Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP048

Section: Medical Benefit Policy

Subject: Surgical and Minimally Invasive Therapies for the Treatment of Benign Prostatic Hypertrophy

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Surgical and Minimally Invasive Therapies for the Treatment of Benign Prostatic Hypertrophy

II. Purpose/Objective:
To provide a policy of coverage regarding Surgical and Minimally Invasive Therapies for the Treatment of Benign Prostatic Hypertrophy

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an

illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

INDICATIONS:
Transurethral Microwave Thermotherapy (TUMT), Transurethral Radiofrequency Thermotherapy (TUNA), Transurethral incision of the prostate (TUIP), Transurethral water vaporization of the prostate [e.g. Rezum™] (TUVP), Transurethral enucleation of the prostate (TUEP), Laser Prostatectomy (Holmium laser ablation of the prostate [HoLAP]) , Holmium laser enucleation of the prostate [HoLEP] , Holmium laser resection of the prostate [(HoLRP]), transurethral ultrasound-guided laser induced prostatectomy (TULIP), visually-guided laser ablation of the prostate (VLAP) and Water Induced Thermotherapy (WIT) are outpatient ablation treatments for symptomatic benign prostatic hypertrophy (BPH). These procedures are non-surgical alternatives to transurethral resection of the prostate (TURP). The desired outcome is to relieve urinary symptoms and improve urinary function by reducing urinary obstruction caused by BPH. A urethral probe is used to apply thermal energy to the prostate, causing damage and eventual necrosis of excess prostatic tissue. These procedures are considered to be medically necessary when the following criteria are met:

- Diagnosis of symptomatic BPH with duration of symptoms greater than 3 months
- Failed trial, intolerance, contraindication to medication therapy (alpha-blocker and/or finasteride) or medication management is felt to be ineffective.
- Recent PSA that resulted in a value of 2.5 ng/ml or less for members up to age 50; 4.0 ng/ml or less for members over age 50
- Peak urine flow rate (Qmax) less than 15 cc on a voided volume of greater than 125cc
- Post void residual (PVR) greater than 50cc or less than 350cc

Prostatic Urethral Lift (UroLift ®) is a minimally invasive implant developed to treat lower urinary tract outflow obstruction secondary to BPH in men 45 years of age or older. Permanent implants are delivered via the urethra, deployed, and implanted into each lobe of the prostate to retract the tissue away from the urethral walls to increase the opening of the urethra. This procedure is considered medically necessary when the following criteria are met:

- Diagnosis of symptomatic BPH with duration of symptoms greater than 3 months
- Prostate gland volume is less than or equal to 100 ml
- Prostate anatomy demonstrates urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH), including lateral and median lobe hyperplasia Therapeutic failure or intolerance to medical therapy (e.g. α1-adrenergic antagonists, 5α-reductase inhibitors)
- Absence of contraindications*
  *If the member has a diagnosis or history of prostate cancer and:
  - The member is not a candidate for surgical resection of the prostate but will be treated by non-surgical therapy (e.g., radiation) and has symptoms that are so severe that immediate relief is required; or
  - The member is clinically in remission as evidenced by a Prostate Specific Antigen (PSA) less than 1.0 ng/mL.

Endourethral prosthesis (e.g., Urolume® urethral stent) is considered medically necessary to treat obstruction secondary to BPH in men at least 60 years of age or older, or men under 60 years of age who are poor surgical candidates.

See also: MP093 Cystourethroscopy, with Insertion of Urethral Stent

CONTRAINDICATIONS:
Active urinary tract infection
Prostate malignancy
Hyperreflexive neurogenic bladder
Previous prostate surgery
Active cystolithiasis
Gross hematuria
Urethral stricture
Bladder neck contracture
Acute prostatitis
Prior radiation therapy to the pelvic area

EXCLUSIONS:
The Plan does **NOT** provide coverage for *transurethral balloon dilation or Drug-coated balloon catheter systems (e.g., Optilume®)* of the prostatic urethra because it is considered **unproven.** There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies **52284**

The Plan does **NOT** provide coverage for *Transurethral ethanol ablation of the prostate (TEAP)* used in the treatment of prostatic hypertrophy because it is considered **experimental, investigational or unproven.** There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

The Plan does **NOT** provide coverage for High-intensity focused ultrasound (HIFU) ablation used in the treatment of prostatic hypertrophy because it is considered **experimental, investigational or unproven**. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies

The Plan does **NOT** provide coverage for Prostatic arterial embolization (PAE) for the treatment of BPH hypertrophy because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

The Plan does **NOT** provide coverage for Transperineal laser ablation (TPLA) for the treatment of BPH hypertrophy because it is considered unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies. **0655T, 0714T, 0867T**

The Plan does **NOT** provide coverage for temporarily implanted nitinol devices (e.g., iTind) as a minimally invasive alternative to transurethral resection of the prostate (TURP) to treat symptomatic benign prostatic hyperplasia because it is considered unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies. **C9769**

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment.**

Medicaid Business Segment:
Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH: Surgical and Minimally Invasive Therapies for the Treatment of Benign Prostatic Hypertrophy ***The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services.***

37242 Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor
52282 Cystourethroscopy, with insertion of urethral stent
52284 Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed
52441 Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant
52442 each additional permanent adjustable transprostatic implant

52450 Transurethral incision of prostate [TUIP]
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) [laser prostatectomy]
52630 Transurethral resection; residual or regrowth of obstructive prostatic tissue including control of postoperative bleeding, complete
52647 Non-contact laser coagulation of prostate, including control of post-operative bleeding, complete

52648 Contact laser vaporization with or without transurethral resection of prostate, including control of postoperative bleeding, complete
52649 Laser enucleation of the prostate with morcellation, including control of postoperative bleeding, complete
53850 Transurethral destruction of the prostate tissue; by microwave thermotherapy [TUMT]
53852 by radiofrequency thermotherapy [TUNA]
53854 Transurethral destruction of prostate tissue; by radiofrequency water vapor (steam) thermal therapy
53855 insertion of a temporary prostatic urethral stent, including urethral measurement
55873 Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)
C9739 Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740 4 or more implants
C9769 Cystourethroscopy, with insertion of temporary prostatic implant/stent with fixation/anchor and incisional struts (Nitinol, iTind device)
0421T Waterjet prostate ablation cmpl
0582T Transurethral ablation of malignant prostate tissue by high energy water vapor thermotherapy, including intraoperative imaging and needle guidance
0619T Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed
0655T Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging
0714T Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance
0867T Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater or equal to 50 mL

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supercede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 06/02

Revised: 6/03 (definition); 6/04; 6/06 (references); 7/07, 7/08 (added exclusion), 7/09(added exclusion), 6/12, 9/12, 6/16 (added covered therapy), 6/17(clarified covered services), 6/19 (add covered therapies, reformat criteria); 6/20 (revise UroLift criteria); 6/21 (add cross reference and exclusion); 6/22 (revised coverage criteria); 6/23 (added procedures); 6/24 (add exclusions: TPLA. iTind, Optilume)

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CMS UM Oversight Committee Approval: 12/23, 7/24