

MEDICAL POLICY



MEDICAL POLICY DETAILS	
Medical Policy Title	BRACHYTHERAPY OR RADIOACTIVE SEED IMPLANTATION FOR PROSTATE CANCER
Policy Number	6.01.16
Category	Technology Assessment
Effective Date	10/18/01
Revised Date	10/18/01, 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
Product Disclaimer	<ul style="list-style-type: none"> • 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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare 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.

POLICY STATEMENT

- I. Based upon our criteria and assessment of peer-reviewed literature, *permanent* brachytherapy or high dose rate brachytherapy for prostate cancer is **medically appropriate** for the following indications:
- A. Permanent brachytherapy or high dose rate brachytherapy as monotherapy for the following indications:
1. patient diagnosed with clinically organ-confined disease, and
 2. prostate cancer classified stage less than T3a, and
 3. Gleason score less than 8, or
 4. PSA level less than 20 ng/mL.
- B. Permanent brachytherapy or high dose rate brachytherapy in conjunction with EBRT for the following indications:
1. patient diagnosed with clinically localized disease, and
 2. prostate cancer classified stage T2b, T2c, T3a, T4, and
 3. Gleason score greater than or equal to 7 but less than or equal to 10, or
 4. PSA level greater than 10 ng/mL.

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

Refer to Corporate Medical Policy #7.01.01 regarding Cryosurgery for Prostate Cancer.

POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Brachytherapy is the term used to describe radioactive seeds placed inside the body to deliver radiation near the site of the malignancy. Brachytherapy may be thought of as internal radiation in contrast to external beam radiation in which radiation is directed through the body area from an outside source. Seed implant treatment for prostate cancer refers to the placement of tiny radioactive pellets, or seeds, directly into the prostate using needles guided by radiological imaging, usually, but not exclusively, ultrasound. Rows of seeds are deposited uniformly throughout the prostate so that the radiation can cover the entire gland. There are 2 major methods of prostate brachytherapy, permanent seed implantation and high dose rate (HDR) temporary brachytherapy.

Medical Policy: BRACHYTHERAPY OR RADIOACTIVE SEED IMPLANTATION FOR PROSTATE CANCER

Policy Number: 6.01.16

Page: 2 of 6

In *permanent brachytherapy*, the radioactive seeds are implanted interstitially, using the transperineal route with the guidance of transrectal ultrasound, fluoroscopy (*sometimes*) and/or computed tomography. The seeds release radiation at a low dose rate gradually over a period of time (6 to 12 months) after which they become inert. The most common seeds used in permanent 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. The American Brachytherapy Society recommends that postoperative 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 temporary brachytherapy* involves placing tiny plastic catheters into the prostate gland and then delivering multiple radiation treatments (fractions) through these catheters with a high energy radioisotope such as iridium 192. The radioactive source is “afterloaded” or temporarily inserted into the prostate for a calculated duration at various “dwell positions” (usually 8-12 minutes). HDR brachytherapy can be fractionated or delivered in several sessions per day or over a course of several days. Radiation treatment planning and computerized dose calculations are needed 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.

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.

RATIONALE

Brachytherapy as a procedure does not require FDA approval. Radioactive isotopes of iodine-125, palladium-103 and iridium-192 have been cleared for marketing via 510(k).

Peer-reviewed literature demonstrates that permanent brachytherapy using the transperineal approach provides excellent control of the disease in low stage and low to moderate grade tumors, similar to 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, can be performed in an outpatient setting or with a short hospital stay of one or two days.

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

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.*

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

Medical Policy: BRACHYTHERAPY OR RADIOACTIVE SEED IMPLANTATION FOR PROSTATE CANCER**Policy Number: 6.01.16****Page: 3 of 6**

Code	Description
77021	Magnetic resonance guidance for needle placement (eg, 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	Intracavity radiation source application; simple
77762	Intracavity radiation source application; intermediate
77763	Intracavity 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 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

*Copyright © 2019 American Medical Association, Chicago, IL***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

Proprietary Information of Univera Healthcare

Medical Policy: BRACHYTHERAPY OR RADIOACTIVE SEED IMPLANTATION FOR PROSTATE CANCER**Policy Number: 6.01.16****Page: 4 of 6**

