**Name of Policy:**
High-Dose Rate Temporary Prostate Brachytherapy

Policy #: 024       Latest Review Date: **June 2014**
Category: Therapy       Policy Grade: **C**

**Background/Definitions:**
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**

High-dose rate temporary prostate brachytherapy is a technique of delivering a high-intensity radiation source directly to the prostate gland for the treatment of prostate cancer. The radiation source is inserted through hollow catheters or needles inserted precisely into several areas of the prostate gland using ultrasound guidance and treatment planning computed tomography (CT) or ultrasound images. The radiation source is allowed to dwell in the target areas until the prescribed radiation dose is reached and is then removed with the goal of increasing direct tumor necrosis while reducing toxicity and surrounding tissue damage.

Prostate brachytherapy can be delivered in a variety of ways. Perhaps the most familiar technique is the use of radioactive seeds permanently implanted into prostate tissue. These seeds contain isotopes that slowly emit radiation of relatively low energy. In contrast, temporary prostate brachytherapy involves use of higher energy radioisotopes such as iridium-192. These isotopes deliver radiation at higher dose rates, which may be more effective in destroying rapidly dividing cancer cells. In this technique, needle catheters are placed into the prostate gland using transrectal ultrasound guidance. Once the needles are placed, a dosimetric plan is developed, and the radioactive source is inserted into each needle using an afterloading device. The radioactive source is left in the needle for a predetermined time, called the “dwell” time. The radiation usually is delivered once or twice daily over a course of several days. The dwell time can be altered at various positions along the needle’s length to control dose distribution to the target volume and critical surrounding structures, such as the rectum or urethra. This strategy contrasts with permanent seed implantation in which dosimetry is calculated prior to needle placement and which cannot be altered after seed implantation. The treatment typically consists of 4,000 to 5,000 cGy delivered with external beam radiation therapy (EBRT) to the prostate and periprostatic tissues, while the high-dose rate (HDR) brachytherapy is used as the method of dose escalation to the prostate gland. The total boost doses are variable. In addition, studies are also being conducted using HDR brachytherapy as the sole treatment modality (monotherapy) in those with prostate cancer.

It is an accepted premise that increasing doses of radiation therapy are associated with improved biochemical control (i.e., stable levels of prostate-specific antigen [PSA]), and thus there has been keen interest in exploring different techniques of dose escalation while simultaneously limiting both early and late toxicities in surrounding tissues. In patients with locally advanced disease, it is hypothesized that local failure may be related to the large volume of tumor and radioresistant cell clones, both of which might respond to higher radiation doses. High-dose rate prostate brachytherapy has been primarily investigated as an adjunct to external-beam radiotherapy (EBRT) as a technique of dose escalation. Other techniques for dose escalation include EBRT using intensity-modulated radiation therapy (IMRT) for treatment planning and delivery, proton beam radiotherapy (which may also use IMRT), or EBRT combined with brachytherapy using interstitial seeds.
Policy:

**High-dose rate prostate brachytherapy meets** Blue Cross and Blue Shield of Alabama’s criteria for coverage as monotherapy or in conjunction with external beam radiation therapy in the treatment of localized prostate cancer.

**High-dose rate prostate brachytherapy does not meet** Blue Cross and Blue Shield of Alabama’s criteria for coverage and is considered investigational in the treatment of prostate cancer when used as salvage therapy.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

This policy was originally created in 2000 and was updated regularly with searches of the MEDLINE database. The most recent literature review was performed through May 26, 2014. The following is a summary of the key literature to date.

An evidence-based approach to the analysis of data on the various treatment options for prostate cancer is problematic for the following reasons:

- The lack of controlled clinical trials comparing various different treatment options in homogeneous groups of patients. Thus far, the only randomized comparisons of alternatives for managing early-stage prostate cancer compared active surveillance (watchful waiting) with radical prostatectomy, and external beam radiation therapy (EBRT) with high-dose rate (HDR) brachytherapy or with EBRT alone.
- Similar trials are limited to compare surgery with radiation or to compare different methods of radiation. In a recent review of 2991 consecutive patients receiving a variety of therapies for localized prostate cancer, the authors concluded that it is still not possible to determine which of the treatment options leads to the best metastasis-free or overall survival (OS). Therefore, at the present time, there is no evidence-based criterion standard of treatment, which limits the ability to assess emerging approaches.
- The numerous patient variables, including tumor stage, size of tumor (i.e., percent positive biopsy score), Gleason score, and prostate-specific antigen (PSA) level.
- The indolent natural history of many early-stage prostate cancers, requiring prolonged follow-up to determine final patient outcomes.
- A variety of intermediate outcomes have been used, most commonly biochemical failure as evidenced by rising PSA levels.
The evolving nature of radiotherapy. Over the past 10 years, major advances have occurred in the planning and delivery of radiotherapy, including conformal therapy and intensity-modulated radiation therapy (IMRT), both of which permit dose escalation. There are variables in the total dosage of radiotherapy, variations in the planning and delivery of radiotherapy, and multiple different combinations of therapy (i.e., EBRT plus brachytherapy). Fractionation of doses is another treatment variable that intends to balance the treatment effectiveness with both early and late morbidities to surrounding normal tissues.

