MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Brachytherapy or Radioactive Seed Implantation for Prostate Cancer**
Policy Number	**6.01.16**
Category	**Technology Assessment**
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Archived Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, permanent low-dose rate (LDR) brachytherapy or temporary high-dose-rate (HDR) brachytherapy for prostate cancer is considered **medically appropriate** for the following indications:
   A. Permanent LDR brachytherapy or temporary HDR brachytherapy as monotherapy for patients with **ALL** of the following indications:
      1. clinically organ-confined disease; and
      2. prostate cancer classified as stage less than T3a; and
      3. Gleason score 7 or lower; or
      4. Prostate-specific antigen (PSA) level less than 20 ng/mL.
   B. Permanent LDR brachytherapy or temporary HDR brachytherapy in conjunction with external beam radiation therapy (EBRT) for patients with **ALL** of the following indications:
      1. patient diagnosed with clinically localized disease; and
      2. prostate cancer classified as stage T2b, T2c, T3a, T4; and
      3. Gleason score 7 or greater; or
      4. PSA level 10 ng/ml or greater.

II. Based upon our criteria and assessment of the peer reviewed literature, temporary HDR brachytherapy alone as monotherapy for high-risk prostate cancer has not been proven to be medically effective and, therefore, is considered **investigational.**

Refer to Corporate Medical Policy #7.01.01 Focal Therapies for Prostate Cancer Treatment

POLICY GUIDELINE

I. One technique of image-guided radiation therapy (IGRT) is allowed daily when criteria for brachytherapy are met.

DESCRIPTION

The American Brachytherapy Society (ABS) defines brachytherapy as "Internal radiation treatment given by placing radioactive material directly into a tumor or close to it. Also called interstitial radiation therapy, intracavitary radiation therapy, intravascular radiation therapy, or seed implantation." The radioactive material is sealed in needles, seeds, wires, or catheters which are inserted and guided by radiological imaging, usually, but not exclusively, ultrasound.

There are two major methods of prostate brachytherapy; permanent low dose rate (LDR) brachytherapy and temporary high dose rate (HDR) brachytherapy.

In LDR brachytherapy, radioactive seeds are implanted interstitially, using the transperineal route with the guidance of transrectal ultrasound, fluoroscopy and/or computed tomography. The seeds release radiation gradually at a low-dose rate, over a period of time (six to 12 months), after which they become inert. The most common seeds used in LDR brachytherapy are Iodine-125 and Palladium-103. The seeds do not have to be removed and can remain in the prostate for the rest of the patient's life. ABS recommends that post-operative dosimetry be performed on each patient who has undergone permanent radioactive seed implantation. Without this information it is impossible to confirm the actual dose delivered or to identify any variance from the treatment plan.

In contrast, HDR brachytherapy involves placing tiny plastic catheters into the prostate gland and then delivering multiple radiation treatments, or "fractions," through these catheters with a high energy radioisotope such as iridium-192. The radioactive source is "afterloaded," which means it is temporarily inserted into the prostate for a calculated duration at various "dwell positions," usually eight to 12 minutes. HDR brachytherapy can be delivered in "fractions," which is the delivery during several sessions per day or over a course of several days. Radiation treatment planning and computerized dose calculations are needed, both to determine the prostate and tumor dose distribution and to control the radiation dose to the adjacent normal tissues such as rectum, bladder, and urethra. HDR brachytherapy permits precise delivery of radiation at a high rate to the prostate and immediate surrounding areas. In addition to efficacy in the low- and intermediate-grade prostate cancers, it is believed to be more effective in destroying rapidly dividing cancer cells, as seen in poorly differentiated malignancies.

Brachytherapy is commonly used in conjunction with EBRT and Androgen Deprivation Therapy (ADT).

A number of devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process to deliver brachytherapy to the prostate. The Martinez Prostate Template Set and Photon Technologies HDR Prostate Template and Accessories are examples of radiation application devices. These devices are intended as accessories to commercially available HDR remote afterloader systems for prostate brachytherapy. Seed (Theragenics), Proxcelan Cs-131 (IsoRay Medical), and BrachySource Brachytherapy Seed Implants are examples of permanently implanted seeds available and cleared by the FDA through the 510(k) process.

The American Society for Radiation Oncology (ASTRO) defines Image-guided radiation therapy (IGRT) as the use of dedicated devices for fraction-by-fraction imaging and guidance within the treatment room that localizes the target and normal structures at the time of treatment to assure precise and accurate placement of the radiation, and thereby pursue highly conformal dose distributions, higher dose prescriptions, and shorter fractionation schedules. IGRT can be conducted using computed tomography (CT), magnetic resonance imaging (MRI), ultrasound (US) and x-ray. Scans are compared to simulation reference images and allow the radiation oncologist to adjust based on the tumor position, size, shape.

Hormone therapy may be considered as a neo-adjuvant therapy to permanent seed implantation, HDR brachytherapy, or external beam radiation therapy to selectively reduce prostate size and induce tumor regression.

