewed and approved by the Medical Card System (MCS) Medical Advisory Committee (MAC) on December 10, 2012.
February 20, 2013	Revised	Coding Information Revision: CPT Code 0084T deleted. CPT Code 53855 added.
September 30, 2013	Revised	References updated. Added new references, numbers 3-6, 8-13, 16, 18-19, & 22-26. To the Description Section: <ul style="list-style-type: none"> • 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

		<p>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 (523 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.</p> <p>To the Indications Section:</p> <ul style="list-style-type: none"> • 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). • Added Note1: 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). <p>To the Contraindications/Limitations Section: Added #2 & #3.</p> <p>To the Coding Information: Added new ICD-9 Code 222.2.</p>
<p>February 21,2014</p>	<p>Revised</p>	<p>To the Coding section: A new ICD-10 Codes (Preview Draft) section was added to the policy.</p>
<p>October 3, 2014</p>	<p>Revised</p>	<p>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.</p> <p>To the Indications Section:</p> <ul style="list-style-type: none"> • 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

		<p>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 & Classicare Lines of Business (LOB), under the following clinical scenario.</p> <ul style="list-style-type: none"> Deleted the following indication: Treatment for patients with BPH who have clinically documented obstructive and voiding symptoms and no clinical signs of prostate cancer. 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. 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. <p>To the Contraindications Section:</p> <ul style="list-style-type: none"> Separated from the Limitations Section. 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. <p>To the Limitations Section:</p> <ul style="list-style-type: none"> 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. <p>To the Coding Information:</p> <ul style="list-style-type: none"> Added the following ICD-9-CM Codes: 596.0, 599.60 & 599.69.
<p>November 23, 2015</p>	<p>Revised</p>	<p>To the coding section:</p> <ul style="list-style-type: none"> Eliminate ICD-9 codes since they are no longer valid for diagnosis classification. Add new section of ICD-10 codes which are the valid diagnosis classification system since October 1, 2015.
<p>September 8, 2016</p>	<p>Revised</p>	<p>To the Description Section:</p> <ul style="list-style-type: none"> Phrase “in a hybrid laser technique with Nd: YAG (neodymium-doped yttrium aluminum garnet; Nd: Y3Al5O12)” was deleted from the Second Paragraph. <u>New Information was added to the Second Paragraph:</u> Since 2006, a 120-watt High Performance Laser System is available, which results in faster and more powerful vaporization, while maintaining a low complication rate even in high-risk patients. <u>This Information was deleted from the Third Paragraph:</u> 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 (ECRI, 2012). <p>To the Indications Section:</p> <ul style="list-style-type: none"> <u>This Information was deleted from the coverage statement:</u>

		<p>(e.g., by means of the 120-W GreenLight laser [potassium-titanyl-phosphate laser], holmium laser, not an all-inclusive list).</p> <p><u>To the Limitations Section:</u></p> <ul style="list-style-type: none"> At the Limitations #2: Phrase “The device for PVP’ was substitute for the Phrase “These devices”. <p><u>To the Coding Information:</u></p> <ul style="list-style-type: none"> ICD-10 Codes (N13.9, R33.0, R33.8, R33.9 and R39.14) were deleted from this Policy. <p><u>To the References Section:</u></p> <ul style="list-style-type: none"> The Following References were deleted from this Policy: 2, 14, 15, 17, 18, 23, 25, and 26. New References (#12, 19 and 29) were added to the Policy.
June 13, 2018	Revised	<p><u>To the Coding Information Section:</u></p> <ul style="list-style-type: none"> <u>To the CPT Code Section:</u> CPT Code 53855 was deleted from this Policy. <u>To the ICD-10 Code Section:</u> N40.0 and N40.2 were deleted from this Policy. <p><u>To the References Section:</u></p> <ul style="list-style-type: none"> <u>The following References were deleted from this Policy:</u> 1, 8, 10, and 21.
July 16, 2019	Revised	<p><u>To the Description Section:</u></p> <ul style="list-style-type: none"> <u>New Information was added in Substitution to the Old one in the first and second paragraph:</u> 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 performs this type of procedure in the hospital and observes 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. <p><u>To the References Section:</u></p>

		<ul style="list-style-type: none"> The following References were deleted from this Policy: #7, 10, 11, 13, 14, 18, and 21.
June 17, 2020	Revised	<p>To the Indications Section:</p> <ul style="list-style-type: none"> New Phrase was added to the Indication #2b: “Urodynamics and Post-void Residual Volume examinations”. New Phrase was added to the Indication #2C: “bladder outlet obstruction (BOO)”. <p>New documentation Requirements Section was added to the Policy:</p> <ol style="list-style-type: none"> The patient's medical record must contain documentation that fully supports the medical necessity for services included within this Medical Policy. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. The medical record/progress notes must document the duration of BPH, AUA symptoms index, and the urodynamics studies and/or post-void residual volume results if performed.
May 28, 2021	Revised	<p>To the Indications Section: New Phrase “the treatment Must Be” was added to Indication #2.</p> <p>To the References Section:</p> <ul style="list-style-type: none"> The following References were deleted from this Policy: #6 and 9.
June 8, 2022	Revised	<p>References updated. Deleted former #3 & #4. Added new #3, #4 & 5.</p> <p>To the Description Section:</p> <ul style="list-style-type: none"> To 1st paragraph, first sentence: Deleted phrase “of the prostate”. Added phrase “is a histologic diagnosis that” and “prostatic”.
June 16, 2023	Revised	<p>To the Documentation Requirements Section: New Documentation requirements #3 was added: Documentation must be available to MCS Medical Consultant Physician upon request.</p> <p>To the Coding Information Section:</p> <ul style="list-style-type: none"> To the ICD-10 Code Section: Description for ICD-10 Code N40.1 was corrected. <p>To the References Section: New References #12 was added to the Policy.</p>
April 11, 2024	UMC Approval	

This document is for informational purposes only. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. Medical Card System, Inc., (MCS) medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Medical Card System, Inc., (MCS) reserves the right to review and update its medical policies at its discretion. Medical Card System, Inc., (MCS) medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.