The role of dose escalation in radiotherapy of prostate cancer. A dose-response relationship in the treatment of prostate cancer is generally accepted among clinicians and physicists, and in fact serves as the scientific rationale of HDR brachytherapy, as well as other recent techniques for radiation planning and delivery (i.e., IMRT). While a few randomized controlled trials (RCTs) have examined this issue, the data suggest that dose escalation is associated with improved biochemical control. However, data regarding the impact of total radiation dose on survival among patients with different prognostic factors are minimal. In addition, the optimal radiotherapy dose is unknown.

Large case series of conventional brachytherapy have reported data on both morbidity and the intermediate outcome of biochemical relapse-free survival (RFS) (i.e., survival-free from increasing PSA levels). These studies show that conventional brachytherapy is associated with similar outcomes when compared with the alternative (EBRT). Therefore, given the uncertainty for choosing between the established treatment options of watchful waiting, radical prostatectomy, EBRT, or conventional brachytherapy, some may consider patient preference to be particularly appropriate in selecting conventional brachytherapy. Questions have also been asked about patient acceptance of HDR brachytherapy compared with low-dose rate (LDR) brachytherapy. Given these significant limitations, the following results have been reported for HDR as an adjunct to EBRT.

Systematic/literature reviews
In 2014, Zaorsky reviewed 38 prospective and retrospective studies reporting on a total of 8008 patients treated with HDR brachytherapy for prostate cancer. Five-year freedom from biochemical failure rates were 85% to 100% for low-risk, 80% to 98% for intermediate-risk, 59% to 96% for high-risk, and 34% to 85% for locally advanced patients. In all risk groups, five-year rates of cancer-specific survival, overall survival, local recurrence and distant metastases were 99% to 100%, 85% to 100%, 0% to 8%, and 2% to 12%, respectively. Late Radiation Therapy Oncology Group Grade 3 to 4 genitourinary (GU) or gastrointestinal (GI) toxicities occurred in less than 6% of patients. Comparisons of HDR brachytherapy to other radiation techniques were inconclusive. Interpretation of results from the review is limited by reports from single-institution studies, the lack of comparative studies, and insufficient reporting on toxicity and quality of life.

In 2011, Bannuru et al analyzed 75 studies (ten RCTs, 65 nonrandomized comparative studies) on radiotherapy for clinically localized prostate cancer. Radiation therapies included brachytherapy, HDR brachytherapy and EBRT (conformal radiation, IMRT, or proton therapy). The authors found the evidence was insufficient to compare the effectiveness of different forms
of radiation treatments. Additionally, the effects of radiation treatments on patient survival were unclear compared with no treatment or no initial treatment. However, evidence considered to be of moderate strength showed higher EBRT dosages were consistently associated with increased long-term biochemical control rates compared with EBRT delivered at lower dosages. Yamada et al conducted a review of the literature and published consensus guidelines for HDR brachytherapy for the American Brachytherapy Society in 2012. The authors reported dosing schedule differences and heterogeneous studies make HDR brachytherapy difficult to evaluate systematically. However, HDR brachytherapy was found to have favorable five-year biochemical disease control ranging from 85% to 100% for low-risk, 83% to 98% for intermediate-risk, and 51% to 96% for high-risk prostate cancer.

