

National Imaging Associates, Inc.*	
Clinical guideline PROSTATE CANCER	Original Date: March 2011
Radiation Oncology	Last Revised Date: February 2020
Guideline Number: NIA_CG_124	Implementation Date: January 2021

INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS (NCCN, 2018):

Very Low Recurrence Risk (Primary Tumor Stage [T] is T1c, PSA <10 ng/ml, and Gleason score ≤ 6, PSA density <0.15ng/nl per g, < 3 biopsy cores positive with ≤ 50% cancer in each)

- Active surveillance (discussed with patient as treatment option)
- External Beam Radiation Therapy - *Various fractionation and dose regimes can be considered depending on clinical scenarios*
 - Highly conformal radiation therapy technique (3D-CRT/IMRT) – with IGRT (up to 45 fractions)
 - SBRT delivered at five fractions or less at 6.5 Gy per fraction or greater. Appropriate as a standalone radiation modality and not as a boost to other conventional methods of radiation treatment
- LDR (low dose-rate) or HDR (high dose-rate) Brachytherapy

Low Recurrence Risk (Primary Tumor Stage [T] is T1-T2a, PSA <10 ng/ml, and Gleason score ≤ 6)

- Active surveillance (discussed with patient as treatment option)
- External Beam Radiation Therapy - *Various fractionation and dose regimes can be considered depending on clinical scenarios*
 - Highly conformal radiation therapy technique (3D-CRT/IMRT) –with IGRT (up to 45 fractions)
 - SBRT delivered at five fractions or less at 6.5 Gy per fraction or greater. Appropriate as a standalone radiation modality and not as a boost to other conventional methods of radiation treatment.
- LDR (low dose-rate) or HDR (high dose-rate) Brachytherapy

Intermediate Recurrence Risk (Primary Tumor Stage [T] T2b-T2c or PSA 10-20 ng/ml or Gleason score 7)

- External Beam Radiation Therapy -*Various fractionation and dose regimes can be considered depending on clinical scenarios*
 - Highly conformal radiation therapy technique (3D-CRT/IMRT) with IGRT – (up to 45 fractions)

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- SBRT delivered at five fractions or less at 6.5 Gy per fraction or greater. Appropriate as a standalone radiation modality and NOT as a boost to other conventional methods of radiation treatment.
- Brachytherapy (LDR/HDR) boost combined with EBRT after 40 -50 Gy

High Recurrence Risk (Primary Tumor Stage [T] T3a or PSA > 20 ng/ml or Gleason score 8 -10 , or two or more intermediate risk factors)

- External Beam Radiation Therapy- *Various fractionation and dose regimes can be considered depending on clinical scenarios*
 - Highly conformal radiation therapy technique (3D-CRT/IMRT) – with IGRT (up to 45 fractions)
- Brachytherapy (LDR/HDR) boost combined with EBRT after 40-50 Gy

Very High Recurrence Risk (Primary Tumor Stage [T] T3b-T4) with Gleason score 8-10 without Metastasis

- External Beam Radiation Therapy - *Various fractionation and dose regimes can be considered depending on clinical scenarios*
 - Highly conformal radiation therapy technique (3D-CRT/IMRT) –with IGRT (up to 45 fractions)
- Brachytherapy (LDR/HDR) boost combined with EBRT after 40-50 Gy

Radiation Therapy for Patients with Locally Advanced or Metastatic Prostate (T3b – T4, or any T and N1, M0 disease)

- External Beam Radiation Therapy- *Various fractionation and dose regimes can be considered depending on clinical scenarios*
 - Highly conformal radiation therapy technique (3D-CRT/IMRT) – with IGRT (up to 45 fractions)
- Brachytherapy (LDR/HDR) boost combined with EBRT after 40-50 Gy

Post-Prostatectomy

- External Beam Radiation Therapy
 - Highly conformal radiation therapy technique (3D-CRT/IMRT) Doses 64 – 72 Gy (up to 40 fractions) with IGRT
- One of the following must be met:
 - Detectable PSA or initially undetectable PSA, but with recent detectable and rising values on 2 or more measurements with no evidence of metastatic disease
 - Positive margins
 - Seminal vesicle invasion
 - Gleason 8-10
- Pathological T3 disease

TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW:

The radiation treatment options below require review by a physician reviewer and may include deliberation on whether or not active surveillance and surgery have been considered prior to the decision to request radiation therapy:

- Brachytherapy alone (monotherapy) may be approved for Intermediate Recurrence Risk (Primary Tumor Stage [T] T2b-T2c or PSA 10-20 ng/ml or Gleason score 7) upon review with a physician reviewer. Brachytherapy alone is not considered appropriate if the patient has unfavorable or poor prognostic risk factors intermediate risk factors and is thus higher risk.
 - Proton beam is not an approved treatment option for 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 (ASTRO, 2018a; Dutz, 2019; Fang, 2015; NCCN, 2018b; Santos, 2019).
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BACKGROUND:

Prostate cancer is diagnosed by biopsy and evaluated (staged) to determine extent of disease (local, regional, or distant metastatic). Both surgery and radiation therapy is used to treat prostate cancers that are organ-confined or extend into tissues adjacent to the prostate. 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 very low risk disease should be considered for active surveillance if their life expectancy is less than or equal to 20 years. Active surveillance is as well, recommended for patients with favorable intermediate-risk prostate cancer. Observation is the preferred action for men with low-risk prostate cancer with a life expectancy of less than 10 years. Patients with intermediate risk disease may be considered for short course (4-6 months) of neoadjuvant/concomitant/adjuvant ADT. Patients with high risk disease may be considered for pelvic lymph node irradiation and 2-3 years of neoadjuvant/adjuvant ADT.

POLICY HISTORY:

Review Date: February 2019

Review Summary:

- External Beam Radiation Therapy: Added: ' SBRT delivered at five fractions or less at 6.5 Gy per fraction or greater. Appropriate as a standalone radiation modality and not as a boost to other conventional methods of radiation treatment'
- Added and updated references

Review Date: February 2020

Review Summary:

- Proton Beam: Clarification of Proton Beam Guideline whereby the term *localized* was removed from the following statement: Proton Beam is not an approved treatment option for ~~localized~~ prostate cancer.
- Added and updated References

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