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.

**Prior Authorization Information**

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

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

<table>
<thead>
<tr>
<th>Commercial Managed Care (HMO and POS)</th>
<th>Prior authorization is not required.</th>
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</thead>
<tbody>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>Prior authorization is not required.</td>
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<tr>
<td>Medicare HMO BlueSM</td>
<td>Prior authorization is not required.</td>
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<tr>
<td>Medicare PPO BlueSM</td>
<td>Prior authorization is not required.</td>
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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:

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<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>
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<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>
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</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:

<table>
<thead>
<tr>
<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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</table>

**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.\(^6,7,8\). 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.\(^9,5\).

**Radiotherapy Techniques**
Radiation therapy may be administered externally (ie, a beam of radiation is directed into the body) or internally (ie, a radioactive source is placed inside the body, near a tumor).\(^10\). External radiotherapy (RT) techniques include "conventional" or 2-dimensional (2D) RT, 3-dimensional (3D) conformal RT, and intensity-modulated radiation therapy (IMRT).

**Conventional External-Beam Radiotherapy**
Methods to plan and deliver RT have evolved that permit more precise targeting of tumors with complex geometries. Conventional 2D treatment planning utilizes X-ray films to guide and position radiation...
beams. Bony landmarks bones visualized on X-ray are used to locate a tumor and direct the radiation beams. The radiation is typically of uniform intensity.

Three-Dimensional Conformal Radiotherapy
Radiation treatment planning has evolved to use 3D images, usually from computed tomography (CT) scans, to more precisely delineate the boundaries of the tumor and to discriminate tumor tissue from adjacent normal tissue and nearby organs at risk for radiation damage. Three-dimensional conformal RT (3D-CRT) involves initially scanning the patient in the position that will be used for the radiation treatment. The tumor target and surrounding normal organs are then outlined in 3D on the scan. Computer software assists in determining the orientation of radiation beams and the amount of radiation the tumor and normal tissues receive to ensure coverage of the entire tumor in order to minimize radiation exposure for at risk normal tissue and nearby organs. Other imaging techniques and devices such as multileaf collimators (MLCs) may be used to “shape” the radiation beams. Methods have also been 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.

Intensity-Modulated Radiotherapy
IMRT is the more recent development in external radiation. Treatment planning and delivery are more complex, time-consuming, and labor-intensive for IMRT than for 3D-CRT. Similar to 3D-CRT, the tumor and surrounding normal organs are outlined in 3D by a scan and multiple radiation beams are positioned around the patient for radiation delivery. In IMRT, radiation beams are divided into a grid-like pattern, separating a single beam into many smaller “beamlets”. Specialized computer software 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 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 is proposed to 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.

Other 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.

Summary
Radiotherapy (RT) is an integral component of prostate cancer treatment. Intensity-modulated radiotherapy (IMRT) has been proposed as a method of external-beam (RT) that delivers adequate radiation to the tumor volume while minimizing the radiation dose to surrounding normal tissues and structures.

For individuals who have localized prostate cancer and are undergoing definitive RT who received IMRT, the evidence includes several prospective comparative studies, retrospective studies, and systematic reviews. Relevant outcomes are overall survival (OS), disease-free survival (DFS), quality of life, and treatment-related morbidity. Although there are few prospective comparative trials, the evidence has generally shown that IMRT provides survival outcomes similar to 3-dimensional conformal radiotherapy (3D-CRT) while reducing gastrointestinal (GI) and genitourinary (GU) 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. Relevant outcomes are (OS), (DFS), quality of life, and treatment-related morbidity. Although the comparative studies are primarily retrospective, the evidence has generally shown that IMRT compared favorably to 3D-CRT with regard to GI and GU toxicity. 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

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>1/2018</td>
<td>Clarified coding information.</td>
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<tr>
<td>8/2017</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<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>
</tr>
<tr>
<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>
</tr>
<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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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

References
   17765406
4. Xu N, Rossi PJ, Jani AB. Toxicity analysis of dose escalation from 75.6 gy to 81.0 gy in prostate
   Jul 2019; 9(4): 208-213. PMID 31051281
   16099293
   prostatectomy compared with radical prostatectomy alone in pT3 prostate cancer with postoperative
   2924-30. PMID 19433689
10. Shinohara E, Whaley JT. Radiation therapy: which type is right for me? Last reviewed: March 3,
    therapy-which-type-is-right-for-me. Accessed May 29, 2020
    ONE. 2016; 11(5): e0154499. PMID 27171271
    14(47): 1-108, iii-iv. PMID 21029717
    biochemical control compared with 3-dimensional conformal radiotherapy for prostate cancer: A
    Treatment-Related Toxicity in Men Who Received Intensity Modulated Versus 3-Dimensional
    Conformal Radical Radiation Therapy for Prostate Cancer. Int J Radiat Oncol Biol Phys. Dec 01
    2017; 99(5): 1253-1260. PMID 28974414


Endnotes

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