Medical Policy

Intensity-Modulated Radiotherapy of the Prostate

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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 BlueSM and Medicare PPO BlueSM 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.

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**Prior Authorization Information**
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required.

Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Commercial PPO and Indemnity</th>
<th>Medicare HMO BlueSM</th>
<th>Medicare PPO BlueSM</th>
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</table>

**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

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77301</td>
<td>Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications</td>
</tr>
<tr>
<td>77338</td>
<td>Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan</td>
</tr>
<tr>
<td>77385</td>
<td>Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple</td>
</tr>
<tr>
<td>77386</td>
<td>Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex</td>
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</table>

HCPCS Codes

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>G6015</td>
<td>Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic mlc, per treatment session</td>
</tr>
<tr>
<td>G6016</td>
<td>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</td>
</tr>
</tbody>
</table>

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-9 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-9-CM codes:</th>
<th>Code Description</th>
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<tr>
<td>185</td>
<td>Malignant Neoplasm of Prostate</td>
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ICD-10-CM Diagnosis Codes

<table>
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<th>ICD-10-CM codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>C61</td>
<td>Malignant neoplasm of prostate</td>
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Description

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 recommend adjuvant RT to patients with adverse pathologic findings at the time of prostatectomy and salvage RT for patients with prostate-specific antigen (PSA) or local recurrence after prostatectomy in the absence of metastatic disease.

RT Techniques

Conventional (2-Dimensional) External Beam Radiotherapy

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 or 2-dimensional external beam radiotherapy. Methods to plan and deliver RT have evolved in ways that permit more precise targeting of tumors with complex geometries.
Three-Dimensional Conformal Radiation
Treatment planning evolved by using 3-dimensional images, usually from computed tomography (CT) 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 also were 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 and CT and magnetic resonance imaging images, offers better conformity than 3D-CRT, because IMRT modulates the intensity of the overlapping radiation beams projected on the target and uses multiple-shaped treatment fields. IMRT uses a device (a multileaf collimator), which, coupled to a computer algorithm, allows for “inverse” treatment planning. The radiation oncologist 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 radiograph of the tumor and surrounding tissues and organs at risk, computer software optimizes the location, shape, and intensities of the beam’s ports, to achieve the treatment plan’s goals.

Increased conformity permits 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 help avoid underdosing and decrease overdosing.

Because most tumors move as patients breathe, dosimetry with stationary targets may not accurately reflect doses delivered within target volumes and adjacent tissues in patients. 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 compared to 3D-CRT.

Methodologic Issues in IMRT Research
Multiple-dose planning studies have generated 3D-CRT and IMRT treatment plans from the same scans, and then compared predicted dose distributions within the target and adjacent organs at risk. Results of such studies have shown that IMRT improves on 3D-CRT with respect to conformity to, and dose homogeneity within, the target. Dosimetry using stationary targets generally confirms these predictions. Thus, radiation oncologists have hypothesized that IMRT may provide better treatment outcomes than 3D-CRT. However, these types of studies offer indirect evidence for IMRT treatment benefit, and it is difficult to relate dosing study results to actual effects on health outcomes.

Comparative studies of radiation-induced adverse effects from IMRT versus alternative radiation delivery are probably the most important evidence for establishing the benefit of IMRT. Such studies would answer whether the theoretic benefit of IMRT in sparing normal tissue translates into real health outcomes. Single-arm series of IMRT can give insights into the potential for benefit, particularly if an adverse effect that is expected to occur at high rates is shown to decrease by a large amount. Studies of treatment benefit are also important to establish whether IMRT is at least as good as other types of delivery, but, absent such comparative trials, it is likely that benefit from IMRT is at least as good as with other types of delivery.

Summary
Radiotherapy (RT) is an integral component of treatment for prostate cancer. Intensity-modulated radiotherapy (IMRT) has been proposed as a method of external beam radiotherapy that delivers adequate radiation to the tumor volume, minimizing the radiation dose to surrounding normal tissues and structures.
The evidence for IMRT in individuals who have localized prostate cancer and are undergoing definitive RT includes largely of retrospective cohort studies, case series, and systematic reviews. Relevant outcomes are overall survival, disease-free survival, quality of life, and treatment-related morbidity. Although there are few comparative controlled trials, the evidence generally shows that IMRT provides tumor control and survival outcomes similar to 3-dimensional conformal radiotherapy (3D-CRT). Treatment planning studies predict that IMRT improves target volume coverage and sparing of adjacent organs compared to 3D-CRT; however, the present evidence shows only similar survival outcomes. Notably, some studies have shown reductions in gastrointestinal and genitourinary toxicity with IMRT. A reduction in clinically significant complications of RT is likely to improve quality of life for treated patients. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for IMRT in individuals who have prostate cancer and are undergoing RT after prostatectomy includes mostly phase 2 trials and both prospective and retrospective series of consecutive patients. Relevant outcomes are overall survival, disease-free survival, quality of life, and treatment-related morbidity. Although the comparative studies are limited to case series, the evidence generally shows that IMRT provides tumor control and survival outcomes similar to 3D-CRT. Although treatment planning studies predict that IMRT improves target volume coverage and sparing of adjacent organs compared to 3D-CRT, the present evidence shows only similar survival outcomes. Notably, a small series found a significant improvement in acute gastrointestinal toxicity with IMRT than with 3D-CRT, mainly due to better bowel sparing with IMRT. A reduction in clinically significant complications of RT is likely to improve quality of life for treated patients. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

### Policy History

<table>
<thead>
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<th>Date</th>
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<tr>
<td>8/2017</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>8/2016</td>
<td>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.</td>
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<td>2/2016</td>
<td>Local Coverage Determination (LCD) for Intensity Modulated Radiation Therapy (IMRT) (L3244) removed. 2/1/2016</td>
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<tr>
<td>8/2015</td>
<td>Added coding language.</td>
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<tr>
<td>1/2015</td>
<td>Clarified coding information.</td>
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<tr>
<td>9/2014</td>
<td>Clarified that clinical exception/notification form is not required.</td>
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<tr>
<td>8/2014</td>
<td>BCBSA National medical policy review; investigational indications clarified. Clinical exception and notification clarified.</td>
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<tr>
<td>8/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
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<td>6/2013</td>
<td>New references from BCBSA National medical policy.</td>
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<tr>
<td>9/1/2011</td>
<td>References added. Policy Description updated.</td>
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References


Endnotes

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