Highmark Commercial Medical Policy- PA, WV, DE, NY

Medical Policy:	S-275-~~009~~010
Topic (or Title):	Prostate Disease: Diagnosis, Staging, and Treatment
Section:	Surgery
Effective Date:	~~July 1~~October 20, 2025
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Annual Review:	~~June 2024~~August 2025

Diagnosing and Staging of Prostate Cancer
Saturation biopsy, either initial or repeat, for a high-risk individual provides pathologists with an extensive selection of cells to test and can be used to help diagnose and stage prostate cancer when previous conventional prostate biopsies have been negative.

Treatment of Benign Prostate Hypertrophy or Prostate Cancer
A wide variety of minimally invasive therapies and surgery are available for diseases of the prostate and may include but are not limited to:

- Cryoablation of the prostate; **or**
- Cystourethroscopy with insertion of permanent adjustable transprostatic implant; **or**
- Holmium laser:
  - Ablation of the prostate [HoLAP]; **or**
  - Enucleation of the prostate [HoLEP]; **or**
  - Resection of the prostate [HoLRP]; **or**
- Photoselective laser vaporization (PVP); **or**
- Prostatic stents; **or**
- Prostatic urethral lift (PUL); **or**
- Radical prostatectomy; **or**
- Simple prostatectomy; **or**
- Transuretheral anterior prostate commissurotomy; **or**
- Transurethral electrovaporization of the prostate (TUEVP, TUVAP or TUEVAP); **or**
- Transuretheral incision of the prostate (TUIP); **or**
- Transurethral microwave thermotherapy (TUMT); **or**
- Transurethral resection of the prostate (TURP); **or**
- Transuretheral waterjet ablation of the prostate; **or**
- Transurethral ultrasound-guided laser-induced prostatectomy (TULIP); **or**
- Water-induced thermotherapy (WIT), also called thermourethral hot-water therapy; **or**
- Water vapor thermal therapy when prostate volume is less than 80 grams.

Polyethylene glycol (PEG) hydrogel is a slowly resorbing hydrogel injected into Denonvillier's space to limit rectal toxicity before radiation therapy for prostate cancer.

Note: Oral pharmacological treatments and prostate specific antigen testing are not addressed in this policy.

Policy Position

Diagnosis and Staging: Prostate Cancer

Saturation biopsy of the prostate (taking 20 or more core tissue samples at one time) may be considered medically necessary for **ANY** of the following indications in individuals with two (2) prior extended transrectal prostate biopsies (up to 12 core tissue samples) negative for invasive cancer:

- Individuals with an elevated prostate specific antigen (PSA) that is persistently rising; **or**
- Individuals with histologic evidence of atypia on prior prostate biopsy; **or**
- Individuals with histologic findings of high-grade prostatic intraepithelial neoplasia (PIN) on prior biopsy.

Saturation needle biopsy of the prostate not meeting the criteria as indicated in this policy is considered experimental/investigational and, therefore, non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Procedure Codes

0443T	55700	55706

Treatment of the Prostate: Benign Prostate Hypertrophy, Prostate Cancer

The surgical and minimally invasive treatment of urinary outlet obstruction due to BPH may be considered medically necessary when **ALL** the following criteria are met:

- The individual has a diagnosis of lower urinary tract symptoms (LUTS) secondary to BPH that interfere with activities of daily living; **and**
- The individual has a peak urine flow rate (Qmax) less than 15 cc/sec on a voided volume that is greater than 125 cc; **and**
- The individual has failed a trial of satisfactory voiding with medication (alpha blocker and/or alpha-reductase inhibitor) or intolerance to medication (alpha blocker and/or 5-alpha-reductase inhibitor).

The surgical and minimally invasive treatment of urinary outlet obstruction due to prostate cancer may be considered medically necessary when **ONE** the following criteria are met:

- The individual has a diagnosis or history of prostate cancer and is not a candidate for surgical resection of the prostate but will be treated by radiation therapy and has symptoms that are so severe that immediate relief is required; **or**
- The individual has a diagnosis or history of prostate cancer and is clinically in remission as evidenced by a prostate specific antigen (PSA) less than 1.0 ng/mL.

The use of any treatments/procedures not meeting the criteria as indicated in this policy are considered not medically necessary.

Procedure Codes

0421T	0582T	0619T	51721	52282	52441	52442
52450	52601	52630	52640	52647	52648	52649
53850	53852	53854	55821	55831		

Prostatectomy

A simple prostatectomy may be considered medically necessary for individuals with a diagnosis of localized prostate cancer.

A simple prostatectomy not meeting the criteria as indicated in this policy is considered not medically necessary.