**HDR brachytherapy with EBRT**

**Randomized controlled trials**

Hoskin et al reported on a European single-center randomized trial of 220 patients that was conducted between 1997 and 2005, which compared 55 Gy of EBRT with 35.75 Gy of EBRT with HDR brachytherapy. With a median follow-up of 30 months, the authors noted an improvement in actuarial biochemical RFS, as well as a lower incidence of acute rectal discharge. In 2012, Hoskin et al subsequently reported on longer term follow-up of 218 patients from this Phase 3 trial. Seventy-six percent of patients also received androgen-deprivation therapy. Biochemical RFS was greater in the combination treatment group after four years, with a median time to relapse of 116 months versus 74 months in the EBRT-only treatment group. Estimates of biochemical RFS for the combination group at 5, 7, and 10 years were 75%, 66%, and 46% versus 61%, 48% and 39% for the EBRT-only group, all respectively (p=0.04). However, OS was not significantly different between treatment arms. Estimates of OS for the combination group at 5, 7, and 10 years were 88%, 81% and 67% versus 89%, 88%, and 79% for the EBRT-only group, all respectively (p=0.2). Severe urinary symptoms (26% to 31%) and bowel events (6% to 7%) were not significantly different between groups at five and seven years. Erectile dysfunction rates were not reported.

**Nonrandomized, comparative studies**

In a case series at William Beaumont Hospital (WBH) in Royal Oak, Michigan, Martinez et al reported on 472 patients with intermediate- to high-risk prostate cancer (PSA level, ≥10 ng/mL; and/or a Gleason score, ≥7; and/or clinical stage, ≥T2b) treated with pelvic EBRT and an HDR boost using ultrasound guidance during the period of 1992 to 2007. Patients received a hypofractionated regimen of pelvic EBRT delivered in 23 fractions of 2Gy for a total dose of 46Gy over a five-week period. Initially, HDR brachytherapy consisted of three implants of 5.5 Gy, 6.0 Gy, and 6.5 Gy each. Subsequently, the HDR brachytherapy dosages were changed to two implants using 8.25 Gy, 8.75 Gy, 9.5 Gy, 10.5 Gy, and 11.5 Gy to achieve dosages equivalent to the three implant dosages delivered initially in the study. EBRT was not delivered on the days the patients received HDR brachytherapy boost (e.g., on days five and 15 when two implants were used). The authors reported the 10-year results were significantly better in the groups that received higher dose levels (i.e., >268 Gy biologically equivalent dose), using the Phoenix definition for biochemical failure (43.1% vs 18.9%), clinical failure (23.4% vs 7.7%), and distant metastasis (12.4% vs 5.7%, all respectively). Biologically equivalent dose (BED) is calculated to obtain a more significant measure of the dose absorbed by the prostate tissue rather than simply the quantity of radiation dose delivered. In this study, BED was calculated with an
alpha/beta ratio of 1.2 Gy. Overall survival at 10 years was better in the higher dose group, but the difference was not statistically significant. Adverse events included Grade 3 GU and GI tract complications of 2% to 3% and less than 5%, respectively.

Researchers at WBH reported on the outcomes of a series of 207 patients treated between 1991 and 2000. All patients had poor prognostic factors, which included tumor stage T2B, a Gleason score of 7, or a PSA greater than 10 ng/mL. EBRT was alternated with HDR radiotherapy as a boost. At a mean follow-up of 4.7 years, overall biochemical control rate was 74%, but was 85% if one poor prognostic factor was present, 75% if two were present, and 50% if all three were present. Late toxicity was minimal. The authors suggest that these results are similar or better than other treatment alternatives for prostate cancer with poor prognostic features.

An international group of investigators reported on the use of HDR brachytherapy as an adjunct to conformal EBRT with or without androgen-deprivation therapy in a case series of 611 patients. A total of 209 patients were treated at WBH, and thus it is likely that there are overlapping patients with the study previously reviewed. While the authors reported that adjunctive HDR was associated with excellent long-term outcomes in terms of biochemical control, disease-free survival and cause-specific survival, interpretation of the findings is limited due to the absence of a control group.

Investigators from the California Endocurietherapy (CET) Cancer Center reported on outcomes (median follow-up, 7.25 years) of 209 consecutive patients with localized prostate cancer treated with HDR brachytherapy combined with EBRT. The PSA PFS rate was 90%, 87%, and 69% for the low-, intermediate-, and high-risk groups, respectively.

Phan et al reported on a case series of 309 patients treated with EBRT (40-45 Gy) and HDR brachytherapy (22-24 Gy). At a median follow-up of 59 months, the five-year biochemical control rate was 86%, and OS was 91%; rates were higher for those with lower-risk disease. However, these results are difficult to interpret without having a comparison group.

