Medical Coverage Policy | Intensity-Modulated Radiotherapy: Prostate

EFFECTIVE DATE: 02|15|2016
POLICY LAST UPDATED: 09|17|2020

OVERVIEW

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

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial Products

Intensity-modulated radiotherapy of the prostate is considered medically necessary when one of the following criteria is met:

- For the treatment of localized prostate cancer at radiation doses of 75.6 to 79.2 GY:
  - Localized prostate cancer is confined to the prostate, or;
  - Locally advanced cancer that is confined to adjacent structures, and/or;
  - Local lymph nodes

- For treatment after radical prostatectomy as:
  - Adjuvant therapy when there are adverse pathologic findings at prostatectomy or with a persistently detectable PSA level post-prostatectomy
  - Salvage therapy when there is evidence of biochemical or local recurrence when there is no evidence of distant metastatic disease

PRIOR AUTHORIZATION

Prior authorization is recommended and obtained via the online tool for participating providers.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Intensity-modulated radiotherapy may be considered medically necessary when the criteria above is met.

IMRT is considered not covered for BlueCHiP for Medicare and not medically necessary for Commercial Products for the treatment of non-localized prostate cancer as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for radiology benefits/coverage.

BACKGROUND

For localized prostate cancer, radiotherapy is one accepted option for primary (definitive) treatment. Other options include surgery (radical prostatectomy [RP]), 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, which showed a significant increase in biochemical recurrence-free survival. Major society guidelines recommend adjuvant radiotherapy to patients

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

The evidence for IMRT in individuals who have localized prostate cancer and are undergoing definitive radiotherapy includes mainly retrospective cohort studies and case series, and systematic reviews of these studies; well-designed randomized controlled studies comparing IMRT with 3-dimensional conformal radiotherapy (3D-CRT) are lacking. Relevant outcomes are overall survival, disease-free survival, quality of life, and treatment-related morbidity. Although the available evidence is of lower quality, limited evidence suggests that IMRT provides tumor control and survival outcomes comparable with 3D-CRT. Treatment planning studies have shown that the use of IMRT provides better target volume coverage and better sparing of adjacent organs at risk than with 3D-CRT. In the treatment of localized prostate cancer, although results are not uniform, some studies have shown reductions in gastrointestinal and genitourinary toxicity with the use of IMRT. A reduction in clinically significant complications of RT is likely to lead to an improved 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.

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

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

Post-Prostatectomy: Radiotherapy as Adjuvant or Salvage Therapy
Adjuvant therapy is the use of radiotherapy post-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 value after surgery that is ≥0.2 ng/mL with a second confirmatory level of ≥0.2 ng/mL.

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

Fractionation
In the treatment of prostate cancer, conventional radiotherapy applies total doses of greater than 74 Gy over the course of up to 9 weeks, whereas hypofractionated radiotherapy involves daily doses greater than 2 Gy and has an overall shorter treatment time. Published randomized controlled trials (RCTs) have failed to demonstrate superiority of hypofractionation in definitive radiotherapy for prostate cancer, either for efficacy or late toxicity. Additional, ongoing phase 3 noninferiority trials may provide further insight.

NCCN guidelines state that because, in the treatment of prostate cancer, moderately hypofractionated IMRT regimens (2.4-4 Gy per fraction over 4-6 weeks) have been tested in RCTs and efficacy and toxicity have been similar to conventionally fractionated IMRT, that hypofractionation may be considered as an alternative to conventionally fractionated regimens when clinically indicated.

Radiation Techniques

Conventional External Beam Radiotherapy

Over the past several decades, 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 (EBRT).

3-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 discriminate tumor tissue from adjacent normal tissue and nearby organs at risk for radiation damage. 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. Collectively, these methods are termed 3-dimensional conformal radiotherapy.

Intensity-Modulated Radiotherapy

IMRT, which uses computer software and CT and magnetic resonance imaging images, offers better conformality than 3D-CRT, as it is able to modulate the intensity of the overlapping radiation beams projected on the target and to use multiple-shaped treatment fields. It 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 radiographic image 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 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. 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 when compared with 3D-CRT.

Methodologic Issues in IMRT Research

Multiple-dose planning 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 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. However, these types of studies offer indirect evidence on treatment benefit from IMRT, and it is difficult to relate results of dosing studies to actual effects on health outcomes.

Comparative studies of radiation-induced adverse effects from IMRT versus alternative radiation delivery are probably the most important type of evidence in establishing the benefit of IMRT. Such studies would answer the question of whether the theoretic benefit of IMRT in sparing normal tissue translates into real health outcomes. Single-arm series of IMRT can give some 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 that IMRT is at least as good as other types of delivery, but

in the absence of such comparative trials, it is likely that benefit from IMRT is at least as good as with other types of delivery.

The evidence base for IMRT of the prostate consists largely of lower quality studies, with a lack of high-quality comparative studies reporting on clinical outcomes. In general, where the radiation doses are similar, the available evidence suggests that IMRT provides tumor control rates comparable with existing radiotherapy techniques. In addition, while results are not uniform and are based primarily on retrospective cohort trials, some studies show reductions in gastrointestinal and genitourinary toxicity. A reduction in clinically significant complications of RT is likely to lead to an improved quality of life for treated patients. Thus, despite limitations in the published literature, IMRT is another technique that can be used to deliver RT in the treatment of localized prostate cancer, and its use for this clinical application may be considered medically necessary.

CODING

BlueCHiP for Medicare and Commercial Products

A4648 Tissue marker, implantable, any type, each (Note: This code is not separately reimbursed for institutional providers.)

Note To ensure correct pricing of HCPC code **A4648** for the Calypso 4D localization system, the procedure/clinical notes and the invoice must be submitted.

The following codes are covered for BlueCHiP for Medicare and Commercial Products when the criteria above is met:

Intensity-modulated radiation therapy

77301 Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications

77338 Multi-lear collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan

77385 Intensity modulated radiation treatment delivery (IMRT), includes guicance and tracking, when performed; simple (Institutional providers)

77386 Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex (Institutional providers)

G6015 Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session: (Professional providers)

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: (Professional providers)

RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures
Intensity Modulated Radiotherapy: Abdomen and Pelvis
Intensity Modulated Radiotherapy: Breast and Lung
Intensity Modulated Radiotherapy: Central Nervous System Tumors
Intensity Modulated Radiotherapy: Head, Neck and Thyroid

PUBLISHED

Provider Update, January 2021
Provider Update, October 2019
Provider Update, November/December 2018
Provider Update, October 2017
Provider Update, July 2016

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