Keywords: Cancer, Prostate Cancer, Treatments, Treatments for Prostate Cancer

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I. ACTION

x New Policy

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II. POLICY DISCLAIMER

Johns Hopkins HealthCare LLC (JHHC) provides a full spectrum of health care products and services for Employer Health Programs, Priority Partners, Advantage MD and US Family Health Plan. Each line of business possesses its own unique contract and guidelines which, for benefit and payment purposes, should be consulted to know what benefits are available for reimbursement. Specific contract benefits, guidelines or policies supersede the information outlined in this policy.

Specific contract benefits, guidelines or policies supersede the information outlined in this policy.

III. POLICY

For US Family Health Plan see TRICARE Policy Manual 6010.60-M, February 1, 2008, Surgery: Chapter 4 Section 15.1 Male Genital System.

For Advantage MD, see Medicare Coverage Database:

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National Coverage Determination (NCD) for Cryosurgery of Prostate (230.9)

Note ~ Selecting initial treatment requires assessing the risk of the disease spreading or progressing, which is based on evaluating the patient’s life expectancy, comorbidities, biopsy grade (Gleason score), clinical stage, and prostate-specific antigen (PSA) level. Signs of disease progression will usually trigger intervention with another therapy.

In certain conditions conservative monitoring with active surveillance or watching waiting may be the most appropriate plan of care.

The most common treatment options for prostate cancer are listed below

**IV. POLICY CRITERION**

A. When benefits are provided under the member’s contract, JHHC considers the following treatments potentially appropriate for prostate cancer under specific parameters noted below:

1. Active Surveillance if the following criteria are met:
   a. Men with very low-risk and low-risk prostate cancer which includes:
   b. Low grade of 1, OR;
   c. Gleason score of 6, AND;
   d. PSA<10, AND;
   e. Cancer is confined to the prostate, AND;

B. Watchful Waiting if the following criteria are met;

1. Men who are considered to have less than 10 years to live, AND/OR;
2. Have significant comorbidities, precluding definitive treatment, OR;

C. Hormone Therapy (also called androgen deprivation therapy(ADT) or androgen suppression therapy), if the following criteria are met:

1. If the cancer has spread too far to be cured by surgery or radiation, or if a patient can’t have these treatments for some reason, OR;
2. If the cancer remains or comes back after treatment with surgery or radiation therapy, OR;
3. Before radiation to try to shrink the cancer to make treatment more effective, OR;
4. At the same time as radiation therapy as initial treatment if patient is at higher risk of the cancer cell coming back after treatment (based on a high Gleason score, high PSA level, and/or growth of the cancer outside the prostate), OR;

D. Brachytherapy, see Policy CMS02.17 Brachytherapy, OR;

E. E. Proton Beam Radiotherapy, see Policy CMS16.09 Proton Beam Radiotherapy, OR;

F. F. External Beam Radiation Therapy (EBRT) (which includes: Three-Dimensional Conformal Radiation Therapy (3D-CRT), Intensity Modulated Radiation Therapy (IMRT) and Stereotactic Body Radiation Therapy (SBRT))

1. Three-Dimensional Conformal Radiation Therapy (3D-CRT) is considered medically necessary for prostate cancer when there is a concern about damage to surrounding critical structures and the need to focus precisely on the tumor.
2. Intensity Modulated Radiation Therapy (IMRT) is considered medically necessary for prostate cancer when there is a concern about damage to surrounding critical structures.
3. Stereotactic Body Radiation Therapy (SBRT) (Cyberknife, gamma knife, or linear accelerator) is considered medically necessary for localized malignant prostate cancer where highly precise application of high-dose radiotherapy is required and clinically appropriate and must meet the following criteria:
   a. Prostate cancer in individuals with organ-confined prostate cancer with:
      i. Gleason score less than or equal to eight, AND
ii. Prostate-specific antigen (PSA) less than 20; OR;

G. Cryotherapy (also called cryosurgery or cryoablation), if the following criteria are met:
   1. Age # 18 years of age, AND;
   2. Initial treatment of prostate cancer diagnosed by biopsy, OR;
   3. Recurrent prostate cancer, AND;
   4. Cancer localized to prostate, AND;
   5. Prostate # 80 grams by transrectal ultrasound (TRUS), AND;
   6. Appropriate as primary treatment of patients with clinically localized prostate cancer (stages T1-T3), OR;
   7. Only for patients with localized disease who have the following:
      a. Failed a trial of radiation therapy as a primary treatment, AND;
      b. Meet one of the following criteria: Stage 2b or below, Gleason score < 9, PSA, 8ng/mL, OR;

H. Surgery (which include the following procedures for Radical Prostatectomy: Laparoscopically, Open, Robotic-Assisted, and Laparoscopic), if the following criteria are met:
   1. Age # 18 years of age, AND;
   2. Prostate cancer diagnosed by biopsy, AND;
   3. Cancer localized to prostate, AND;
   4. Stage # T1 and # T2c, AND;
   5. Life expectancy # 10 years, OR;
   6. Stage # T3

**Note ~ A member who is requesting prostate surgery or any type of radiation therapy and has the following: a low grade of 1 or a Gleason score of 6 or less and a PSA< 10 will need to have it documented that the member has been offered Active Surveillance as a treatment option.

