MASSACHUSETTS

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Medical Policy

Intensity-Modulated Radiotherapy of the Prostate

Table of Contents

Policy Number: 090

BCBSA Reference Number: 8.01.47
NCD/LCD: N/A

Related Policies

- Stereotactic Radiosurgery and Stereotactic Body Radiotherapy, #277
- Charged-Particle (Proton or Helium Ion) Radiotherapy, #437
- Brachytherapy for Clinically Localized Prostate Cancer Using Permanently Implanted Seeds, #175
- High-Dose Rate Temporary Prostate Brachytherapy, #353
- IMRT of the Breast and Lung, #163
- IMRT of the Head and Neck or Thyroid, #164
- IMRT of the Abdomen and Pelvis, #165
- IMRT of the Central Nervous System Tumors, #910

Policy

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

Intensity-modulated radiotherapy (IMRT) may be considered **MEDICALLY NECESSARY** in the treatment of localized prostate cancer.

Localized Prostate Cancer: Radiotherapy as Definitive Treatment

Localized prostate cancer can be defined as cancer confined to the prostate gland T1-T2N0-NXM0 or as locally advanced cancer. Locally advanced cancer is confined to adjacent structures and includes T3a-T3bN0-NXM0. The presence of tumor invasion beyond extracapsular extension or other than seminal vesicles, or with evidence of regional lymph node involvement, in the absence of distant metastases T4N0-N1M0, does not necessarily preclude definitive therapy.

The National Comprehensive Cancer Network (NCCN) has recommended a dose of 75.6 to 79.2 gray (Gy) in conventional fractions (with or without seminal vesicles) for patients with low-risk cancers (based on findings from Kuban et al, 2008). Low-risk features in localized prostate cancer are defined as stage T1-T2a, a Gleason score of 6 or less, and prostate-specific antigen (PSA) level less than 10 ng/mL.

NCCN has recommended doses up to 81.0 Gy for patients with intermediate- and high-risk cancers, defined as: intermediate risk: stage T2b-T2c or Gleason score of 7 or PSA levels between 10 ng/mL and 20 ng/mL; and high risk: stage T3a or Gleason score of 8 to 10 or PSA level greater than 20 ng/mL (based on Eade et al, 2007; Zelefsky et al, 2008, and Xu et al, 2011).

IMRT may be considered **MEDICALLY NECESSARY** after radical prostatectomy as:

- Adjuvant therapy when there are adverse pathologic findings at prostatectomy or with a persistently detectable prostate-specific antigen level after prostatectomy
- Salvage therapy when there is evidence of biochemical or local recurrence when there is no evidence of distant metastatic disease.

Post Prostatectomy: Radiotherapy as Adjuvant or Salvage Therapy

Adjuvant therapy is the use of radiotherapy after prostatectomy in patients at a higher risk of recurrence (before recurrence). In the adjuvant setting, adverse pathologic findings at prostatectomy include positive surgical margins, seminal vesicle invasion, extraprostatic extension, and Gleason scores of 8 to 10. Salvage therapy is the use of radiotherapy to the prostate bed and possibly to surrounding tissues, including lymph nodes, in a patient with locoregional recurrence after surgery. In the salvage setting, biochemical recurrence is a detectable or rising PSA level of 0.2 ng/mL or higher after surgery, with a confirmatory test level of 0.2 ng/mL or higher.

American Urological Association and American Society for Radiation Oncology (2013) guidelines recommend a minimum dose of 64 to 65 Gy in the post-prostatectomy setting.

IMRT is considered **INVESTIGATIONAL** for the treatment of prostate cancer when the above criteria are not met.

IMRT and IMRT in combination with brachytherapy for the treatment of prostate cancer are **INVESTIGATIONAL** for all other indications.[1]

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** if the procedure is performed inpatient.

Outpatient

- For services described in this policy, see below for situations where prior authorization might be required if the procedure is performed outpatient.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **not required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue℠	Prior authorization is **not required**.
Medicare PPO Blue℠	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 medical necessity criteria MUST 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
77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex

HCPCS Codes

HCPCS codes:	Code Description
G6015	Intensity modulated treatment delivery, single or multiple fields/arcs,via narrow spatially and temporally modulated beams, binary, dynamic mlc, per treatment session
G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session

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-CM Diagnosis Codes

ICD-10-CM codes:	Code Description
C61	Malignant neoplasm of prostate

Description

PROSTATE CANCER TREATMENT

For localized prostate cancer, radiotherapy (RT) is an accepted option for primary (definitive) treatment. Other options include surgery (radical prostatectomy), hormonal treatment, or active surveillance.

In the postoperative setting, RT to the prostate bed is an accepted procedure for patients with an increased risk of local recurrence, based on 3 randomized controlled trials that showed a significant increase in biochemical recurrence-free survival. Professional society guidelines have recommended adjuvant RT to patients with adverse pathologic findings at the time of prostatectomy and salvage RT for patients with prostate-specific antigen recurrence or local recurrence after prostatectomy in the absence of metastatic disease.

RT Techniques

Conventional External-Beam Radiotherapy

Methods to plan and deliver RT have evolved in ways that permit more precise targeting of tumors with complex geometries. Most early trials 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 external-beam radiotherapy*.

Three-Dimensional Conformal Radiotherapy
Treatment planning evolved by using 3-dimensional images, usually from computed tomography scans, to delineate the boundaries of the tumor and to discriminate tumor tissue from adjacent normal tissue and nearby organs at risk for radiation damage. Computer algorithms were developed to estimate cumulative radiation doses delivered to each volume of interest by summing the contribution from each shaped beam. Methods were also developed to position the patient and the radiation portal reproducibly for each fraction and to immobilize the patient, thus maintaining consistent beam axes across treatment sessions. Collectively, these methods are termed *3-dimensional conformal radiotherapy* (3D-CRT).