Khor et al reported on a matched pair analysis of 344 patients who received EBRT (46 Gy in 23 fractions) plus HDR brachytherapy (19.5 Gy in three fractions) compared with 344 patients who received only EBRT (74 Gy in 37 fractions) for intermediate- or high-risk prostate cancer. Median biochemical follow-up was 60.5 months. Freedom from biochemical failure at five years was 79.8% (95% confidence interval [CI], 74.3% to 85.0%) for the HDR brachytherapy group and 70.9% (95% CI, 65.4% to 76.0%) for the EBRT only group. However, significantly more Grade 3 urethral strictures occurred with HDR brachytherapy (11.8%) than EBRT (0.3%; p<0.001).

In a retrospective analysis, Deutsch et al compared patients who had received HDR brachytherapy and IMRT to those who had received ultra-high dose IMRT alone for low- to high-risk prostate cancer. In the HDR and IMRT treatment group, 160 patients received three fractions of HDR dosages of 5.5 to 7.0 Gy, delivered once on the day of implant and twice on the next day, followed with IMRT one month later at a dose of 45.0 to 50.4 Gy. The ultra-high dose IMRT group of 470 patients received 86.4 Gy delivered in 48 fractions with five to seven beams of 15-MV photons. In the only outcome measured in this analysis, overall, the HDR and IMRT
group had statistically significant improvement in the five-year PSA RFS (PSA nadir + 2) compared with IMRT alone (97.7% vs 82%, respectively; p=0.001). The authors hypothesized the higher BED in HDR and IMRT (229 Gy) may have translated to better outcomes than the highest BED of IMRT alone (190.08 Gy). When the risk groups were separated out, the PSA-relapse survival for HDR plus IMRT over IMRT remained significant in the intermediate-risk group (98% vs 84%, respectively; p=0.001). However, improvement was not significant in the low-risk group (100% vs 98%) or the high-risk group (93% vs 71%, both respectively; p=0.23). The authors noted having fewer patients in the low- and high-risk groups may have influenced results. Additionally, androgen-deprivation therapy may have confounded the outcomes in the high-risk group.

In another retrospective comparison of HDR brachytherapy and IMRT compared with IMRT alone, Wilder et al found no significant differences in three-year biochemical disease-free (PSA nadir + 2) survival between treatment groups in low-, intermediate-, and high-risk patients (100% vs 100%, 98% vs 100%, and 93% vs 67%, all respectively). The rates of toxicity incidence were reported to be similar in both treatment groups. In this study, 240 patients received HDR boost at 5.5 Gy twice on the day of implant and again one week later totaling 22 Gy followed by IMRT of up to 50.4 Gy administered one to four days later. The 44 patients in the IMRT-alone group received 79 to 81 Gy. The BEDs calculated at an alpha/beta ratio of 1.5 Gy were 213.6 Gy in the HDR and IMRT group versus 174.2 to 178.2 Gy in the IMRT-alone group. The authors noted longer follow-up is needed to further understand the roles of HDR and IMRT in prostate cancer treatment.

**HDR brachytherapy as monotherapy**

Publications on use of HDR as monotherapy for treatment of prostate cancer are fewer than those that report its use as combined modality therapy with EBRT. In 2013, Tselis et al reported on short-term outcomes of 351 patients with clinically localized prostate cancer treated with HDR brachytherapy as monotherapy. At 36 and 60 months, biochemical control rates were 98% and 94% and metastasis-free survival rates were 99% and 98%, all respectively. No acute Grade 3 GI toxicity occurred and acute Grade 3 GU events were 4.8%. Late Grade 3 GU toxicity events were 3.4% and GI toxicity events were 1.4%. There were no Grade 4 or greater acute or late adverse events reported.