A. Chemotherapy (a regimen usually consists of a specific number of cycles given over a set period of time) which will be determined by the oncologist.

B. Unless specific benefits are provided under the member’s contract, JHHC considers all other treatments for prostate cancer experimental and investigational as they do not meet Technology Evaluation Criteria (TEC) #2-5. Refer to: CMS01.00 Medical Policy Introduction Technology Evaluation Criteria (TEC) #2-5.

V. DEFINITIONS

**Active Surveillance** (A treatment approach for men with very low-risk and low-risk prostate cancer (low Grade (grade 1 or Gleason 6), PSA <10 and the cancer is confined to the prostate) that involves regular doctor visits and close monitoring of their disease.7 Gleason score (GS) - The Gleason scoring system is used to grade prostate cancer. The

Gleason score - is based on biopsy samples taken from the prostate. The pathologist checks the samples to see how similar the tumor tissue looks to normal prostate tissue. Both a primary and a secondary pattern of tissue seen in the tumor, and the secondary pattern represents the next most common pattern. Each pattern is given a grade from 1 to 5, with 1 looking the most like normal prostate tissue and 5 looking the most abnormal. The two grades are then added to give a Gleason score. The American Joint Committee on Cancer recommends grouping Gleason scores into the following categories: Gleason X: Gleason score cannot be determined, Gleason 2-6: The tumor is well differentiated, Gleason 7: The tumor tissue is moderately differentiated, Gleason 8-10: The tumor tissue is poorly differentiated or undifferentiated.17 A low Gleason score means the cancer cells are similar to normal prostate cells and are less likely to spread; a high Gleason score means the cancer cells are very different from normal and are more likely to spread.16
Prostate-specific antigen, or PSA - is a protein produced by normal, as well as malignant, cells of the prostate gland. The PSA test measures the level of PSA in a man’s blood. A blood sample is sent to the laboratory for analysis. The results are usually reported as monograms of PSA per milliliter (ng/mL) of blood. The blood level of PSA is often elevated in men with prostate cancer. Men who report prostate symptoms often undergo PSA testing (along with DRE (digital rectal exam)) to help doctors determine the nature of the problem. There is no specific normal or abnormal level of PSA in the blood, and levels may vary over time in the same man. In the past, most doctors considered PSA levels of 4.0 ng/mL and lower as normal. Therefore, if a man had a PSA level above 4.0 ng/mL, doctors would often recommend a prostate biopsy to determine whether prostate cancer was present. However, more recent studies have shown that some men with PSA levels below 4.0 ng/mL have prostate cancer and that many men with higher levels do not have prostate cancer.14 Also, various factors can cause a man’s PSA level to fluctuate such as a man’s PSA level often rises if he has prostatitis or a urinary tract infection. Prostate biopsies and prostate surgery also increase PSA level. PSA level may also vary somewhat across testing laboratories. In general, however, the higher a man’s PSA level, the more likely it is that he has prostate cancer. Moreover, a continuous rise in a man’s PSA level over time may also be a sign of prostate cancer.14

Definitive Treatment /Therapy - The treatment plan for a disease or disorder that has been chosen as the best one for a patient after all other choices have been considered.

Watchful Waiting (A treatment approach whereby the patient is watched closely by the physician without having treatment unless the problem gets worse. The goal of watchful waiting is to only treat symptoms that bother the patient rather than cure the cancer).7

Hormone Therapy- also called androgen deprivation therapy(ADT) or androgen suppression therapy). The goal is to reduce the levels of male hormones, called androgens, in the body, or to stop them from affecting prostate cancer cells. Androgens stimulate prostate cancer cells to grow. The main androgens in the body are testosterone and dihydrotestosterone (DHT). Most of the androgens are made by the testicles, but the adrenal glands (glands that sit above your kidneys) also make a small amount. By lowering the androgen levels or stopping them from getting into prostate cancer cells often makes prostate cancers shrink or grow more slowly for a time. Hormone therapy alone does not cure prostate cancer.5

Brachytherapy- is an advanced form of radioactive treatment for cancer, particularly prostate and gynecologic cancers. In addition, brachytherapy is currently uses as a treatment option for breast, head and neck, gastrointestinal (rectal/anal, biliary, esophageal), skin, lymphoma, and lung cancer. The procedure involves inserting radioactive implants/seeds directly on top of the tumor or affected tissue. Once administered, the radiation damages any cancerous cells and prohibits the cancer cells ability to replicate and grow. Patients may receive brachytherapy treatment alone or in conjunction with other therapies.8