Procedure Codes

55801 55867

Prostatic Urethral Lift (PUL)

PUL in individuals 45 years of age or older with moderate-to-severe lower urinary tract obstruction due to BPH may be considered medically necessary when **ALL** the following criteria are met:

- Persistent or progressive lower urinary tract symptoms despite medical therapy (α1-adrenergic antagonists maximally titrated, 5α-reductase inhibitors, or combination medication therapy maximally titrated) over a trial period of four (4) -12 weeks or is unable to tolerate medical therapy; **and**
- Prostate gland volume is less than or equal to 100 mL; **and**
- Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe; **and**
- Individual does not have an active urinary tract infection or recent prostatitis (within the last 12 months); **and**
- Individual has had appropriate testing to exclude diagnosis of prostate cancer; **and**
- Individual does not have a known allergy to nickel, titanium, or stainless steel.

PUL not meeting the criteria indicated in this policy is considered not medically necessary.

Procedure Codes

52441 52442

Cryoablation

Whole gland cryoablation of the prostate gland as treatment of clinically localized (organ-confined) prostate cancer may be considered medically necessary when performed:

- As initial treatment; **or**
- As salvage treatment of disease that recurs following radiotherapy.

Whole gland cryosurgical ablation of the prostate gland not meeting the criteria as indicated in this policy is considered not medically necessary.

Subtotal prostate cryoablation for the treatment of prostate cancer is considered E/I experimental/investigational and therefore non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Procedure Codes

55873

High-Intensity Focused Ultrasound (HIFU)

Whole gland HIFU may be considered medically necessary as a local treatment for recurrent prostate cancer following radiation therapy when individual meets **ALL** the following criteria:

- Original clinical stage (Please see staging tables below):
  - $T_1 - T_2$; **and**
  - NX or NO; **and**
- Life expectancy of greater than 10 years; **and**

- PSA of less than 10 ng/mL; **and**
- Positive post-RT transrectal (TRUS) biopsy; **and**
- No evidence of metastatic disease.

HIFU not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore, non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Procedure Codes

55880	55899	0950T

Polyethylene-glycol Hydrogel (PEG)

PEG hydrogel may be considered medically necessary in individuals diagnosed with prostate cancer and are going to be treated with radiotherapy.

PEG hydrogel usage not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore non-covered because the safety and or effectiveness of this service cannot be established by the available published peer-reviewed literature.

Procedure Codes

55874

The use of **ANY** focal therapy modality, including but not limited to the following procedures, for individuals with localized prostate cancer is considered experimental/investigational and therefore, non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature:

- Radiofrequency ablation; **or**
- Photodynamic therapy; **or**
- Transperineal focal laser ablation.

Procedure Codes

0655T	0738T	0739T	55881	55882	55899

The following procedures/treatments for BPH, including but not limited to the following procedures, are considered experimental/investigational and therefore non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature:

- HIFU ablation for the treatment for BPH; **or**
- Placement of temporary prostatic stents for the treatment for BPH; **or**
- Prostatic arterial embolization; **or**
- Focal laser ablation; **or**
- Transperineal laser ablation for the treatment of BPH.

Procedure Codes

0714T	0867T	37243	53855	53865	53866	53899
55873	55880	55899				

Outpatient HCPCS (C Codes)

C2596 C9739 C9740

Tumor (T) Staging

T_1	The tumor is too small to be seen on scans or felt during examination of the prostate (it has been discovered by needle biopsy).
T_2	The tumor is completely inside the prostate gland.
T_3	The tumor has broken through the capsule of the prostate gland.
T_4	The tumor has spread into other body organs.

Lymph Node (N) Staging

NO	No cancer cells found in any lymph nodes
N1	One positive lymph node smaller than 2 cm across.
N2	More than 1 positive lymph node; or one that is between 2cm and 5 cm across.
N3	Any positive lymph node that is bigger than 5 cm across.
NX	Lymph nodes cannot be assessed

Related Policies

Refer to Medical Policy L-260, Prostate Specific Antigen, for additional information.

Professional Statements and Societal Positions

National Comprehensive Cancer Network (NCCN) – 2024
Saturation Biopsy
Current NCCN Prostate Cancer guidelines (v.4.2024) do not mention saturation biopsy. The guideline mentions prostate cancer is identified as follows:

Risk Group	Recommendation
Very Low Risk Group	Has all of the following: • cT1c • Grade Group 1 • PSA <10 ng/mL • <3 prostate biopsy fragments/cores positive, ≤50% cancer in each fragment/corek • PSA density <0.15 ng/mL/g
Low Risk Group	Has all of the following but does not qualify for very low risk: • cT1–cT2a • Grade Group 1 • PSA <10 ng/mL
Intermediate Risk Group	Has all of the following: • No high-risk group features • No very-high-risk group features • Has one or more intermediate risk factors (IRFs): -cT2b–cT2c -Grade Group 2 or 3 PSA 10–20 ng/mL Favorable intermediate Has all of the following:

