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Medical Policy Manual

Topic: Intensity Modulated Radiation Therapy (IMRT) of the Prostate

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Intensity-modulated radiation therapy (IMRT), which uses computer software, CT, and magnetic resonance imaging (MRI) 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, MLC) 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 beams 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.

Since 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.

MEDICAL POLICY CRITERIA

Note: For metastatic prostate cancer, refer to the policy applicable to the location of the metastasis.

I. Intensity-modulated radiation therapy (IMRT) to the prostate or to the prostate and pelvic lymph nodes as a treatment of prostate cancer *without* prostatectomy and without metastases may be considered **medically necessary**

   A. In the primary treatment of prostate cancer, either as a stand-alone therapy or in combination with brachytherapy; or

   B. For failed primary treatment.

II. IMRT of the prostate bed or prostate bed and pelvic lymph nodes for *post-prostatectomy* treatment of prostate cancer *without metastases* may be considered **medically necessary** in the following circumstances:

   A. Adjuvant radiation therapy within 6 months following prostatectomy; or

   B. Salvage therapy for failed prostatectomy (positive margins, positive lymph nodes, or confirmed failure of PSA to fall to undetectable levels); or

   C. Salvage therapy for suspected recurrence of localized prostate cancer as evidenced by detectable PSA that increases on two subsequent measures.

SCIENTIFIC EVIDENCE[1]

Background

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 side 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 theoretical 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.

Literature Appraisal

Evidence from randomized controlled trials (RCTs) comparing intensity-modulated radiation therapy (IMRT) with other radiation techniques is needed in order to establish safety and efficacy of IMRT in the treatment of prostate cancer.

IMRT has not been compared in RCTs with other radiation techniques for the treatment of prostate cancer. The available evidence comes from observational studies with methodological limitations. A majority of these studies report outcomes for patients with localized prostate cancer. These studies consistently demonstrate reduced rates of toxicity in IMRT-treated patients. However, it is not known whether IMRT leads to improvements in health outcomes (e.g., overall survival) compared with other radiation techniques.

Systematic Reviews

Several systematic reviews have evaluated the use of IMRT in patients with localized prostate cancer:

- In 2012, Bauman and colleagues published a systematic review that examined the evidence for IMRT in the treatment of prostate cancer in order to quantify its potential benefits and to make recommendations for radiation treatment programs considering adopting this technique.[2] Based on a review of 11 published reports through March 2009 (nine retrospective cohort studies and two RCTs) including 4,559 patients, the authors put forth the recommendation for IMRT over 3D-CRT for aggressive treatment of localized prostate cancer where an escalated radiation (>70 Gy) dose is required. There were insufficient data to recommend IMRT over 3D-CRT in the postoperative setting.

  Nine of 11 studies reviewed by Bauman and colleagues reported on adverse effects.[2] Six of 9 studies reported on acute gastrointestinal (GI) effects. Four studies (3 retrospective cohort studies and 1 RCT) reported differences in adverse effects between IMRT and 3D-CRT. Both RCTs reported on acute toxicity outcomes of IMRT compared to 3D-CRT. The first RCT by Al-Mamgani and colleagues[3], included a total of 78 patients, and reported that acute GI toxicity was significantly less frequent in the IMRT group compared to 3D-CRT. This was true for grade 2 or higher toxicities (20% vs. 61%, p=0.001), grade 3 or higher toxicity (0 vs. 13%, p=0.001) and for acute proctitis (15% vs. 38%, p=0.03). In contrast, the second RCT included in this systematic review reported that there were no differences in toxicity between IMRT and 3D-CRT.[4]

  Six of 9 studies reported on acute genitourinary (GU) effects. A single study, which was a retrospective cohort study including 1,571 patients, reported a difference in overall acute GU effects in favor of 3D-CRT (37% IMRT vs. 22% 3D-CRT, p=0.001). For late GI toxicity, 4 retrospective cohort studies with a total of 3,333 patients, reported differences between IMRT and 3D-CRT, of which only one reported a difference between groups in favor of treatment with IMRT. One RCT reported on late GI toxicity and did not find any differences between IMRT and 3D-CRT. Five of 9 studies reported on late GU effects, and only one reported a difference in late GU effects in favor of 3D-CRT (20% vs. 12%, p=0.01). Two retrospective cohort studies reported mixed findings on quality of life outcomes. A subsequent economic analysis (based on this systematic review data) demonstrated that for radical radiation treatment (>70 Gy) of prostate cancer, IMRT seems to be cost-effective when compared with an equivalent dose of 3D-CRT from the perspective of the Canadian health care system for 2009.

