Treatment of the Prostate

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Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 9

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary treatment of the prostate.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

PROCEDURES

1. A prior authorization is required.

2. A wide variety of minimally invasive therapies and surgery are available for enlarged prostate and may include but is not limited to:

    - Cryoablation of the prostate; 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 urethral lift (PUL); or
- Radical prostatectomy; or
- Simple prostatectomy; or
- Transurethral electrovaporization of the prostate (TUEVP, TUVAP or TUEVAP); or
- Transurethral microwave thermotherapy (TUMT); or
- Transurethral resection of the prostate (TURP); or
- Transurethral ultrasound-guided laser-induced prostatectomy (TULIP); or
- Water-induced thermotherapy (WIT), also called thermourethral hot-water therapy; or
- Water vapor thermal therapy (e.g., Rezum) when prostate volume is less than 80 grams.

Conditions requiring treatment of the prostate gland may include but are not limited to:

- Benign prostatic hyperplasia (BPH); or
- Prostate cancer; or
- Prostatitis.

Oral pharmacological treatments and hydrogel spacer are not addressed in this policy.

3. The surgical and minimally invasive treatment (e.g., HoLAP, HoLEP, HOLRP, PVP, TUEVP, TUVAP, TUEVAP, TUMT, TURP, TULIP, WIT) 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 (e.g., HoLAP, HoLEP, HOLRP, PVP, TUEVP, TUVAP, TUEVAP, TUMT, TURP, TULIP, WIT) of urinary outlet obstruction due to prostate cancer may be considered medically necessary when ONE the following criteria are met:

    - The individual with 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 with a diagnosis or history of prostate cancer and is clinically in remission as evidenced by a prostate specific antigen (PSA) less than1.0 ng/mL.

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

4. Prostatectomy

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

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

5. 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 no less than 6 months, or is unable to tolerate medical therapy; and,
   - Prostate gland volume is less than or equal to100 mL; and,
   - Prostate anatomy demonstrates normal bladder neck without an obstructive or protruding median lobe; and,
   - Individual does not have urinary retention, urinary tract infection, or recent prostatitis (within past year); 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.

6. 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 noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

7. 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 noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

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 noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature:

- Radiofrequency ablation; or
- Photodynamic therapy.

The following procedures/treatments for BPH, including but not limited to the following procedures, are considered experimental/investigational and therefore noncovered 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 (Visualase).

8. Post-payment audit statement

   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

9. Place of service: inpatient/outpatient

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

   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 comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT codes	Description
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant.
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional implant; each additional permanent adjustable transprostatic implant (list separately in addition to code for primary procedure).
52450	Transurethral incision of prostate.
52601	Transurethral electrosurgical resection of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included).
52630	Transurethral resection; residual or regrowth of obstructive prostate tissue including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included).
52640	Transurethral resection; of postoperative bladder neck contracture.

52647	Laser coagulation of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included if performed).
52648	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).
52649	Laser enucleation of the prostate with morcellation, 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).
53850	Transurethral destruction of prostate tissue; by microwave thermotherapy.
53852	Transurethral destruction of prostate tissue; by microwave thermotherapy.
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor.
55821	Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); suprapubic, subtotal, 1 or 2 stages.
55831	Prostatectomy (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy); retropubic, subtotal.
55801	Prostatectomy, perineal, subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy).
55810	Prostatectomy, perineal radical.
55812	Prostatectomy, perineal radical; with lymph node biopsy(s) (limited pelvic lymphadenectomy).
55815	Prostatectomy, perineal radical; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric and obturator nodes.
55840	Prostatectomy; retropubic radical.
55842	Prostatectomy; retropubic radical, w/ lymph node biopsy.
55845	Prostatectomy; retropubic radical, w/ bilateral pelvic lymphadenectomy.
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance for interstitial cryosurgical probe placement). Pay for this service only as a primary treatment for patients with clinically localized prostate cancer, stages T1-T3.
55880	Ablation of malignant prostate tissue using transrectal high intensity focused ultrasound (HIFU).
37243	Vascular embolization or occlusion, for tumors, organ ischemia, or infarction.
53855	Insertion of a temporary prostatic urethral stent, including urethral measurement.

COVERED DIAGNOSIS CODES FOR PROCEDURE CODES: 52441, 52442, 52450, 52601, 52630, 52640, 52647, 52648, 52649, 53850, 53852, 53854, 55801, 55810, 55812, 55815, 55821, 55831, 55840, 55842, 55845, AND 55866.

Codes						
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	N42.83	N42.89	N42.9		

COVERED DIAGNOSIS CODES FOR PROCEDURE CODES: 52441, 52442, 52601, 52630, 52640, 52647, 52648, 52649, 53850, 53852, 55866, 55873, AND 55880

Codes						
C61	C79.82	D07.5	Z85.46			

COVERED DIAGNOSIS CODES FOR PROCEDURE CODES: 55810, 55812, 55815, 55840, 55842, 55845 AND 55866

Codes						
C61	C79.82	D07.5	D40.0			

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

POLICY SOURCES

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.

National Comprehensive Cancer Network – 2020.

The National Comprehensive Cancer Network guidelines (v.3.2020) for prostate cancer indicate cryosurgery and high-intensity focused ultrasound are options for radiotherapy recurrence in patients who have no evidence of metastatic disease.

American Urological Association – 2020.

In 2018, the American Urological Association published guidelines on the surgical management of LUTS attributed to BPH; the 2018 guidelines were amended in 2019 and 2020. The guidelines made the following recommendations and statements:

- Conditional recommendations regarding prostatic urethral lift (PUL):
  - "PUL may be offered as an option for patients with LUTS [lower urinary tract symptoms] attributed to BPH [benign prostatic hyperplasia] provided prostate volume <80g and verified absence of an obstructive middle lobe "
  - "PUL may be offered to eligible patients concerned with erectile and ejaculatory function for the treatment of LUTS attributed to BPH."
  - "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 secondary to BPH."
- Conditional recommendations regarding water vapor thermal therapy:
  - Water vapor thermal therapy may be offered to patients with LUTS attributed to BPH provided prostate volume <80g.
  - Water vapor thermal therapy may be offered to eligible patients who desire preservation of erectile and ejaculatory function.

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POLICY UPDATE HISTORY

11/10/2021	Approved in Medical Policy Committee
12/2021	Approved in QI/UM
02/22/2023	Annual review; approved in Medical Policy Committee
02/28/2023	Approved in QI/UM