	• 1 IRF • Grade Group 1 or 2 • <50% biopsy cores positive (eg, <6 of 12 cores) Unfavorable intermediate Has one or more of the following: • 2 or 3 IRFs • Grade Group 3 • ≥ 50% biopsy cores positive (eg, ≥ 6 of 12 cores)
High	Has no very-high-risk features and has exactly one high-risk feature: • cT3a OR • Grade Group 4 or Grade Group 5 OR • PSA >20 ng/mL
Very High	Has at least one of the following: • cT3b–cT4 • Primary Gleason pattern 5 • 2 or 3 high-risk features • >4 cores with Grade Group 4 or 5

Cryosurgery/HIFU
Current NCCN Prostate guidelines (v.4.2024) recommends only cryosurgery and high-intensity focused ultrasound as local therapy options for RT recurrence in the absence of metastatic disease.

Polyethylene-glycol Hydrogel (PEG)
Current NCCN Prostate guidelines (v.4.2024) state, "Overall, the panel believes that biocompatible and biodegradable perirectal spacer materials may be implanted between the prostate and rectum in patients undergoing external radiotherapy with organ-confined prostate cancer in order to displace the rectum from high radiation dose regions. Patients with obvious rectal invasion or visible T3 and posterior extension should not undergo perirectal spacer implantation."

American Urological Association (AUA) - 2021
The AUA guidelines (2021) address surgical interventions for BPH/LUTS as follows:

- Surgery is recommended for patients who have renal insufficiency secondary to BPH, refractory urinary retention secondary to BPH, recurrent urinary tract infections (UTIs), recurrent bladder stones or gross hematuria due to BPH, and/or with LUTS/BPH refractory to or unwilling to use other therapies.
- Clinicians should inform patients of the possibility of treatment failure and the need for additional or secondary treatments when considering surgical and minimally invasive treatments for LUTS/BPH.

Procedure/Patient Population	**Recommendation**
Laser Enucleation	Holmium laser enucleation of the prostate (HoLEP) or thulium laser enucleation of the prostate (ThuLEP) should be considered as an option, depending on the clinician's expertise with these techniques, as prostate size-independent options for the treatment of LUTS/BPH.
Medically Complicated Patients	HoLEP, PVP, and ThuLEP should be considered as treatment options in patients who are at higher risk of bleeding.
PUL	PUL should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80cc and verified absence of an obstructive middle lobe. PUL may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function
PVP	PVP should be offered as an option using 120W or 180W platforms for the treatment of LUTS/BPH.

Robotic Waterjet Treatment	Robotic waterjet treatment (RWT) may be offered as a treatment option to patients with LUTS/BPH provided prostate volume 30-80cc.
Simple Prostatectomy	Open, laparoscopic, or robotic assisted prostatectomy should be considered as treatment options by clinicians, depending on their expertise with these techniques, only in patients with large to very large prostates.
TURP	TURP should be offered as a treatment option for patients with LUTS/BPH.
TUIP	TUIP should be offered as an option for patients with prostates ≤30cc for the surgical treatment of LUTS/BPH.
TUMT	TUMT may be offered as a treatment option to patients with LUTS/BPH.
TUNA	TUNA is not recommended for the treatment of LUTS/BPH.
TUVP	Bipolar TUVP may be offered as an option to patients for the treatment of LUTS/BPH.
WVTT	WVTT should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80cc. WVTT may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function.

Diagnosis Codes

Covered diagnosis codes for procedure codes: 0421T, 0582T, 51721, 52441, 52442, 52450, 52601, 52630, 52640, 52647, 52648, 52649, 53850, 53852, 53854, 55801, 55821, 55831, and 55867

D29.1	D40.0	D49.59	N32.0	N32.89	N32.9	N39.41
N39.42	N39.43	N39.44	N39.45	N39.46	N40.0	N40.1
N40.2	N40.3	N41.0	N41.1	N41.2	N41.3	N41.4
N41.8	N41.9	N42.31	N42.32	N42.83	N42.89	N42.9
R97.20	R97.21					

Covered diagnosis codes for procedure codes: 0582T, 0950T, 51721, 52441, 52442, 52601, 52630, 52640, 52647, 52648, 52649, 53850, 53852, 55873, and 55880

C61	C79.82	D07.5

Covered diagnosis codes for procedure codes: 0443T, 55700, 55706, and 55874

C61	C79.82	D07.5	D40.0

Covered diagnosis codes for procedure code: 0619T

N40.0	N40.1

Place of Service: Inpatient/Outpatient

Experimental/Investigational (E/I) services are not covered regardless of place of service.

Diagnosis, staging, and treatment of the prostate is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

The policy position applies to all commercial lines of business

Links

- Link to References

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

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U.S. Department of Health and Human Services

200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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