The following table was compiled utilizing the National Comprehensive Cancer Network (NCCN) v.4.2023 Prostate Cancer guidelines risk stratification and recommendations for the use of brachytherapy in the treatment of prostate cancer:

Risk Group	Clinical/Pathologic Features	Brachytherapy
Very low	Has all of the following: • cT1c	N/A

	• Grade Group 1 • PSA <10ng/mL • Fewer than 3 prostate biopsy fragments/cores positive, ≤50% cancer in each fragment/core • PSA density <0.15ng/mL/g	
Low	Has all of the following but does not qualify for very low risk: • cT1-cT2a • Grade Group 1 • PSA <10 ng/mL	If prognosis is ≥ 10 years
Favorable Intermediate	Has all of the following: • No high-risk or very high-risk group features • Has one or more intermediate risk factors: o cT2b-cT2c o Grade Group 2 o PSA 10-20 ng/mL o <50% biopsy cores positive	If prognosis is 5- 10 years
Unfavorable Intermediate	Has all of the following: • No high-risk or very high-risk group features • Has 2 or 3 intermediate risk factors: o cT2b-cT2c o Grade Group 3 o PSA 10-20 ng/mL o ≥50% biopsy cores positive	If prognosis is 5- 10 years (Brachytherapy + EBRT+ ADT)
High	Has no very-high-risk features and has exactly one high-risk feature: o cT3a OR o Grade Group 4 or Grade Group 5 OR o PSA >20 ng/mL	If prognosis is > 5 years or symptomatic (Brachytherapy +EBRT + ADT)
Very high	Has at least one of the following: o cT3b-cT4 o Primary Gleason pattern 5 o 2 or 3 high-risk features o >4 cores with Grade Group 4 or 5	N/A

RATIONALE

Peer-reviewed literature demonstrates that LDR brachytherapy using the transperineal approach provides excellent control of the disease in low-stage and low- to moderate-grade tumors, like those with 3D conformal EBRT or radical prostatectomy. For patients with intermediate-risk disease, 3D conformal EBRT, with or without brachytherapy, or radical prostatectomy provided comparable long-term, disease-free survival. The transperineal approach offers minimal morbidity in appropriately selected patients, generally results in minimal impairment of the patient's lifestyle, and can be performed either in an outpatient setting or with a short hospital stay of one to two days.

Considering the widespread increase in the use of LDR brachytherapy and HDR brachytherapy as a treatment option, evidence is sufficient to permit conclusions as to its safety and efficacy in a select patient population. There is no data to support that HDR brachytherapy as monotherapy is superior to other existing modalities as a lone treatment option for high-risk prostate cancer.

The NCCN v.4.2023 state patient selection should consider aspects of gland size, baseline urinary symptoms, and prior procedures (i.e., transurethral resection of the prostate) that may increase risk of adverse effects. Neoadjuvant androgen deprivation therapy (ADT) may be used to shrink the prostate to an acceptable size; however, increased toxicity would be expected from ADT and prostate size may not decline in some men despite neoadjuvant ADT. Potential toxicity of ADT must be balanced against the potential benefit of target reduction. NCCN states that the accuracy of treatment should be verified daily with any of the following: techniques of IGRT using CT, ultrasound, implanted fiducials or electromagnetic targeting/tracking.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
55875	Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy
55876	Placement of interstitial device(s) for radiation therapy guidance (e.g. fiducial markers, dosimeter), prostate (via needle, any approach), single or multiple
76965	Ultrasonic guidance for interstitial radioelement application
77014	Computed tomography guidance for placement of radiation therapy fields
77021	Magnetic resonance guidance for needle placement (e.g., for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation
77316	Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s)
77317	Brachytherapy isodose plan; intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2-12 channels), includes basic dosimetry calculation(s)
77318	Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s)
77387	Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed
77761	Intracavitary radiation source application; simple
77762	Intracavitary radiation source application; intermediate
77763	Intracavitary radiation source application; complex
77778	Interstitial radiation source application; complex includes supervision, handling, loading of radiation source, when performed
77789	Surface application of low dose rate radionuclide source
77790	Supervision, handling, loading radiation source

Code	Description
77799	Unlisted procedure, clinical brachytherapy
The following codes may be E/I if used alone.	
77770	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel
77771	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2-12 channels
77772	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels

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HCPCS Codes

Code	Description
C1716	Brachytherapy source, nonstranded, gold-198, per source
C1719	Brachytherapy source, nonstranded, non -high dose rate iridium-192, per source
C2637	Brachytherapy source, nonstranded, ytterbium-169, per source
C2638	Brachytherapy source, stranded, iodine-125, per source
C2639	Brachytherapy source, nonstranded, iodine-125, per source
C2640	Brachytherapy source, stranded, palladium-103, per source
C2641	Brachytherapy source, nonstranded, palladium-103, per source
C2645	Brachytherapy planar source, palladium-103, per square millimeter
G0458	Low dose rate (LDR) prostate brachytherapy services, composite rate
Q3001	Radioelements for brachytherapy, any type, each
The following codes may be E/I if used alone.	
C1717	Brachytherapy source, nonstranded, high dose rate iridium-192, per source
C9725	Placement of endorectal intracavity applicator for high intensity brachytherapy

ICD10 Codes

Code	Description
C61	Malignant neoplasm of prostate
D07.5	Carcinoma in situ of prostate

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KEY WORDS

High-dose rate brachytherapy, Low-dose rate brachytherapy, Permanent brachytherapy, Prostate brachytherapy, Temporary brachytherapy, image-guided radiation therapy.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, Brachytherapy is not addressed in National or Regional Medicare coverage determinations or policies.