MEDICAL POLICY

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Medical Policy Title	**Brachytherapy or Radioactive Seed Implantation for Prostate Cancer**
Policy Number	**6.01.16**
Current Effective Date	**December 22, 2025**
Next Review Date	**November 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Permanent low-dose rate (LDR) brachytherapy or temporary high-dose-rate (HDR) brachytherapy for localized prostate cancer is considered **medically appropriate** for the following indications:

   A. When used alone as monotherapy for **ANY** of the following Risk Groups (Refer to Policy Guideline II):

      1. Very Low Risk;
      2. Low Risk;
      3. Favorable Intermediate Risk; **or**
      4. Unfavorable Intermediate Risk;

   OR

   B. When used as Brachytherapy Boost in conjunction with external beam radiation therapy (EBRT) for **ANY** of the following Risk Groups (Refer to Policy Guideline II):

      1. Unfavorable Intermediate Risk;
      2. High Risk; **or**
      3. Very High Risk.

II. Temporary HDR brachytherapy alone as monotherapy for high-risk prostate cancer is considered **investigational.**

RELATED POLICIES

Corporate Medical Policy

7.01.01 Focal Therapies for Prostate Cancer Treatment

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. One (1) technique of image-guided radiation therapy (IGRT) is allowed daily when the criteria for brachytherapy are met.

II. Prostate Cancer Risk Group Definitions

The following table was compiled utilizing the National Comprehensive Cancer Network (NCCN) V.2.2026 Prostate Cancer Guidelines Risk Stratification and Recommendations for the Use of Brachytherapy in the Treatment of Prostate Cancer:

Risk Group	Clinical/Pathologic Features			Brachytherapy
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
Intermediate	Has all of the following: • No high-risk or very high-risk group features • Has one or more intermediate risk factors: ○ cT2b-cT2c ○ Grade Group 2 or 3 ○ PSA 10-20 ng/mL	Favorable	Has all the following: • 1 IRF • Grade Group 1 or 2 • <50% biopsy cores positive (e.g., <6 or 12 cores)	If prognosis is 5- 10 years
		Unfavorable	Has one or more of the following: • 2 or 3 IRFs • Grade Group 3 • >50% biopsy cores positive (e.g ., >6 of 12 cores)	Unfavorable: RT+ADT (4-6 months)
High	Has one or more high-risk features, but does not meet criteria for very high risk: ○ cT3a OR ○ Grade Group 4 or Grade Group 5 OR ○ PSA >20 ng/mL			If prognosis is > 5 years or symptomatic (Brachytherapy +EBRT + ADT)

Very high	Has at least two of the following: o cT3-cT4 o Grade Group 4 or 5 o PSA>40ng/ml	Prognosis >5 years or symptomatic (Radiation Therapy +ADT+Abiraterone

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 in 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).

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.

SUPPORTIVE LITERATURE

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.

Morris et al (2017) reported on the Androgen Suppression Combined with Elective Nodal and Dose Escalated Radiation Therapy trial, which evaluated patients who received androgen deprivation therapy (ADT) and EBRT. The investigators compared EBRT boost with an LDR brachytherapy boost. The primary outcome (biochemical progression-free survival [PFS]) at a median follow-up of 6.5 years significantly favored the LDR brachytherapy group (p=.004). In a subgroup analysis limited to patients with intermediate-risk prostate cancer (i.e., clinically localized disease), biochemical PFS was significantly higher in the brachytherapy boost group(p=.003). Overall and disease-specific survival did not differ significantly between the LDR brachytherapy boost and the EBRT boost groups. In 2018, Morris published a reanalysis of the Androgen Suppression Combined with Elective Nodal and Dose Escalated Radiation Therapy trial comparing biochemical failure using a prostate-specific antigen (PSA)threshold of >0.2 ng/mL to the Phoenix threshold (nadir +2 ng/mL). At follow-up times greater than 4 years, patients receiving LDR permanent brachytherapy were less likely to experience biochemical failure (log rank p=.001). The Kaplan-Meier biochemical progression free survival was superior for LDR permanent brachytherapy compared with dose-escalated EBRT.

Kee et al (2018) published a systematic review and meta-analysis comparing brachytherapy boost and EBRT boost after EBRT for patients with prostate cancer. Three RCTs with a total of 703 participants were included. Brachytherapy boost had a significant benefit over EBRT boost for 5-year progression-free survival (hazard ratio [HR], 0.49; 95% confidence interval [CI], 0.37 to 0.66; p<.01); there was no significant difference between the two treatments for overall survival (HR, 0.92; 95% CI, 0.64 to 1.33; p=.65). There was also no difference in rates of greater than or equal to grade 3 late genitourinary (GU) or late gastrointestinal (GI) toxicities). No limitations for this analysis were reported.

