

National Imaging Associates, Inc.	
Clinical guidelines/considerations <u>PROSTATE CANCER - RADIATION</u> <u>ONCOLOGY</u>	Date: March 2011 Page 1 of 11
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INTRODUCTION:

Prostate cancer is diagnosed by biopsy and evaluated (staged) to determine extent of disease (local, regional, or distant metastatic). To apply the most appropriate treatment option, which may include active surveillance, radical prostatectomy or radiation therapy, an initial multidisciplinary interaction may include the participation of an urologist, radiation oncologist, and medical oncologist. Together these disciplines agree on stratification of patients into risk categories. Treatment options exist within each risk category and the specific course of treatment is based on disease extent and prognosis, acceptance of risks and benefits, as well as consideration of possible changes in quality of life.

Radiation therapy is used to treat prostate cancers that are organ-confined or extend into tissues adjacent to the prostate. Such cancers are treated aggressively (for cure) with tolerance doses of radiation to achieve control of localized cancers yielding 5- and 10-year disease-free survival results that are comparable to those obtained by surgical options.

GOAL OF THE GUIDELINE:

This guideline outlines several methods suitable for delivering prostate radiation therapy. These include the use of external radiation (teletherapy) and internal radiation (brachytherapy). Advances in the treatment of prostate cancer with radiation have been the direct result of improved diagnostic accuracy and integration of imaging with precise treatment delivery. Improvements in technology result in more favorable distributions of radiation doses, and by extension should result in enhanced tumor control due to dose escalation or altered fractionation, and decreased complications by limiting dose to normal tissues. Fortunately, these complex improvements offer a myriad of regimens; the goal of this program is to guide diagnosis and treatment to the most efficient, comparatively effective treatment pathway.

GENERAL CONSIDERATIONS:

- Patients with very low/low risk disease should not receive androgen deprivation therapy (ADT) unless it is used to reduce the prostate size prior to implant or the receipt of pelvic node irradiation.
- Combined treatment (3D-CRT/IMRT) + implants) is not considered standard for very low/low risk patients.

- Patients with history of recent transurethral resection of the prostate (TURP), elevated international symptom score (IPSS), bladder outlet obstruction, or enlarged gland (even after short course of Luteinizing hormone-releasing hormone [LHRH] agonist) may not be ideal candidates for implant due to increased risk of side effects.
- Patients with intermediate risk disease may be considered for short course (4-6 months) of neoadjuvant/concomitant/adjuvant ADT.
- Daily prostate localization can be accomplished with imaging modalities, e.g., ultrasound images, computed tomography (CT) images, or implanted fiducial markers, incorporated into an image guided radiation therapy (IGRT) system.
- Patients with high risk disease may be considered for pelvic lymph node irradiation and 2-3 years of neoadjuvant/adjuvant ADT.
- 3D-CRT/intensity modulated radiation therapy (3D-CRT/IMRT) techniques should be employed.
- Patients with adverse pathologic factors following prostatectomy, without evidence of metastatic disease, should be offered salvage irradiation.

MEDICALLY NECESSARY INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS:

- **Very Low Recurrence Risk (Primary Tumor Stage [T] is T1c, PSA <10 ng/ml, and Gleason score \leq 6, PSA density <0.15ng/ml per g, < 3biopsy cores positive with < 50% cancer in each)**
 - Active surveillance
 - External Beam Radiation Therapy
 - 3D-CRT) - Doses 72 -75 Gy
 - IMRT with or without IGRT – Doses 75.6 -79 Gy
 - Image guidance with ultrasound, (kV) match, or cone beam CT
 - Brachytherapy
 - Low-dose-rate (LDR) Iodine (I)-125
 - Palladium-103
- **Low Recurrence Risk (Primary Tumor Stage [T] is T1-T2a, PSA <10 ng/ml, and Gleason score \leq 6)**
 - Active surveillance
 - External Beam Radiation Therapy
 - 3D-CRT - Doses 72 -75 Gy
 - IMRT with or without IGRT – Doses 75.6 -79 Gy
 - Image guidance with ultrasound, kV match, or cone beam CT
 - Brachytherapy
 - LDR I-125
 - Palladium-1

