

Corporate Medical Policy

Intensity-Modulated Radiation Therapy (IMRT) of the Prostate

File Name:	intensity_modulated_radiation_therapy_imrt_of_the_prostate
Origination:	11/2009
Last CAP Review:	8/2011
Next CAP Review:	8/2012
Last Review:	8/2011

Description of Procedure or Service

For prostate cancer, external-beam radiation therapy (EBRT) is one accepted option for treatment. Over the past several decades, methods to plan and deliver radiation therapy have evolved in ways that permit more precise targeting of tumors with complex geometries. These methods used 2-dimensional treatment planning based on flat images, and radiation beams with cross-sections of uniform intensity that were sequentially aimed at the tumor along 2 or 3 intersecting axes. Collectively, these methods are termed conventional EBRT.

Treatment planning first evolved by using 3-dimensional images, usually from computed tomography (CT) scans, to delineate the tumor, its boundaries with adjacent normal tissue, and organs at risk for radiation damage. Radiation oncologists used these images, displayed from a “beam’s-eye view,” to shape each of several beams (e.g., with compensators, blocks, or wedges) to conform to the patient’s tumor geometry perpendicular to the beam’s axis. Computer algorithms were developed to estimate cumulative radiation dose delivered to each volume of interest by summing the contribution from each shaped beam. Methods also were developed to position the patient and the radiation portal reproducibly for each fraction, and immobilize the patient, thus maintaining consistent beam axes across treatment sessions. However, “forward” planning used a trial and error process to select treatment parameters (the number of beams and the intensity, shape, and incident axis of each). The planner/therapist modified one or more parameters and re-calculated dose distributions, if analysis predicted underdosing for part of the tumor or overdosing of nearby normal tissue. Furthermore, since beams had uniform cross-sectional intensity wherever they bypassed shaping devices, it was difficult to match certain geometries (e.g., concave surfaces). Collectively, these methods are termed 3-dimensional conformal radiation therapy (3D-CRT). Over the past decade, other methods were developed to permit beam delivery with non-uniform cross-sectional intensity. This technique often relies on a device (a multi-leaf collimator, MLC) situated between the beam source and patient, that moves along an arc around the patient. As it moves, a computer varies aperture size independently and continuously for each leaf. Thus, MLCs divide beams into narrow “beamlets,” with intensities that range from zero to 100% of the incident beam. With an alternative, termed tomotherapy, a small radiation portal emitting a single narrow beam moves spirally around the patient, with intensity varying as it moves. Each method (MLC-based or tomotherapy) is coupled to a computer algorithm for “inverse” treatment planning. The planner/radiotherapist delineates the target on each slice of a CT scan, and specifies the target’s prescribed radiation dose, acceptable limits of dose heterogeneity within the target volume, adjacent normal tissue volumes to avoid, and acceptable dose limits within the normal tissues. Based on these parameters and a digitally-reconstructed radiographic image of the tumor and surrounding tissues and organs at risk, computer software optimizes the location and shape of beam ports, and beam and beamlet intensities, to achieve the treatment plan’s goals. Collectively, these methods are termed intensity-modulated radiation therapy (IMRT).

Multiple studies have generated 3D-CRT and IMRT treatment plans from the same scans, then compared predicted dose distributions within the target and in adjacent organs at risk. Results of such planning studies show that IMRT improves on 3D-CRT with respect to conformality to, and dose homogeneity

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within, the target. Dosimetry using stationary targets generally confirms these predictions. Thus, radiation oncologists hypothesized that IMRT may improve treatment outcomes compared with those of 3D-CRT by one or more of the following mechanisms.

Increased conformality may permit escalated tumor doses without increasing normal tissue toxicity (e.g., proctitis), and may thus improve local tumor control. Better dose homogeneity within the target may also improve local tumor control by avoiding underdosing (cold spots) within the tumor and may decrease toxicity by avoiding overdosing (hot spots). Finally, enhanced conformality for standard doses may reduce dose outside the target volume and thus decrease toxicity.

However, IMRT aims radiation at the tumor from many more directions, and thus subjects more normal tissue to low-dose radiation than occurs with conventional EBRT or 3D-CRT. This may increase late effects of radiation therapy. Furthermore, treatment planning and delivery are more complex, time-consuming, and labor-intensive for IMRT than for 3D-CRT. Thus, clinical studies must test whether IMRT improves tumor control or reduces acute and late toxicities, when compared with 3D-CRT. Testing this hypothesis requires direct comparative data on outcomes for separate groups of similar patients treated with each method.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Intensity-Modulated Radiation Therapy (IMRT) of the Prostate when it is determined to be medically necessary because the medical criteria and guidelines shown below have been met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Intensity-Modulated Radiation Therapy (IMRT) of the Prostate is covered

