

National Imaging Associates, Inc.*	
Clinical guideline PROSTATE CANCER	Original Date: March 2011
Radiation Oncology	Last Revised Date: February 2021
Guideline Number: NIA_CG_124	Implementation Date: January 2022

MEDICALLY NECESSARY INDICATIONS FOR RADIATION THERAPY (Morgan, 2018; NCCN, 2021)
EBRT/IMRT hypofractionation of 20-28 fractions are recommended to treat localized prostate cancer when pelvic nodes are not treated. Other treatment regimens require physician review and clinical documentation that supports medical necessity.

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
 - Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Hypofractionation 20-28 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
 - Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Hypofractionation 20-28 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

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- Highly conformal radiation therapy technique (3D-CRT/IMRTwith IGRT). Hypofractionation-20-28 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.
- Brachytherapy (LDR/HDR) boost combined with EBRT after 20-28 fractions

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
 - Highly conformal radiation therapy technique (3D-CRT/IMRTwith IGRT). Hypofractionation-20-28 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.
- Brachytherapy (LDR/HDR) boost combined with EBRT after 20-28 fractions.

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

- External Beam Radiation Therapy
 - Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Hypofractionation-20-28 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.
- Brachytherapy (LDR/HDR) boost combined with EBRT after 20-28 fractions

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

- External Beam Radiation Therapy
 - Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Up to 45 fractions are medically necessary for localized or locally recurrent prostate cancer when pelvic nodes are treated.
- Brachytherapy (LDR/HDR) boost combined with EBRT after 20-28 fractions

Adjuvant Post-Prostatectomy or Salvage Radiation Therapy

- 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 or extracapsular extension.
- 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.
- EBRT/IMRT hypofractionation of 20-28 fractions are recommended to treat localized prostate cancer when pelvic nodes are not treated. Other treatment regimens require physician review and clinical documentation that supports medical necessity.
- 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).

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

Date	Summary
February 2021	<p>Deleted: INDICATIONS FOR RADIATION THERAPY AND TREATMENT OPTIONS Changed to: MEDICALLY NECESSARY INDICATIONS FOR RADIATION THERAPY (NCCN, 2021; Morgan et al, 2018): EBRT/IMRT hypofractionation of 20-28 fractions are recommended to treat localized localized prostate cancer when pelvic nodes are not treated. Other treatment regimens require physician review and clinical documentation that supports medical necessity.</p> <p>For Very Low/Low, Intermediate and High/Very High Recurrence Prostate Cancer. The following was deleted:</p> <ul style="list-style-type: none"> • <i>Various fractionation and dose regimens can be considered based on medical necessity.</i> • Highly conformal radiation therapy technique 3D-CRT/IMRTwith IGRT up to 45 fractions <p>For Very Low/Low, Intermediate and High/Very High Recurrence Prostate Cancer. The following was updated :</p> <ul style="list-style-type: none"> • Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Hypofractionation 20-28 fractions <p>For Intermediate and High/Very High Recurrence Prostate Cancer. The following was deleted:</p> <ul style="list-style-type: none"> • Brachytherapy (LDR/HDR) boost combined with EBRT after 40-50 Gy <p>For Intermediate and High/Very High Recurrence Prostate Cancer. The following was updated :</p> <ul style="list-style-type: none"> • Brachytherapy (LDR/HDR) boost combined with EBRT after 20-28 Fx <p>Radiation Therapy for Patients with Locally Advanced or Metastatic Prostate (T3b – T4, or any T and N1, M0 disease)</p> <ul style="list-style-type: none"> • Deleted: Various fractionation and dose regimens can be considered based on medical necessity. • Deleted: Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Up to 45 fractions ○ Updated: Highly conformal radiation therapy technique (3D-CRT/IMRT with IGRT). Up to 45 fractions are medically necessary for localized or locally recurrent prostate cancer when pelvic nodes are treated. ○ Deleted: Brachytherapy (LDR/HDR) boost combined with EBRT after40-50 Gy ○ Updated : Brachytherapy (LDR/HDR) boost combined with EBRT after 20-28 fractions

	<p>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) and</p> <p>Very High Recurrence Risk (Primary Tumor Stage [T] T3b-T4) with Gleason score 8-10 without Metastasis</p> <p>Under the above sections added update:</p> <ul style="list-style-type: none"> ○ 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. <p>Post-Prostatectomy guideline heading changed to “Adjuvant Post-Prostatectomy or Salvage Radiation Therapy” to include criteria for Salvage Therapy. Guideline also updated to include extracapsular extension. Updated guideline to: Seminal vesicle invasion or extracapsular extension.</p> <p>TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW</p> <p>Added</p> <ul style="list-style-type: none"> ● EBRT/IMRT hypofractionation of 20-28 fractions are recommended to treat localized prostate cancer when pelvic nodes are not treated. Other treatment regimens require physician review and clinical documentation that supports medical necessity. <p>Added and Updated References</p>
February 2020	<ul style="list-style-type: none"> ● Proton Beam: Clarification of Proton Beam Guideline whereby the term <i>localized</i> was removed from the following statement: Proton Beam is not an approved treatment option for localized prostate cancer. ● Added and updated References
February 2019	<ul style="list-style-type: none"> ● 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

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Reviewed / Approved by NIA Clinical Guideline Committee

GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

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