Intensity-Modulated Radiotherapy
Intensity-modulated radiotherapy (IMRT), which uses computer software along with computed tomography and magnetic resonance images, offers better conformality than 3D-CRT because it modulates the intensity of the overlapping radiation beams projected on the target and uses multiple shaped treatment fields. Treatment planning and delivery are more complex, time-consuming, and labor intensive for IMRT than for 3D-CRT. The technique uses a multileaf collimator [MLC]), which, when coupled with a computer algorithm, allows for “inverse” treatment planning. The radiation oncologist delineates the target on each slice of a computed tomography 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, surrounding tissues, and organs at risk, computer software optimizes the location, shape, and intensities of the beam ports to achieve the treatment plan’s goals.

Increased conformality may permit escalated tumor doses without increasing normal tissue toxicity and thus may improve local tumor control, with decreased exposure to surrounding, normal tissues, potentially reducing acute and late radiation toxicities. Better dose homogeneity within the target may also improve local tumor control by avoiding underdosing within the tumor and may decrease toxicity by avoiding overdosing.

Technologic development has advanced techniques that may further improve RT treatment by improving dose distribution. These techniques are considered variations of IMRT. Volumetric modulated arc therapy delivers radiation from a continuous rotation of the radiation source. The principal advantage of volumetric modulated arc therapy is greater efficiency in treatment delivery time, reducing radiation exposure and improving target radiation delivery due to less patient motion. Image-guided RT involves the incorporation of imaging before and/or during treatment to more precisely deliver RT to the target volume.

IMRT methods to plan and deliver RT are not uniform. IMRT may use beams that remain on as MLCs move around the patient (dynamic MLC) or that are off during movement and turn on once the MLC reaches prespecified positions (“step and shoot” technique). A third alternative uses a very narrow single beam that moves spirally around the patient (tomotherapy). Each method uses different computer algorithms to plan treatment and yields somewhat different dose distributions in and outside the target. Patient position can alter target shape and thus affect treatment plans. Treatment plans are usually based on a single imaging scan, a static 3D-CT image. Current methods seek to reduce positional uncertainty for tumors and adjacent normal tissues by various techniques. Patient immobilization cradles and skin or bony markers are used to minimize day-to-day variability in patient positioning. In addition, many tumors have irregular edges that preclude drawing tight margins on computed tomography scan slices when radiation oncologists contour the tumor volume. It is unknown whether omitting some tumor cells or including some normal cells in the resulting target affects the outcomes of IMRT.

Summary
For individuals who have localized prostate cancer and are undergoing definitive RT who receive IMRT, the evidence includes several prospective comparative studies, retrospective studies, and systematic reviews of these studies. Relevant outcomes are overall survival, disease-free survival, quality of life, and treatment-related morbidity. Although there are few prospective comparative trials, the evidence

has generally shown that IMRT provides tumor control and survival outcomes similar to 3D-CRT while reducing gastrointestinal and genitourinary toxicity. These findings are supported by treatment planning studies, which have predicted that IMRT improves target volume coverage and sparing of adjacent organs compared with 3D-CRT. A reduction in clinically significant complications of RT is likely to improve the quality of life for treated patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have prostate cancer and are undergoing RT after prostatectomy who receive IMRT, the evidence includes retrospective comparative studies, single-arm phase 2 trials, and systematic reviews of these studies. Relevant outcomes are overall survival, disease-free survival, quality of life, and treatment-related morbidity. Although the comparative studies are primarily retrospective, the evidence has generally shown that IMRT provides tumor control and survival outcomes similar to 3D-CRT. Notably, a retrospective comparative study found a significant reduction in acute upper GI toxicity with IMRT compared with 3D-CRT, mainly due to better bowel sparing with IMRT. Another retrospective comparative study found a reduction in GU toxicity. A reduction in clinically significant complications of RT is likely to improve the quality of life for treated patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Policy History

Date	Action
9/2018	BCBSA National medical policy review. No changes to policy statements. New references added. Background and summary clarified.
1/2018	Clarified coding information.
8/2017	New references added from BCBSA National medical policy.
8/2016	BCBSA national medical policy review. Policy statements changed to remove radiation dose constraints for definitive therapy of localized prostate cancer, with policy guidelines providing additional details on dose for low-risk versus intermediate- to high-risk prostate cancer. A policy statement was added to address the use of IMRT post prostatectomy. Effective 8/1/2016.
2/2016	Local Coverage Determination (LCD) for Intensity Modulated Radiation Therapy (IMRT) (L3244) removed. 2/1/2016
8/2015	Added coding language.
6/2015	BCBSA National medical policy review. Title changed from “radiation therapy” to “radiotherapy.” Effective 6/1/2015.
1/2015	Clarified coding information.
9/2014	Clarified that clinical exception/notification form is not required.
8/2014	BCBSA National medical policy review; investigational indications clarified. Clinical exception and notification clarified.
8/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
6/2013	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.
9/1/2011	References added. Policy Description updated.
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.
9/2009	Reviewed - Medical Policy Group - Hematology and Oncology. No changes to policy statements.
6/2009	Updated to reflect change in BCBSA policy number.

	No changes to policy statements.
1/1/2009	Medical Policy 090 created.

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

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Endnotes

[1] Based on local expert opinion, September 5, 2011.