Intensity-modulated radiation therapy (IMRT) may be considered medically necessary in the treatment of prostate cancer when the following criteria are met:

- A. In patients with localized prostate cancer who will receive definitive dose escalated external beam radiation therapy at prescribed radiation doses of 75 to 80 Gy.
- B. In patients who are status-post prostatectomy with evidence of local recurrence, who will be receiving salvage radiation therapy at a prescribed dose of 66 Gy or more to the prostate bed.
- C. In patients who are status-post prostatectomy who are at high risk for recurrence due to extracapsular extension, pathologic T3 disease, seminal vesicle invasion, positive margins and/or positive nodes, who will receive adjuvant (post-operative) radiation therapy at a prescribed dose of at least 66 Gy to the prostate bed and/or pelvis.

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When Intensity-Modulated Radiation Therapy (IMRT) of the Prostate is not covered

Intensity-modulated radiation therapy (IMRT) of the prostate is considered **investigational** for other indications not listed above including but not limited to:

Patients receiving a combination of radioactive implant treatment and external beam radiotherapy.

Policy Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for prostate cancer (v.2.2009) indicate “no further workup or treatment” for those patients with prostate cancer and a life expectancy of 5 years or less who are asymptomatic until symptoms occur. An exception is noted for the “high-risk patient” where high-risk factors include bulky T3-T4 disease or Gleason score 8–10. In these high-risk patients, complications such as hydronephrosis or metastasis can occur within 5 years and androgen deprivation therapy or radiation therapy may be considered.

(http://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf)

The U.S. Preventive Services Task Force (USPSTF) recommendations on screening for prostate cancer include the following statements: “Even if prostate cancer screening is determined to be effective, the length of time required to experience a mortality benefit is greater than 10 years. Because a 75-year-old man has an average life expectancy of about 10 years, very few men age 75 years or older would experience a mortality benefit. Similarly, men younger than age 75 years who have chronic medical problems and a life expectancy of fewer than 10 years are also unlikely to benefit from screening and treatment.” (<http://www.ahrq.gov/clinic/uspstf08/prostate/prostaters.htm>)

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 77301, 77338, 77418, 0073T

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.47, 4/24/09

Wilt TJ, Shamlivan T, Taylor B, MacDonald R, Tacklind J, Rutks I, Koeneman K, Cho C-S, Kane RL. Comparative

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Effectiveness of Therapies for Clinically Localized Prostate Cancer. Comparative Effectiveness Review No. 13. (Prepared by Minnesota Evidence-based Practice Center under Contract No. 290-02-0009.)

Rockville, MD: Agency for Healthcare Research and Quality, February 2008. Retrieved 8/13/09 from www.effectivehealthcare.ahrq.gov/reports/final.cfm

Cahlong O, Zelefsky JM, Shippy A, et al. Ultra-high dose (86.4 Gy) IMRT for localized prostate cancer: toxicity and biochemical outcomes. *Int J Radiat Oncol Biol Phys* 2008; 71(2):330-7

Senior Medical Director review, 3/2010

Specialty Matched Consultant Advisory Panel 5/2010

Senior Medical Director Review, 10/2010

Specialty Matched Consultant Advisory Panel 8/2011

Policy Implementation/Update Information

12/21/09 New policy issued. Intensity-modulated radiation therapy (IMRT) may be considered medically necessary in the treatment of localized prostate cancer in patients who will receive definitive dose escalated external beam radiation therapy at prescribed radiation doses of 75 to 80 Gy. Notification

12/21/09 Effective date 3/30/10. (adn)

6/22/10 Specialty Matched Consultant Advisory Panel review 5/24/10. No changes to policy statement. Medical policy number removed. (lpr)

11/9/10 Under "When Covered" section added the following statements: Intensity-modulated radiation therapy (IMRT) may be considered medically necessary in the treatment of prostate cancer when the following criteria are met: A. In patients with localized prostate cancer who will receive definitive dose escalated external beam radiation therapy at prescribed radiation doses of 75 to 80 Gy. B. In patients who are status-post prostatectomy with evidence of local recurrence, who will be receiving salvage radiation therapy at a prescribed dose of 66Gy or more to the prostate bed. C. In patients who are status-post prostatectomy who are at high risk for recurrence due to extracapsular extension, pathologic T3 disease, seminal vesicle invasion, positive margins and/or positive nodes, who will receive adjuvant Y(post-operative) radiation therapy at a prescribed dose of at least 66Gy to the prostate bed and/or pelvis. Under "When Not Covered" section deleted the statement "post-prostatectomy patients." Reviewed with medical director. (lpr)

9/30/11 Specialty Matched Consultant Advisory Panel review 8/31/2011. No changes to policy statement. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.