- The 2010 Agency for Healthcare Research and Quality (AHRQ) comparative evaluation of radiation treatments for clinically localized prostate cancer concluded that data on comparative effectiveness between different forms of radiation treatments are inconclusive with respect to overall or disease-specific survival. In addition, the AHRQ technology assessment states that more studies of better quality are needed to confirm or refute the suggested findings in the studies that compared outcomes in patients treated with different forms of radiation therapy.[5]

- The 2008 comparative effectiveness study of therapies for clinically localized prostate cancer reached the following conclusions:[6]

  "There was no direct evidence that IMRT results in better survival or disease-free survival than other therapies for localized prostate cancer. Based on non-randomized data, the absolute risks of clinical and biochemical outcomes (including tumor recurrence), toxicity, and quality of life after IMRT are comparable with conformal radiation."

  "[For IMRT,] The percents of Grade 1 and 2 acute GI toxicity were 22% and 4%, respectively, and rectal bleeding 1.6–10%."

  "Case series data suggested that IMRT provide at least as good a radiation dose to the prostate with less radiation to the surrounding tissues (that is undesirable) compared with conformal radiation therapy."

  A subsequent report undertaken in 2012 by the AHRQ Comparative Effectiveness Review Surveillance Program using the search strategy employed for the 2008 systematic review found no new data on IMRT.[7]

- Hummel and colleagues reported similar findings to the AHRQ report in a review of the clinical effectiveness of IMRT for the radical treatment of prostate cancer undertaken by the UK Health Technology Assessment Programme in 2010.[8] The authors also performed a subsequent economic analysis which concluded IMRT to be cost-effective if this treatment modality can be used to prolong survival.[9]

- Another recent review of IMRT for localized prostate cancer by the Institute for Clinical and Economic Review[10] reached the following conclusions:

  "The literature on comparative rates of toxicity has serious methodological weaknesses. There are no prospective randomized trials or cohort trials, and the case series that exist are hampered by the lack of contemporaneous cohorts and/or by a failure to describe the selection process by which patients were assigned to IMRT vs. 3D-CRT. Published case series demonstrate consistent findings of a reduced rate of GI toxicity for IMRT at radiation doses from approximately 75–80 Gy. Data on GU toxicity have not shown superiority of IMRT over 3D-CRT, nor do the existing data suggest that IMRT provided a lower risk of erectile dysfunction."

  "The literature suggests that the risk of Grade 2 GI toxicity is approximately 14% with 3D-CRT and 4% with IMRT. Thus, the number of patients needed to treat to prevent one case of moderate-severe proctitis is 10, and for every 100 patients treated with IMRT instead of 3D-CRT, 10 cases of GI toxicity would be expected to be prevented."

- In another recent review of IMRT, no randomized, controlled trials were identified in the treatment of prostate cancer.[11] As summarized in this review, 5 studies reported biochemical control outcomes and showed no difference between IMRT and 3D-CRT, except for one study where IMRT patients received a median dose of 75.6 Gy compared with a median dose of 68.4 Gy in the 3D-CRT cohort. Of 14 studies that reported late toxicity, 7 reported a statistically significant reduction in late gastrointestinal (GI) toxicity for IMRT and 7 showed no significant difference. The median incidence of grade 2 or greater GI toxicity for the IMRT cohorts was 6% (range: 0–24%) and for 3D-CRT was 15% (range: 9–37%).

