MEDICALLY NECESSARY INDICATIONS FOR RADIATION THERAPY\textsuperscript{1,2}

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 \(T1c\), \(PSA <10 \text{ ng/ml}\), and \(\text{Gleason score} \leq 6\), \(\text{PSA density} <0.15 \text{ng/ml per g} \), \(< 3 \text{ biopsy cores positive with} \leq 50\% \text{ cancer in each}\))

- 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 \(T1-T2a\), \(PSA <10 \text{ ng/ml}\), and \(\text{Gleason score} \leq 6\))

- 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 \(PSA 10-20 \text{ ng/ml} \) or \(\text{Gleason score} 7\))

- External Beam Radiation Therapy

\textsuperscript{*} National Imaging Associates, Inc. (NIA) is a subsidiary of Evolent Health LLC.

\textsuperscript{1}—Prostate Cancer Rad Onc


- 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
  - 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
  - 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 N1 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

Palliative Radiotherapy:

- 30Gy/10FX or
- 37.5Gy/15FX

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:
  o Detectable PSA or initially undetectable PSA, but with recent detectable and rising values on 2 or more measurements with no evidence of metastatic disease
  o Positive margins
  o Seminal vesicle invasion or extracapsular extension.
  o Gleason 8-10
  o 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.

DOSAGE GUIDELINES

• Moderate Hypofractionation (preferred, for all but low-volume M1, including N1):
  o 3Gy x 20 fractions
  o 2.7Gy x 26 fractions
  o 2.5 x 28 fractions

• Ultra-Hypofractionation (for all but N1 and M1):
  o 7.25-8Gy x 5 fractions & 6.1Gy x 7 fractions

• Ultra-Hypofractionation (for low-volume M1):
  o 6Gy x 6 fractions

• Low-volume metastatic disease
  o Per STAMPEDE phase 3 randomized trial, 3 55Gy in 20 fractions (i.e., 2.75Gy x 20) or 6Gy x 6 fractions can be used.

• High-volume metastatic disease (Visceral met, 4 or more bone mets with at least one metastasis beyond the pelvis vertebral column):
  o Based on HORRAD 4 & STAMPEDE trials no RT to prostate would be medically necessary.
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.1, 2, 5-8

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

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| January 2022| • Changed “Radiation Therapy for Patients with Locally Advanced or Metastatic Prostate (T3b – T4, or any T and N1, disease)” to “Radiation Therapy for Patients with Locally Advanced or N1 Prostate (T3b – T4, or any T and N1, M0 disease)”  
• Added Palliative Radiotherapy  
  o 30Gy/10FX or  
  o 37.5Gy/15FX  
• Added Dosage Guidelines section within Treatment Options Requiring Physician Review |
| February 2021| 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. |
For Very Low/Low, Intermediate and High/Very High Recurrence Prostate Cancer. The following was deleted:

- **Various fractionation and dose regimens can be considered based on medical necessity.**
- Highly conformal radiation therapy technique 3D-CRT/IMRT with IGRT up to 45 fractions

For Very Low/Low, Intermediate and High/Very High Recurrence Prostate Cancer. The following was updated:

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

For Intermediate and High/Very High Recurrence Prostate Cancer. The following was deleted:

- Brachytherapy (LDR/HDR) boost combined with EBRT after 40-50 Gy

For Intermediate and High/Very High Recurrence Prostate Cancer. The following was updated:

- Brachytherapy (LDR/HDR) boost combined with EBRT after 20-28 Fx

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

- 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 after 40-50 Gy
  - Updated: 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) and

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

Under the above sections added update:

- 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.
Post-Prostatectomy guideline heading changed to “Adjuvant Post-Prostatectomy or Salvage Radiation Therapy” to include criteria for Salvage Therapy. Guideline also updated to include extracapular extension. Updated guideline to: Seminal vesicle invasion or extracapsular extension.

**TREATMENT OPTIONS REQUIRING PHYSICIAN REVIEW**

**Added**
- 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.

**Added and Updated References**

| February 2020 | 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 |
| February 2019 | 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 |
REFERENCES


ADDITIONAL RESOURCES

Health Care Authority, Health Technology Assessment Program Olympia, WA: Washington State Health Care Authority, Health Technology Assessment Program. 2012;

8—Prostate Cancer Rad Onc

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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