

Blue Cross Blue Shield of Massachusetts is an Independent Licenses of the Blue Cross and Blue Shield Association

Medical Policy

Brachytherapy for Clinically Localized Prostate Cancer Using Permanently Implanted Seeds

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Policy Number: 175

BCBSA Reference Number: 8.01.14

NCD/LCD: NA

Related Policies

- Intensity-Modulated Radiotherapy of the Prostate, #090
- Stereotactic Radiosurgery & Stereotactic Body Radiotherapy, #277
- Cryosurgical Ablation of Miscellaneous Solid Tumors Other Than Liver, Prostate, or Dermatologic Tumors, #260
- High-Dose Rate Temporary Prostate Brachytherapy, #353
- Charged-Particle (Proton or Helium Ion) Radiotherapy, #437
- Focal Treatments for Prostate Cancer, #733

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Brachytherapy using permanent transperineal implantation of radioactive seeds in treatment of localized prostate cancer when used as monotherapy or in conjunction with external beam radiation therapy (EBRT) may be considered **MEDICALLY NECESSARY**.

Focal prostate brachytherapy is considered **INVESTIGATIONAL** in the treatment of prostate cancer.

Prior Authorization Information

Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed **inpatient**.

Outpatient

For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO Blue SM	Prior authorization is not required .
Medicare PPO Blue SM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
55875	Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy
76873	Ultrasound, prostate volume study for brachytherapy treatment planning (separate procedure)
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)
77778	Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed

HCPCS Codes

HCPCS	
codes:	Code Description
C2636	Brachytherapy source, nonstranded, palladium-103, per 1 mm
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
Q3001	Radioelements for brachytherapy, any type, each

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and/or HCPCS codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
C61	Malignant neoplasm of prostate
D07.5	Carcinoma in situ of prostate

Description

Prostate Cancer

In 2020, it has been estimated that 10.6% of all new cancer diagnoses will involve the prostate. In addition, as of 2017, estimates have suggested that over 3 million men in the U. S. are living with prostate cancer.^{1,}

Brachytherapy

Brachytherapy is a procedure in which a radioactive source (eg, radioisotope "seeds") is used to provide extremely localized radiation doses. With brachytherapy, the radiation penetrates only short distances; this procedure is intended to deliver tumoricidal radioactivity directly to the tumor and improve local control while sparing surrounding normal tissue. Brachytherapy has been used for localized prostate cancer to provide local tumor control, which has been associated with lower distant metastasis rates and improved patient survival. Seeds can be permanently or temporarily implanted. Permanent (low-dose rate [LDR]) brachytherapy is generally used for low-risk disease; temporary (high-dose rate) brachytherapy is typically reserved for intermediate- or high-risk disease. This evidence review only assesses permanent LDR brachytherapy in prostate cancer.

The proposed biologic advantages of brachytherapy compared with external-beam radiotherapy (EBRT) are related to the dose delivered to the target and the dose delivery rate. The dose rate of brachytherapy sources is generally in the range of 40 to 60 centigray per hour, whereas conventional fractionated EBRT dose rates exceed 200 centigray per minute. Enhanced normal tissue repair occurs at the LDRs. Repair of tumor cells does not occur as quickly, and these cells continue to die during continued exposure. Thus, from a radiobiologic perspective, LDR radiation causes ongoing tumor destruction in the setting of normal tissue repair. Additionally, brachytherapy is performed as a single procedure in the outpatient setting, which many patients may find preferable to the multiple EBRT sessions. The total doses of radiotherapy that can be delivered may also vary between EBRT and brachytherapy, especially with newer forms of EBRT such as 3-dimensional conformal radiotherapy and intensity-modulated radiotherapy.

Brachytherapy has not been considered appropriate for patients with a large prostate or those with a urethral stricture because the procedure results in short-term swelling of the prostate, which can lead to urinary obstruction. As with all forms of radiotherapy, concerns exist with the long-term risk of treatment-related secondary malignancies. Reports have also suggested that the clinician's level of experience with brachytherapy correlates with disease recurrence rates.

Studies of permanent brachytherapy have generally used iodine 125 or palladium 103. Use of cesium 131 is also being studied. Use of iodine 125 requires more seeds, thus reducing dosimetric dependence on any single seed. Postimplant dosimetric assessment should be performed to ensure the quality of the implant and optimal source placement (ie, targeted tumor areas receive the predetermined radiation dosages while nearby structures and tissues are preserved).