Code	Description
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

REFERENCES

- Agarwal M, et al. Long-term outcomes analysis of low-dose-rate brachytherapy in clinical T3 high-risk prostate cancer. Brachytherapy 2018 Nov - Dec;17(6):882-887.
- *Aluwini S, et al. High-dose-rate brachytherapy and external-beam radiotherapy for hormone-naïve low-and intermediate-risk prostate cancer: a 7 year experience. Int J Oncol Biol Phys 2012 Aug 1;83(5):1480-5.
- Amini A, et al. Survival outcomes of combined external beam radiotherapy and brachytherapy vs. brachytherapy alone for intermediate-risk prostate cancer patients using the National Cancer Data Base. Brachytherapy 2016 Mar-Apr;15(2):136-46.
- *Barkati M, et al. High-dose-rate brachytherapy as a monotherapy for favorable risk prostate cancer: a phase II trial. Int J Radiat Oncol Biol Phys 2012 Apr 1;82(5):1889-96.
- Bece A, et al. High-dose rate brachytherapy boost for prostate cancer: outcomes and genitourinary toxicity. Brachytherapy 2015 Sep-Oct;14(5):670-6.
- *BlueCross BlueShield Association. Brachytherapy for clinically localized prostate cancer using permanently implanted seeds. Medical Policy Reference Manual Policy #8.01.14. 2019 Jul11.
- BlueCross BlueShield Association. High-dose rate temporary prostate brachytherapy. Medical Policy Reference Manual Policy #8.01.33. 2019 Jul 11.
- *Buckstein M, et al. Long-term outcomes and toxicity in patients treated with brachytherapy for prostate adenocarcinoma younger than 60 years of age at treatment with minimum 10 years of follow-up. Urology 2013;81(2):364-8.
- *Challapalli A, et al. High dose rate prostate brachytherapy: an overview of the rationale, experience and emerging applications in the treatment of prostate cancer. Br J Radiol 2012 Nov;85(Spec No 1):S18-27.
- Chin J, et al. Brachytherapy for patients with prostate cancer: American Society of Clinical Oncology/Cancer Care Ontario Joint Guideline Update. J Clin Oncol 2017;35(15):1737-1745.

Medical Policy: BRACHYTHERAPY OR RADIOACTIVE SEED IMPLANTATION FOR PROSTATE CANCER

Policy Number: 6.01.16

Page: 5 of 6

- Chao M, et al. A single institution analysis of low-dose-rate brachytherapy: 5-year reported survival and late toxicity outcomes. J Contemp Brachytherapy 2019;10(2):155-161.
- Crook J. Long-term oncologic outcomes of radical prostatectomy compared with brachytherapy-based approaches for intermediate- and high-risk prostate cancer. Brachytherapy 2015 Mar-Apr;14(2):142-7.
- *Demanis DJ, et al. High-dose-rate monotherapy: safe and effective brachytherapy for patients with localized prostate cancer. Int J Radiat Oncol Biol Phys 2011 Dec 1;81(5):1286-92.
- *Demanis DJ, et al. High-dose rate brachytherapy as monotherapy for prostate cancer. Brachytherapy Nov-Dec 2014;13(6):529-41.
- Dess RT, et al. The current state of randomized clinical trial evidence for prostate brachytherapy. Urol Oncol 2019 Sep;37(9):599-610.
- *Ghilezan M, et al. High-dose-rate brachytherapy as monotherapy delivered in two fractions within one day for favorable/intermediate-risk prostate cancer: preliminary toxicity data. Br J Radiat Oncol Biol Phys 2012 Jul 1 83(3):927-32.
- Hegde JV, Collins SP, Fuller DB, et al. A pooled analysis of biochemical failure in intermediate-risk prostate cancer following definitive stereotactic body radiotherapy (SBRT) or high-dose-rate brachytherapy (HDR-B) monotherapy. Am J Clin Oncol. Jun 17 2016.
- *Hoskin P, et al. High-dose-rate brachytherapy alone for localized prostate cancer in patients at moderate or high risk of biochemical recurrence. Int J Radiat Oncol Biol Phys 2012 Mar 15;82(4):1376-84.
- Hsu IC, et al. ACR Appropriateness Criteria high-dose-rate brachytherapy for prostate cancer. Brachytherapy 2014 Jan-Feb;13(1):27-31.
- Jian P, et al. Interstitial high-dose-rate brachytherapy as salvage treatment for locally recurrent prostate cancer after definitive radiation therapy: toxicity and 5-year outcome. Brachytherapy 2017 Jan-Feb;16(1):186-192.
- *Kollmeier MA, et al. Favourable long-term outcomes with brachytherapy-based regimens in men ≤ 60 years with clinically localized prostate cancer. BJU Int 2013 Jun;111(8):1231-6.
- Lacy JM, et al. Salvage brachytherapy for biochemically recurrent prostate cancer following primary brachytherapy. Prostate Cancer 2016;2016:9561494.
- Lee DJ, et al. Comparison of patient-reported outcomes after external beam radiation therapy and combined external beam with low-dose-rate brachytherapy boost in men with localized prostate cancer. Int J Radiat Oncol Biol Phys 2018;102(1):116-126.
- Martinez E, et al. Permanent seed brachytherapy for clinical localized prostate cancer: long-term outcomes in a 700 patient cohort. Brachytherapy 2015 Mar-Apr;14(2):166-72.
- Muralidhar V, et al. Brachytherapy boost and cancer-specific mortality in favorable high-risk versus other high-risk prostate cancer. J Contemp Brachytherapy 2016 Feb;8(1):1-6.
- National Comprehensive Cancer Network (NCCN). Prostate Cancer. Clinical practice guidelines in oncology –V. 4. 2019 [http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf] accessed 10/1/19.
- *Peinemann F, et al. Permanent interstitial low-dose-rate brachytherapy for patients with localized prostate cancer: a systematic review of randomized and nonrandomized controlled clinical trials. Eur Urol 2011 Nov;60(5):881-93.
- *Potters L, et al. Permanent source brachytherapy for prostate cancer. American College of Radiology appropriateness criteria. Radiol 2000 Jun;215(Suppl):1383-400.
- Prada PJ, et al. High-dose-rate interstitial brachytherapy as monotherapy in one fraction of 20.5 Gy for the treatment of localized prostate cancer: toxicity and 6-year biochemical results. Brachytherapy 2018 Nov-Dec;17(6):845-851.