Proton Beam Radiotherapy- is a type of radiation therapy that uses streams of protons(tiny particles with a positive charge) to kill tumor cells. This type of treatment can reduce the amount of radiation damage to healthy tissue near a tumor. It is used to treat cancers of the head and neck and organs such as the brain, eye, lung, spine and prostate. Proton beam radiation is different from x-ray radiation.11

Types of External Beam Radiation Therapy are:

1. Three-dimensional conformal radiation therapy (3D-CRT) delivers radiation beams from different directions designed to match the shape of the tumor. This helps to reduce radiation damage to normal tissues and better kill the cancer by focusing the radiation dose on the tumor. 24
2. Intensity Modulated Radiation Therapy (IMRT) which is a more complex form of 3DCRT. The radiation intensity is varied within each beam in IMRT unlike conventional 3DCRT, which uses the same intensity in each beam. IMRT targets the tumor and avoids healthy tissue better than conventional 3D-CRT.  
3. Stereotactic Radiation Therapy (SBRT) is a treatment that delivers a large, precise radiation dose to a small tumor area. The patient must remain very still. Head frames or individual body molds help limit movement. This therapy is often given as a single or a few treatments. However, some patients may need several treatments. 

Cryoablation - for prostate cancer is also referred to as cryosurgery, cryotherapy, or cryosurgical ablation of the prostate (CSAP). It is a minimally invasive, percutaneous, transperineal surgical technique that uses ultrasound guided cryoprobes to freeze and destroy cancerous prostate tissue. The cryogen is usually liquid nitrogen but argon gas has also been used.

Staging – is a way of describing where the cancer is located, if or where it has spread, and whether it is affecting other parts of the body.

Stages of Prostate Cancer:

Stage T1: Tumor is microscopic, confined to prostate, and is not detectable by digital rectal exam (DRE) or visible by transrectal ultrasound TRUS. Usually discovered by an elevated PSA or biopsy. T1a and T1b lesions are those detected incidentally in pathology specimens of resected prostate tissue. T1c lesions are those diagnosed in a prostate biopsy because of an elevated PSA or prostatic symptoms in the absence of an abnormality on a digital rectal examination.

Stage T2: Tumor is confined to the prostate, has not extended beyond the prostate, and can be detected by DRE. Unilateral T2 lesions are subdivided into T2a and T2b based upon the extent of involvement; if there is bilateral involvement, lesions are classified as T2c.

Stage T3: The tumor extends through the prostate capsule (T3a) and possibly to the seminal vesicles (T3b) but has not spread to any other organs.

Stage T4: The tumor has spread to lymph nodes or organs near the prostate, such as the bladder.

Surgery for prostate cancer is a common choice to try to cure prostate cancer if it has not spread outside the prostate gland. The main type of surgery for prostate cancer is a radical prostatectomy. This type of surgery is where the surgeon removes the entire prostate gland plus some of the tissue around it, including the seminal vesicles. A radical prostatectomy can be done in different ways such as: Open approaches to radical prostatectomy which include: Radical retropubic prostatectomy and Radical perineal prostatectomy. The Laparoscopic approaches to radical prostatectomy include: Laparoscopic radical prostatectomy and Robotic-assisted laparoscopic radical prostatectomy.  

Chemotherapy (chemo) for prostate cancer uses anti-cancer drugs injected into a vein or given by mouth. These drugs enter the bloodstream and go throughout the body, making this treatment potentially useful for cancers that have spread (metastasized) to distant organs. Chemo is sometimes used if prostate cancer has spread outside the prostate gland and hormone therapy isn’t working. Recent research has also shown that chemo might be helpful if given along with hormone therapy. Chemo is not a standard treatment for early prostate cancer.

VI. BACKGROUND

Prostate cancer is typically a slow-growing cancer. It is one of the most common types of cancer in men. Usually prostate cancer grows slowly and is initially confined to the prostate gland, where it may not cause harm. However, while some types
of prostate cancer grow slowly and may need minimal or even no treatment, other types are aggressive and can spread quickly. Prostate cancer that is detected early when it is confined to the prostate gland has a better chance of successful treatment.  

Many men diagnosed with a low grade prostate cancer may be able to avoid treatment and the associated side-effects. If patient’s cancer is low-risk or medium-risk cancer, active surveillance may be an option for a patient. With active surveillance, men can wait to start treatment. Some men will never need treatment and others can delay treatment until tests show their cancer is growing more quickly.

Active surveillance is used because a patient may get better (or not get worse) without treatment. If the cancer continues to grow or spread, the patient and physician will decide what to do next. It means that a patient is being watched closely by his doctor without having treatment unless the problem gets worse. During this time, the patient will have regular checkups and tests, such as biopsies or blood work. Some prostate cancers grow so slowly that men who choose active surveillance may be able to delay or avoid having surgery or radiation.