Permanent brachytherapy may be used as monotherapy or as combination therapy with EBRT as a way to boost the dose of radiotherapy delivered to the tumor; this combined modality therapy can be performed with permanent or temporary brachytherapy. The brachytherapy boost is typically done 2 to 6 weeks after completion of EBRT, although the sequence can vary. In some cases, patients also receive androgen deprivation therapy.

Focal or subtotal prostate brachytherapy is a form of more localized, organ-preserving therapy for small localized prostate cancers. Brachytherapy seeds are placed only in the areas where the tumor has been identified rather than throughout the whole prostate gland. The aim of focal therapy is to reduce the occurrence of adverse events associated with brachytherapy, including urinary, bowel, and sexual dysfunction.

Summary

Description

Brachytherapy is a procedure in which a radioactive source (eg, radioisotope "seeds") is permanently or temporarily implanted in or near the tumor (eg, placed into the prostate gland to treat localized prostate cancer). The radiation from brachytherapy penetrates only short distances and is intended to deliver tumoricidal radioactivity directly to the tumor to improve local control while sparing surrounding normal tissue. Focal (subtotal) prostate brachytherapy is a form of organ-preserving therapy for small localized prostate cancers. This evidence review only assesses permanent low-dose rate (LDR) brachytherapy in prostate cancer.

Summary of Evidence

For individuals who have localized prostate cancer who receive permanent LDR brachytherapy plus external-beam radiotherapy (EBRT), the evidence includes a randomized controlled trial (RCT) on a related comparison and observational studies. Relevant outcomes are overall survival (OS), disease-specific survival, and treatment-related morbidity. No RCTs have compared permanent LDR brachytherapy plus EBRT with EBRT alone in patients who have clinically localized prostate cancer. An RCT comparing boost LDR brachytherapy plus boost EBRT with EBRT alone found better biochemical progression-free survival (BPFS) but not OS or disease-specific survival in patients who had combined treatment. A comparative observational study found a significantly higher BPFS rate in patients who received LDR brachytherapy plus EBRT than with EBRT alone. Rates of genitourinary but not gastrointestinal toxicity were significantly higher with combined treatment. Multicenter and single-center uncontrolled studies found relatively high rates of BPFS after LDR brachytherapy plus EBRT. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have localized prostate cancer who receive permanent LDR brachytherapy as monotherapy, the evidence includes RCTs, systematic reviews, and observational studies. Relevant outcomes are OS, disease-specific survival, and treatment-related morbidity. One RCT compared LDR brachytherapy as monotherapy with radical prostatectomy and found that the 5 year BPFS rate was as high for brachytherapy as it was for radical prostatectomy and erectile function was better after brachytherapy. Comparative observational studies have found similar survival outcomes with LDR brachytherapy compared with other treatments; there were lower rates of some adverse events and higher rates of others. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with localized prostate cancer who receive focal permanent LDR brachytherapy alone or combined with EBRT, the evidence includes case series and systematic reviews. Relevant outcomes are OS, disease-specific survival, and treatment-related morbidity. Systematic reviews of focal prostate cancer therapies have only identified a few case series evaluating focal brachytherapy. Survival outcomes were not reported. Controlled studies in larger numbers of patients are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
11/2020	BCBSA National medical policy review. Description, summary, and references
	updated. Policy statements unchanged.
9/2019	BCBSA National medical policy review. Description, summary, and references
	updated. Policy statements unchanged.

9/2018	BCBSA National medical policy review. No changes to policy statements. New
	references added. Background and summary clarified.
2/2018	Clarified coding information.
8/2017	New references added from BCBSA National medical policy.
12/2016	BCBSA National policy medical review.
	New investigational indications described. Effective 12/1/2016.
1/2016	Clarified coding information.
8/2015	New references added from BCBSA National medical policy.
1/2015	Clarified coding information.
9/2014	New references added from BCBSA National medical policy.
5/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
8/2013	New references from BCBSA National medical policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates.
	No changes to policy statements.
9/2011	Reviewed - Medical Policy Group – Urology, Obstetrics and Gynecology.
	No changes to policy statements.
7/2011	Reviewed - Medical Policy Group – Hematology and Oncology.
	No changes to policy statements.
9/2010	Reviewed - Medical Policy Group -Hematology and Oncology.
	No changes to policy statements.
4/1/10	Medical Policy 175 created, effective 4/1/10

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use

Managed Care Guidelines

Indemnity/PPO Guidelines

Clinical Exception Process

Medical Technology Assessment Guidelines

References

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