Medical Policy: BRACHYTHERAPY OR RADIOACTIVE SEED IMPLANTATION FOR PROSTATE CANCER

Policy Number: 6.01.16

Page: 6 of 6

Prada PJ, et al. High-dose-rate interstitial brachytherapy as monotherapy in one fraction for the treatment of favorable stage prostate cancer: toxicity and long-term biochemical results. Radiother Oncol 2016 Apr 22;S0167-8140(16):31040-4.

*Rogers CL, et al. High dose brachytherapy as monotherapy for intermediate risk prostate cancer. J Urol 2012 Jan;187(1):109-16.

*Rosenthal SA, et al. American Society for Radiation Oncology (ASTRO) and American College of Radiology (ACR) practice guideline for the transperineal permanent brachytherapy of prostate cancer. Int J Radiat Oncol Biol Phys 2011;79(2):335-41.

Siddiqui ZA, et al. Five-year outcomes of a single-institution prospective trial of 19-Gy single-fraction high-dose-rate brachytherapy for low- and intermediate-risk prostate cancer. Int J Radiat Oncol Biol Phys 2019 Aug 1;104(5):1038-1044.

Skowronek J. Low-dose-rate or high-dose-rate brachytherapy in treatment of prostate cancer- between options. J Contemp Brachytherapy 2013 Mar;5(1):33-41.

*Stokes SH, et al. Comparison of biochemical disease-free survival of patients with localized carcinoma of the prostate undergoing radical prostatectomy, transperineal ultrasound-guided radioactive seed implantation, or definitive external beam irradiation. Inter J Rad Onc Bio Phys 2000 Apr 1;41(1):129-36.

*Tselis N, et al. High dose rate brachytherapy as monotherapy for localised prostate cancer: a hypofractionated two-implant approach in 351 consecutive patients. Radiat Oncol 2013 May 8;8:115.

Yamazaki H, et al. Radiotherapy for elderly patients aged ≥ 75 years with clinically localized prostate cancer – ths there a role for brachytherapy? J Clin Med 2018 Nov 8;7(11):E424.

Yaxley JW, et al. Long-term outcomes of high-dose-rate brachytherapy for intermediate- and high-risk prostate cancer with a median follow-up of 10 years. BJU Int. Sep 15 2016.

Yoshioka Y, et al. The emerging role of high-dose-rate (HDR) brachytherapy as monotherapy for prostate cancer. J Radiat Res 2013 Sep;54(5):781-8.

*Zamboglou N, et al. High-dose-rate interstitial brachytherapy as monotherapy for clinically localized prostate cancer: treatment evolution and mature results. Int J Radiat Oncol Biol Phys 2013 Mar 1;85(3):672-8.

*Key Article

KEY WORDS

High-dose rate brachytherapy, Low-dose rate brachytherapy, Permanent brachytherapy, Prostate brachytherapy, Temporary brachytherapy.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Brachytherapy.