Pasalic et al (2021) reported on the Comparative Effectiveness Analysis of Surgery and Radiation (CEASAR) study, a prospective, multicenter study that evaluated 695 patients who received EBRT alone (n=583) and EBRT plus LDR brachytherapy (n=112) for localized prostate cancer. Adjunctive ADT was given based on a risk-based assessment and at the discretion of the clinician. The primary

outcomes were patient-reported, including Expanded Prostate Cancer Index Composite domains (e.g., urinary irritative function, bowel function). After a median follow-up of 73 months, no significant differences were found between EBRT alone and EBRT plus LDR brachytherapy for 5-year and 7-year overall survival, 5-year prostate cancer-specific survival and 7-year prostate cancer-specific survival. Treatment with EBRT plus LDR brachytherapy was associated with clinically meaningful worse urinary irritative function and bowel function scores at three (3) years; but the differences between treatment groups were not considered clinically meaningful at five (5) years.

A 2023 randomized clinical trial by Michalski et al sought to determine whether the addition of EBRT to brachytherapy (COMBO) would improve the five-year freedom from progression (FFP) in intermediate- risk prostate cancer when compared to treatment with brachytherapy (BT) alone. A total of 579 men with prostate cancer stage cT1c-T2bN0M0, Gleason Score 2-6 and PSA 10-20 or GS7, and PSA <10 were included in the trial. The COMBO arm (n=287) received EBRT to the prostate and seminal vesicles followed by BT prostate boost. The BT arm (n=292) had treatment delivered to the prostate only. The primary end point of the study was the FFP derived from PSA failure (as defined by ASTRO or Phoenix) local failure, distant failure or death. After a median follow up of 12.1 years, there were no differences between arms in FFP. However, the COMBO arm experienced significantly higher rates of late genitourinary and gastrointestinal toxicities. Specifically, grade 2+ toxicity occurred in 42.8% of COMBO patients versus 25.8% in the BT group, and grade 3+ toxicity was 8.2% versus 3.8%, respectively. Authors concluded that compared with BT, COMBO did not improve FFP but caused greater toxicity. BT alone can be considered as a standard treatment for men with intermediate-risk prostate cancer.

King et al (2025) conducted a single-institutional retrospective analysis of intermediate risk prostate cancer with the objective to define subgroup of patients suitable for brachytherapy monotherapy. The study assessed 1622 patients with a median follow-up of 10.4 years. The primary endpoint was biochemical failure (BF), defined as prostate specific antigen (PSA) > 0.4 ng/mL. For monotherapy, PSA greater than or equal to 10 ng/mL and cT2b-c disease were associated with BF. The 10-year incidences of BF after monotherapy for patients without and with these risk factors were 5.8% versus 17.2%, respectively. For the cT1-T2a/PSA less than 10 risk group, neither the addition of ADT nor EBRT was associated with biochemical failure. For the cT2b-T2c and/or PSA ≥ 10 subgroup, ADT but not EBRT was associated with BF. Authors concluded that brachytherapy monotherapy is suitable for all FIR, and UIR disease meeting cT1-T2a/PSA less than 10 criteria.

Anderson et al (2021) published a systematic review analyzing the available evidence on HDR brachytherapy as monotherapy for prostate cancer. The review included seven studies representing 2123 patients. Of the included patients, 40% were NCCN low risk, 40% were intermediate, and 20% were high risk. All of the included studies had at least five years of follow-up, a minimum of 80 patients, and biochemical recurrence free survival (BRFS) outcomes. The median follow-up was 74 months. The five-year BRFS rate was 95% (95% CI, 93% to 96%). Grade 3 or 4 genitourinary and gastrointestinal toxicity rates were low (2% and 0.3%, respectively). Given the methodology utilized within the study, patients' treatment characteristics were reported at the study group level and therefore it is not clear whether patients with higher risk disease were included in a cohort that had received ADT. The authors are uncertain as to how this reporting may have impacted associated outcomes.

The current evidence on the use of HDR brachytherapy as a sole treatment for high-risk prostate cancer patients does not demonstrate its superiority over other treatments such as EBRT. More robust clinical trials are needed and the current evidence suggests that it may be more beneficial when used in combination with EBRT or hormone therapy.