Watchful waiting is also an approach where the patient is closely watched by the physician without having treatment unless the problem gets worse. The goal of watchful waiting is to only treat symptoms that bother the patient rather than cure the cancer. If a patient is over the age of 80 years old or has other serious health problems, like heart disease, the patient may choose not to have treatments to cure their cancer. Instead, the patient can have treatments to manage their symptoms. The goal of hormone therapy is to stop or slow the growth of the prostate cancer cells in a patient’s body. Hormone therapy can shrink prostate cancer tumors and may stop or limit the spread of a patient’s prostate cancer. Hormone therapy is used to control a patient’s prostate cancer.

Radiation therapy is the use of high-energy rays to destroy cancer cells. A physician who specializes in giving radiation therapy to treat cancer is called a radiation oncologist. A radiation therapy regimen (schedule) usually consists of a specific number of treatments given over a set period of time. The treatments for prostate cancer can be divided into brachytherapy, or internal radiation and external beam radiation. The main forms of external beam radiation for prostate cancer are Three-Dimensional Conformal Radiation Therapy, Intensity –Modulated Radiation Therapy (IMRT) and Stereotactic Radiation Therapy (SBRT).

Cryotherapy, or cryoblation, for prostate cancer is the controlled freezing of the prostate gland. The freezing destroys cancer cells. Cryotherapy is done under anesthesia. This treatment is for men who are not good candidates for surgery or radiotherapy because of other health issues.

The main type of surgery for prostate cancer is radical prostatectomy. The radical prostatectomy can be done in different ways. In this operation the surgeon removes the entire prostate gland plus some of the tissue around it, including the seminal vesicles.

Chemotherapy is the use of drugs to destroy cancer cells, usually by stopping their ability to grow and divide. Chemotherapy is usually given by a medical oncologist, a physician who specializes in treating cancer with medication.

There is no single treatment option that is right for every man with prostate cancer. Some tumors grow very slowly or not at all, so a patient may never need treatment. Others grow faster and spread to different places in a patient’s body. In either situation, a patient and their physician should work together to decide what is best for the patient.
VII. CODING DISCLAIMER

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member’s specific benefit plan determines coverage and referral requirements. All inpatient admissions require preauthorization.

Compliance with the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits

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<th>Employer Health Programs (EHP) refer to specific Summary Plan Description (SPD). If there is no criteria in the SPD, apply the Medical Policy criteria.</th>
<th>Priority Partners (PPMCO) refer to COMAR guidelines and PPMCO SPD then apply the Medical Policy criteria.</th>
<th>US Family Health Plan (USFHP), TRICARE Medical Policy supersedes JHHC Medical Policy. If there is no Policy in TRICARE, apply the Medical Policy Criteria.</th>
<th>Advantage MD, LCD and NCD Medical Policy supersedes JHHC Medical Policy. If there is no LCD or NCD, apply the Medical Policy Criteria.</th>
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VIII. CODING INFORMATION

PRE-AUTHORIZATION REQUIRED

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<td>Prostatectomy, perineal, subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy)</td>
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<td>55810</td>
<td>Prostatectomy, perineal radical</td>
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<td>55812</td>
<td>Prostatectomy, perineal radical; with lymph node biopsy(s) (limited pelvic lymphadenectomy)</td>
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<td>55815</td>
<td>Prostatectomy, perineal radical; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric and obturator nodes</td>
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<td>55842</td>
<td>Prostatectomy, retropubic radical, with or without nerve sparing; with lymph node biopsy(s) (limited pelvic lymphadenectomy)</td>
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### Treatments for Prostate Cancer

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<td>55705</td>
<td>Biopsy, prostate; incisional, any approach</td>
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<td>55706</td>
<td>Biopsies, prostate, needle, transperineal, stereotactic template guided saturation sampling, including imaging guidance</td>
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<td>84152</td>
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**NO PRE-AUTHORIZATION REQUIRED**

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<td>G0103</td>
<td>Prostate cancer screening; prostate specific antigen test (PSA)</td>
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<td>G6015</td>
<td>Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session</td>
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Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session

**ICD10 CODES ARE FOR INFORMATIONAL PURPOSES ONLY**

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**IX. REFERENCE STATEMENT**

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins HealthCare LLC (JHHC) Medical Policy Team during the development and implementation of this medical policy. Per NCQA standards, the Medical Policy Team will continue to monitor and review any newly published clinical evidence and adjust the references below accordingly if deemed necessary.

**X. REFERENCES**


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My Prostate Cancer Treatment.ORG Retrieved: http://www.myprostatecancertreatment.org


XI. APPROVALS

Effective Date: 03/02/2018 Review Dates: 05/15/18