Demanes et al reported on a prospective case series of 298 patients with previously untreated low- to intermediate-risk localized prostate cancer (median PSA, 6.0 ng/mL) treated with HDR brachytherapy as monotherapy between 1996 and 2005 at CET and WBH. Each facility used a different treatment protocol. At CET, a total of 42 Gy in six fractions of 7 Gy were delivered using computed tomography images for treatment planning. WBH used a total of 38 Gy delivered in four fractions of 9.5 Gy with ultrasound images used for treatment planning. At eight-year follow-up, the authors reported 99% local control, 97% biochemical control (using the Phoenix definition defined as PSA nadir + 2), 99% distant metastasis-free survival, 99% cause-specific survival, and 95% OS. Grade 2 urinary frequency or urgency was transient in 10% of patients, while Grade 3 urinary retention was experienced in 3% of patients. GI tract toxicity was reported to be less than 1%. The authors attribute the low rate of adverse effects to the precision of HDR dosimetry and concluded HDR monotherapy is safe and effective in this population. In a study from the same institutions, Martinez et al reported on a nonrandomized study comparing
454 patients treated with either palladium-103 seed LDR brachytherapy (206 patients) or HDR brachytherapy as monotherapy (171 patients) received at WBH during the period of 1993 through 2004. The patients at WBH selected which treatment option they received. Also included in the study analysis were 77 patients who received HDR brachytherapy as monotherapy at CET during the period of 1996 through 2002. All of the patients selected for this study were low to intermediate risk and had PSA levels equal to or less than 12 ng/mL, Gleason scores of equal to or less than 7, and clinical stage T1c to T2a disease. The HDR brachytherapy dosages were the same as in the previously discussed Demanes et al study (9.5 Gy ´ 4 at WBH and 7 Gy ´ 6 at CET). Treatment outcomes at five years included biochemical control rates (PSA nadir + 2) of 89% in the LDR group at WBH, 91% in the HDR group at WBH, and 88% in the HDR group at CET. Overall and cause-specific survival rates at five years were not statistically different between groups. The HDR groups experienced statistically significant lower rates of dysuria, urinary frequency/urgency, and acute rectal pain. Rates of diarrhea, rectal bleeding, and acute urinary incontinence and retention were similar. Most toxicities were Grade 1 in both groups, but more Grade 3 acute GU toxicities were seen in the LDR group. Potency was 30% in the LDR group and 20% in the HDR groups. The authors of this study concluded HDR brachytherapy as monotherapy is an acceptable choice for treatment of favorable risk prostate cancer. It is likely that there are overlapping patients in the studies previously reviewed that were conducted at WBH. However, the authors do not comment on this.

Corner et al published results of a Phase 2 study of HDR brachytherapy as monotherapy in 110 patients treated with three regimens: 34 Gy in four fractions, 36 Gy in four fractions, and 31.5 Gy in three fractions. At six months, two patients had Grade 3 bladder toxicity, and one patient had Grade 2 GI tract toxicity. No PSA relapses have been detected, although the median follow-up was just 12 months among the 55 patients who received 31.5 Gy. The authors concluded that these early results suggest an excellent biochemical response with no differences seen in acute and late toxicity among the three regimens. Grills et al reported on a series of 149 patients with early-stage prostate cancer who were treated with either permanent or temporary (HDR) brachytherapy monotherapy at one center. In this series, patients selected which of the two treatments they would receive. Treatments were given between 1999 and 2001. The authors note lower acute Grade 1 to 3 symptoms in the HDR group, but many of these symptoms were Grade 1. The reported rates of Grade 2 and 4 chronic GU toxicity did not vary and were 23%. The impotence rate was 16% in the HDR group and 45% in the LDR group. Levels of biochemical control were similar in the two groups with median follow-up of 35 months. Given the nonrandom assignment of patients in this single institution study, additional confirmatory trials may be useful.

Salvage HDR brachytherapy

Data on using HDR as salvage treatment following failed prior radiotherapy are limited. Chen et al reported on a retrospective analysis of 52 men with locally recurrent prostate cancer treated consecutively with salvage HDR (36 Gy in six fractions). Median follow-up was 59.6 months. Median survival was not yet reached, but estimated five-year OS was 92% (95% CI, 80% to 97%) and five-year biochemical control using the Phoenix definition was 51% (95% CI, 34% to 66%). Acute GI tract events of Grade 2 or higher did not occur. Late Grade 2 GI events occurred in 4%. Acute Grade 3 GU tract toxicity occurred in 2%. Late Grade 3 GU tract toxicity occurred in 2%.
Jo et al reported on 11 patients with radio-recurrent local prostate cancer who received salvage high-dose rate brachytherapy with EBRT (n=10) or proton beam (n=1). During mean follow-up of 29 months (range, 18-41 months), PSA levels remained low in seven patients but rose in four patients. No Grade 3 adverse events were reported.

**Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers**

In response to requests, input was received from two physician specialty societies (four reviews) and two academic medical centers while this policy was under review for March 2009. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. There was generally strong support for use of HDR (as monotherapy and with EBRT) as an option in the treatment of prostate cancer.

