Medical Coverage Policy | Intensity-Modulated Radiotherapy of the Prostate

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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 to 80 Gy.
  - Localized prostate cancer is confined to the prostate, or;
  - Locally advanced cancer that is confined to adjacent structures and/or;
  - Local lymph nodes.

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 (IMRT) may be considered medically necessary when the criteria above is met.

IMRT is considered not medically necessary for the treatment of non-localized prostate cancer as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

BACKGROUND

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 (2D) 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).

Three-Dimensional Conformal Radiation

Treatment planning evolved by using 3-dimensional (3D) 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 (3D-CRT).

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 (RT) 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.

Practice Guidelines and Position Statements
The most recent National Comprehensive Cancer Network (NCCN) guidelines (v.1.2015) for prostate cancer indicate, in the principles of RT, highly conformal radiotherapy (CRT) should be used in conventional fraction doses of 75.6 to 79.2 Gy for low-risk prostate cancer and up to 81 Gy for intermediate- and high-risk prostate cancer. A reference in the discussion section indicates IMRT is preferred over 3-dimensional CRT (3D-CRT) because it seems to decrease salvage therapy rates while the risk of adverse effects such as gastrointestinal toxicities are reduced with IMRT. NCCN guidelines also indicate 3D-CRT or IMRT may be considered as initial treatment options in all prostate cancer patients except for patients with a very low risk of recurrence and less than 20 years' expected survival.

The American College of Radiology Appropriateness Criteria indicates IMRT is the standard for definitive external beam RT of the prostate.19

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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:

77301
77338
77385: Use alternate procedure code (G6015)
77386: Use alternate procedure code (G6015)
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

RELATED POLICIES

None

PUBLISHED

Provider Update, February 2016
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