- **Intermediate Recurrence Risk (Primary Tumor Stage [T] T2b-T2c or PSA 10-20 ng/ml or Gleason score 7)**
 - External Beam Radiation Therapy
 - 3D-CRT –Doses 75 – 79 Gy
 - IMRT with IGRT - Doses 78 - 81 Gy
 - 3D –CRT with IMRT Boost –Doses 78 - 81 Gy
 - IGRT with ultrasound, kV match, or cone beam CT is required if dose \geq 78 Gy
 - Brachytherapy boost (combined with EBRT after 40 -50 Gy)
 - LDR I-125 or Palladium-103
 - High-dose-rate (HDR) Iridium (Ir)-192

- **High Recurrence Risk (Primary Tumor Stage [T] T3a or PSA >20 ng/ml or Gleason score \geq 8 or more than two intermediate risk factors)**
 - External Beam Radiation Therapy with ADT (long-term 2-3 years)
 - 3D-CRT 75 -79 Gy
 - IMRT with IGRT - Doses 78 - 81 Gy
 - 3D –CRT with IMRT Boost –Doses 78 - 81Gy
 - IGRT with ultrasound, kV match, or cone beam CT is required if dose \geq 78 Gy
 - Brachytherapy boost (combined with EBRT after 40-50 Gy)
 - LDR I-125 or Palladium-103
 - High-dose-rate (HDR) Iridium (Ir)-192

- **Very High Recurrence Risk (Primary Tumor Stage [T] T3b-T4) without Metastasis**
 - External Beam Radiation Therapy with ADT (long term 2-3 years)
 - 3D-CRT 75-79 Gy
 - IMRT with IGRT - Doses 78 -81 Gy
 - IGRT with ultrasound, kV match, or cone beam CT is required if dose \geq 78 Gy
 - Brachytherapy boost (combined with EBRT after 40-50 Gy)
 - LDR I-125 or Palladium-103
 - High-dose-rate (HDR) Iridium (Ir)-192

- **Radiation Therapy for Patients with Locally Advanced or Metastatic Prostate (T3b – T4, or any T and N1 disease)**
 - External Beam Radiation Therapy
 - 3D-CRT 75-79 Gy
 - IMRT – Doses 78-81 Gy
 - IGRT with ultrasound, kV match, or cone beam CT is required if dose \geq 78 Gy

- **Post-Prostatectomy (detectable PSA or initially undetectable PSA, but with recent detectable and rising values on 2 or more measurements with no evidence of metastatic disease)**
 - External Beam Radiation Therapy
 - 3D-CRT - Doses 64 – 70 Gy
 - IMRT with or without IGRT –Doses 64-70 Gy
 - Image guidance with ultrasound, kV match, or cone beam CT

Unless otherwise indicated standard radiation fractionation consists of 1.8 Gy to 2.0 Gy per day

TREATMENT OPTIONS REQUIRING ADDITIONAL CLINICAL REVIEW:

- Proton beam is not an approved treatment option for localized prostate cancer. Studies comparing proton beam therapy alone to 3-D conformal radiation or IMRT are limited. Overall, studies have not shown clinical outcomes to be superior to conventional radiation therapy. A request for proton beam therapy will require a peer review. For peer review purposes supporting documentation from the radiation oncologist is required and should include the clinical rationale for performing proton beam rather than 3-D conformal or IMRT.
- HDR Brachytherapy as monotherapy for localized prostate cancer is not considered standard of care and will require a peer review for medical necessity determination.
- Real-time intra-fraction target tracking during radiation therapy to adjust radiation doses or monitor target movement during individual radiation therapy treatment sessions is not considered standard of care. A request for intra-fraction tracking will require a peer review for medical necessity determination. Documentation from the provider must include the clinical rationale for using intra-fraction tracking rather than the placement of interstitial devices (e.g. fiducial markers) and standard image guidance such as CT guidance, stereoscopic x-ray or ultrasonic guidance.
- Stereotactic Body Radiation Therapy (SBRT) is not considered a standard form of treatment for prostate cancer. Overall, studies have not shown clinical outcomes to be superior to conventional radiation therapy. A request for SBRT will require a peer review to make a medical necessity determination. Documentation from the radiation oncologist must include the clinical rationale for performing SBRT rather than 3-D conformal or IMRT.

MITIGATING CIRCUMSTANCES FOR TREATMENT PLANNING:

- History of inflammatory bowel disease such as Crohn's disease or ulcerative colitis, or a history of prior pelvic radiotherapy
- History of recent TURP and/or unusual sized prostate (either very large or very small)
- History of bladder obstruction with high IPSS symptom score

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