**Summary**

High-dose rate (HDR) temporary prostate brachytherapy is a technique of delivering a high-intensity radiation source directly to the prostate gland for the treatment of prostate cancer. Based on data from published studies and clinical input, its use may be considered medically necessary combined with external beam radiation therapy (EBRT) in the treatment of patients with localized prostate cancer. While data on HDR monotherapy are more limited, given what is known about temporary and permanent brachytherapy and based on existing data and clinical input, HDR monotherapy may also be considered an option. While quality studies differentiating superiority of any type of radiation technique are not available, the available evidence for use of HDR prostate brachytherapy as monotherapy or in conjunction with EBRT in the treatment of localized (organ-confined) prostate cancer is sufficient to conclude treatments result in improvement in net health outcome.

Because published data are still limited and clinical trials are ongoing, use of HDR in the treatment of prostate cancer as salvage therapy is considered investigational.

**Practice Guidelines and Position Statements**

The National Comprehensive Cancer Network (NCCN) guidelines (v.2.2014) for the treatment of prostate cancer indicate HDR brachytherapy alone or combined with EBRT (40-50 Gy) may be used instead of LDR brachytherapy to increase the dose of radiation for intermediate- to high-risk patients. Boost regimens commonly used include 9.5 to 11.5 Gy ´ two fractions, 5.5 to 7.5 Gy ´ three fractions, and 4.0 to 6.0 Gy ´ four fractions. For HDR brachytherapy alone, 13.5 ´ two fractions is a commonly used regimen. HDR brachytherapy may also be considered to treat local recurrence after EBRT or primary brachytherapy. HDR dosages for recurrence range from 9 to 12 Gy ´ two fractions, depending on the primary radiation dosage delivered.

The American Brachytherapy Society (ABS) Prostate High-Dose Rate Task Group provides the following patient selection criteria for monotherapy: clinical stage T1b to T2b and Gleason score equal to or less than 7, and/or PSA equal to or less than 10 ng/mL. For HDR boost, ABS patient
selection criteria includes: patients with high-risk features such as T3 to T4, Gleason score 7 to 10, and/or PSA greater than 10 ng/mL or patients with bulky T1 to 2b tumor. ABS published a review of the literature and consensus guidelines for HDR brachytherapy in 2012 as previously noted. ABS recommends HDR brachytherapy with or without EBRT for various risk levels of localized prostate cancer especially for intermediate- or high-risk patients as a boost with EBRT. ABS guidelines note HDR brachytherapy is contraindicated in patients, who have a preexisting rectal fistula, are unable to tolerate anesthesia and/or have no proof of malignancy. HDR monotherapy is considered investigational for high-risk patients by the ABS. HDR monotherapy as salvage treatment is only recommended for use in specialty centers or Institutional Review Board-approved protocols.

American College of Radiology (ACR) Appropriateness Criteria for HDR brachytherapy for prostate cancer were issued in 2014. ACR indicates HDR monotherapy, HDR with EBRT, and HDR as salvage treatment may be appropriate treatment options.

**Key Words:**
Brachytherapy, High-Dose Rate, Prostate Cancer, High-Dose Rate Brachytherapy

**Approved by Governing Bodies:**
**Medicare National Coverage**
Brachytherapy sources and services for administration and delivery of brachytherapy are covered by Medicare.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.

**Current Coding:**
CPT Codes: 55875 Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy
76873 Ultrasound, transrectal; prostate volume study for brachytherapy treatment planning
77326 – 77328 Brachytherapy isodose calculation; simple, intermediate, or complex
77776 – 77778 Interstitial radioelement application, simple, intermediate, or complex
77785 – 77787 Remote afterloading high dose rate radionuclide brachytherapy code range (new codes effective 1/1/09)
HCPCS: C1717  Brachytherapy source, non-stranded, high dose rate iridium 192, per source
Q3001  Radioelements for brachytherapy, any type, each

References:

Policy History:
Medical Policy Group, October 2011
Medical Policy Administration Committee, October, 2011
Available for comment October 5 through November 21, 2011
Medical Policy Group, July 2012(4): Updated Key points, ongoing clinical trials, Practice guidelines and position statements, and references.
Medical Policy Group, September 2013 (4): 2013 Update to Key Points and References
Medical Policy Group June 2014 (4): Updated Key Points and References. No changes to policy at this time.
Medical Policy Group, June 2014 (3): Updated policy with link to CareCore National© medical policies effective August 1, 2014
Medical Policy Administration Committee, June 2014
Available for comment June 16 through July 31, 2014
Medical Policy Group, July 2014: Removed CareCore link and ‘Draft’. Transfer to CareCore is on hold until further notice.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.