PROFESSIONAL GUIDELINE(S)

The Groupe Europeen de Curietherapie (GEC), the European SocieTY for Radiotherapy and Oncology (ESTRO) and Advisory Committee for Radiation Oncology Practice (ACROP) published joint prostate brachytherapy guidelines in 2022. The group assigned a Grade B, Level 2a recommendation for the use of fractionated HDR monotherapy for low and intermediate risk prostate cancer. The authors acknowledge that the use of LDR permanent implants for monotherapy is well established, while there is less information available on the optimal dose fractionation schedules for monotherapy using HDR, but state that overall results across comparable risk groups are no different. Given the significant risk of microscopic extracapsular spread, the group recommends brachytherapy be combined with EBRT for individuals with unfavorable intermediate and high risk localized prostate cancer (Grade A, Level 1a).

Deville and colleagues published a summary of the 2022 American Urological Association (AUA)/ASTRO Guideline on Clinically Localized Prostate Cancer in 2023. The multidisciplinary panel developed recommendations based on a systematic literature review to provide guidelines pertinent to radiation oncologists. The authors address the use of radiation therapy for clinically localized prostate cancer as evolving rapidly, with new trial results, therapeutic combinations, and technological advances. Brachytherapy is only mentioned within the guidelines for its use in patients with unfavorable intermediate or high-risk prostate cancer who are electing radiation therapy. In this risk population, the group recommends that clinicians offer dose-escalated hypofractionated EBRT or combined EBRT +brachytherapy (LDR, HDR) along with a risk-appropriate course of ADT (Recommendation: Strong, Grade A/B).

The NCCN V.2.2026 guidelines state that, brachytherapy alone is an option for patients with very low, low, or favorable intermediate-risk prostate cancer, depending on life expectancy. Patients with high-risk cancers are generally considered poor candidates for brachytherapy alone. LDR or HDR brachytherapy can be added as a boost to EBRT plus ADT in patients with unfavorable intermediate-, high-, or very-high-risk prostate cancer being treated with curative intent. Combining EBRT and brachytherapy allows dose escalation while minimizing acute or late toxicity in patients with high-risk localized or locally advanced cancer.

REGULATORY STATUS

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. I-Seed (Theragenics), Proxcelan Cs-131

(IsoRay Medical), and BrachySource Brachytherapy Seed Implants (C.R. Bard, Inc) are examples of permanently implanted seeds available and cleared by the FDA through the 510(k) process.

The U.S Nuclear Regulatory Commission (NRC) is responsible for the regulation of radioactive materials. Whereas the Food & Drug Administration (FDA) is responsible for device regulation.

Refer to U.S. NRC website. Available from: https://www.nrc.gov/about-nrc [accessed 2025 Oct 9].

Refer to the FDA Radiation-Emitting Products website. Available from: https://www.fda.gov/radiation-emitting-products [accessed 2025 Oct 9].

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

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
76873	Ultrasound, transrectal; prostate volume study for brachytherapy treatment planning (separate procedure)
76965	Ultrasonic guidance for interstitial radioelement application
77021	Magnetic resonance imaging 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)

Code	Description
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
77799	Unlisted procedure, clinical brachytherapy
The following codes may be considered as 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

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
C2642	Brachytherapy source, stranded, cesium-131, per source
C2643	Brachytherapy source, nonstranded, cesium-131, per source
C2645	Brachytherapy planar source, palladium-103, per square millimeter

Code	Description
G0458	Low dose rate (LDR) prostate brachytherapy services, composite rate
Q3001	Radioelements for brachytherapy, any type, each
The following codes may be considered as 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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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Brachytherapy is not addressed in National or Regional Medicare coverage determinations or policies.

Billing and Coding: Transrectal Ultrasound (LCA A57427) [accessed 2025 Sept 15]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, 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 HISTORY/REVISION	
Committee Approval Dates	
07/02/99, 07/02/01, 05/16/02, 06/19/03, 05/19/04, 05/18/05, 05/18/06, 04/19/07, 04/17/08, 04/16/09, 05/27/10, 06/16/11, 06/21/12, 06/20/13, 06/19/14, 07/16/15, 07/21/16, 08/17/17, 10/18/18, 11/21/19, 11/19/20, 11/18/21, 11/17/22, 11/16/23, 11/21/24, 11/20/25	
Date	**Summary of Changes**
12/31/25	• Code edit; deleted CPT code 77014, termed 12/31/25.
11/20/25	• Annual review; new medically appropriate criteria added for unfavorable intermediate risk. Policy guideline for Prostate Cancer Risk Group Definitions updated. EviCore effective date will be 12/22/25.
01/01/25	• Summary of changes tracking implemented.
07/02/99	• Original effective date