Primary Studies Reporting On Outcomes And Adverse Effects

- While the use of IMRT for prostate cancer has increased significantly, only a few institutions have reported long-term data on biochemical control rates and toxicity. Zelefsky et al. reported on the incidence and predictors of treatment-related toxicity at 10 years after 3D-CRT and IMRT for localized prostate cancer.[12] Between 1988 and 2000, 1,571 patients with stages T1-T3 prostate cancer were treated with 3D-CRT or IMRT with doses ranging from 66 to 81 Gy. Twenty-two percent were considered to be at low risk, as based on NCCN guidelines. The median follow-up was 10 years. The actuarial likelihood at 10 years for the development of Grade 2 or higher gastrointestinal (GI) toxicities was 9%. The use of IMRT significantly reduced the risk of GI toxicities compared with patients treated with conventional 3D-CRT (13% to 5%; $p<0.001$). Among patients who experienced acute symptoms, the 10-year incidence of late toxicity was 42%, compared with 9% for those who did not experience acute symptoms. The 10-year incidence of late Grade 2 or higher genitourinary (GU) toxicity was 15%. Patients treated with 81 Gy (IMRT) had a 20% incidence of GU symptoms at 10 years, compared with 12% for patients treated with lower doses ($p=0.01$). Among patients who had developed acute symptoms during treatment, the incidence of late toxicity at 10 years was 35%, compared with 12%. The incidence of Grade 3 GI and GU toxicities was 1% and 3%, respectively. The authors concluded that serious late toxicity was unusual despite the delivery of high radiation dose levels in these patients. They also noted that higher doses were associated with increased GI and GU Grade 2 toxicities, but the risk of proctitis was significantly reduced with IMRT.
- Cohlon et al. reported on preliminary biochemical outcomes and toxicity with high-dose IMRT to a dose of 86.4 Gy for localized prostate cancer.[13] For this study, 478 patients were treated between August 1997 and March 2004 with 86.4 Gy using a 5- to 7-field IMRT technique. The median follow-up was 53 months. Thirty-seven patients (8%) experienced acute Grade 2 GI toxicity; none had acute Grade 3 or 4 GI toxicity; 105 patients (22%) experienced acute Grade 2 GU toxicity; and 3 patients (0.6%) had Grade 3 GU toxicity. Sixteen patients (3%) developed late Grade 2 GI toxicity; 2 patients (<1%) developed late Grade 3 GI toxicity; 60 patients (13%) had late Grade 2 GU toxicity; and 12 (<3%) experienced late Grade 3 GU toxicity. The 5-year actuarial PSA relapse-free survival, according to the nadir plus 2 ng/mL definition, was 98%, 85%, and 70% for the low-, intermediate-, and high-risk NCCN prognostic groups. The authors concluded that treatment with ultra-high radiation dose levels of 86.4 Gy using IMRT for localized prostate cancer is well tolerated and the early excellent biochemical control rates are encouraging. These results based on a case series should be considered as preliminary.
- Additional publications of high-dose IMRT consist of case series and non-randomized comparisons that also report reduced GI and/or GU toxicities in patients treated with IMRT.[14-29]
- The evidence on IMRT treatment in post-prostatectomy patients is very limited and consists of case series and non-randomized comparative studies.[30-32]
- Although the research on lower-dose IMRT continues to develop, the evidence is still limited and consists of small case series.[33-39]

Clinical Practice Guidelines

National Comprehensive Cancer Network (NCCN)

Per the NCCN guidelines for the treatment of prostate cancer, "3D conformal and IMRT (intensity-modulated radiation therapy) techniques should be employed." The guidelines also state that "the second generation 3D technique, intensity-modulated radiation therapy (IMRT), significantly reduces the risk of gastrointestinal toxicities compared to 3D-CRT."[40]

Summary

Currently, there are no randomized controlled trials of intensity-modulated radiation therapy (IMRT) compared with other radiation techniques for the treatment of prostate cancer. The available evidence on IMRT for prostate cancer comes from observational studies with methodological limitations. A majority of these studies report outcomes for patients with localized prostate cancer. These studies consistently demonstrate reduced rates of toxicity in IMRT-treated patients. However, it is not known whether IMRT leads to improvements in health outcomes (e.g., overall survival) compared with other radiation techniques. Despite limited evidence, IMRT has evolved into a standard of care for the treatment of prostate cancer. Therefore IMRT may be considered medically necessary in patients meeting the policy criteria.

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Intensity-Modulated Radiation Therapy (IMRT): Central Nervous System (CNS) and Vertebral Tumors, Medicine, Policy No. 147

CODES	NUMBER	DESCRIPTION
CPT	77301	Intensity modulated radiotherapy plan, including dose volume histograms for target and critical structure partial tolerance specification
	77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan (new code 1/1/10)
	77418	Intensity modulated treatment deliver, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary dynamic MLC, per treatment session
	0073T	Compensator-based beam modulation treatment delivery of inverse planned treatment using three or more high resolution compensator convergent beam modulated fields, per treatment session
HCPCS	None	