MEDICAL POLICY

Excellus

SUBJECT: BRACHYTHERAPY OR RADIOACTIVE SEED IMPLANTATION FOR PROSTATE CANCER	**EFFECTIVE DATE: 07/02/99**
	REVISED DATE: 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
POLICY NUMBER: 6.01.16	
CATEGORY: Technology Assessment	**PAGE: 1 OF: 5**

- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

I. Based upon our criteria and assessment of peer-reviewed literature, *permanent* brachytherapy for prostate cancer has been medically proven to be effective and therefore can be considered as a treatment option in the management of prostate cancer. Permanent brachytherapy, as set forth below, is **medically appropriate** as monotherapy or in conjunction with 3D conformal external beam radiation therapy (EBRT).

   A. Permanent brachytherapy is **medically appropriate** 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 is medically appropriate 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.**

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.

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: Number Description

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:	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
	76950	Ultrasonic guidance for placement of radiation therapy fields
	76965	Ultrasonic guidance for interstitial radioelement application

	77014	Computed tomography guidance for placement of radiation therapy fields
	77021	Magnetic resonance guidance for needle placement (eg, for biopsy, needle aspiration, injection or placement of localization device) radiological supervision and interpretation
	77326	Brachytherapy isodose plan: simple (calculation made from single plane,1 to 4 sources/ribbon application, remote afterloading brachytherapy, 1 to 8 sources)
	77327	Intermediate (multiplane dosage calculations, application involving 5 to 10 sources/ribbons, remote afterloading brachytherapy, 9 to 12 sources)
	77328	Complex (Multiplane isodose plan, volume implant calculations, over 10 sources/ribbons used, special spatial reconstruction, remote afterloading brachytherapy, over 12 sources)
	77761	Intracavity radiation source application; simple
	77762	Intracavity radiation source application; intermediate
	77763	Intracavity radiation source application; complex
	77776	Interstitial radiation source application; simple
	77777	Interstitial radiation source application; intermediate
	77778	Interstitial radiation source application; complex
	77789	Surface application of radiation source
	77790	Supervision, handling, loading radiation source
	77799	Unlisted procedure, clinical brachytherapy
	The following codes may be E/I if used alone.	
	77785	Remote afterloading high dose rate radionuclide brachytherapy; 1 channel
	77786	Remote afterloading high dose rate radionuclide brachytherapy; 2-12 channels
	77787	Remote afterloading high dose rate radionuclide brachytherapy; over 12 channels

HCPCS:	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
	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
ICD9:	185	Malignant neoplasm of prostate
	233.4	Carcinoma in situ of prostate
ICD10:	C61	Malignant neoplasm of prostate
	D07.5	Carcinoma in situ of prostate

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* 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.