

Measure #104 (NQF 0390): Prostate Cancer: Adjuvant Hormonal Therapy for High Risk or Very High Risk Prostate Cancer – National Quality Strategy Domain: Effective Clinical Care

2017 OPTIONS FOR INDIVIDUAL MEASURES:

REGISTRY ONLY

MEASURE TYPE:

Process

DESCRIPTION:

Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH [gonadotropin-releasing hormone] agonist or antagonist)

INSTRUCTIONS:

This measure is to be reported once per episode of radiation therapy for all male patients with prostate cancer who receive external beam radiotherapy to the prostate during the reporting period. Each episode of radiation therapy in an eligible patient receiving external beam radiotherapy to the prostate occurring during the reporting period will be counted when calculating the data completeness and performance rates. The quality-data code or equivalent needs to be submitted only once during the episode of radiation therapy (e.g., 8 weeks of therapy). It is anticipated that eligible clinicians who perform external beam radiotherapy to the prostate will submit this measure.

Measure Reporting:

The listed denominator criteria is used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions allowed by the measure. The quality-data codes listed do not need to be submitted for registry-based submissions; however, these codes may be submitted for those registries that utilize claims data.

DENOMINATOR:

All patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence, receiving external beam radiotherapy to the prostate

Definitions:

Risk Strata - Very Low, Low, Intermediate, High, or Very High–

Very Low Risk – PSA < 10 ng/mL; AND Gleason score 6 or less; AND clinical stage T1c; AND presence of disease in fewer than 3 biopsy cores; AND ≤ 50% prostate cancer involvement in any core; AND PSA density ≤ 0.15 ng/mL/cm³.

Low Risk – PSA < 10 ng/mL; AND Gleason score 6 or less; AND clinical stage T1 to T2a.

Intermediate Risk – PSA 10 to 20 ng/mL; OR Gleason score 7; OR clinical stage T2b to T2c.

Note: Patients with multiple adverse factors may be shifted into the high risk category.

High Risk – PSA > 20 ng/mL; OR Gleason score 8 to 10; OR clinically localized stage T3a.

Note: Patients with multiple adverse factors may be shifted into the very high risk category.

Very High Risk – Clinical stage T3b to T4; OR primary Gleason pattern 5; OR more than 4 cores with Gleason score 8 to 10. (NCCN, 2016)

External beam radiotherapy – External beam radiotherapy refers to 3D conformal radiation therapy (3D-CRT), intensity modulated radiation therapy (IMRT), stereotactic body radiotherapy (SBRT), and proton beam therapy.

Denominator Criteria (Eligible Cases):

Any male patient, regardless of age

AND

Diagnosis for prostate cancer (ICD-10-CM): C61

AND

Patient encounter during the reporting period (CPT): 77427, 77435

AND

High or very high risk of recurrence of prostate cancer: G8465

AND NOT

DENOMINATOR EXCLUSION:

Diagnosis for metastatic cancer (ICD-10-CM): C77.0, C77.1, C77.2, C77.3, C77.4, C77.5, C77.8, C77.9, C78.00, C78.01, C78.02, C78.1, C78.2, C78.30, C78.39, C78.4, C78.5, C78.6, C78.7, C78.80, C78.89, C79.00, C79.01, C79.02, C79.10, C79.11, C79.19, C79.2, C79.31, C79.32, C79.40, C79.49, C79.51, C79.52, C79.60, C79.61, C79.62, C79.70, C79.71, C79.72, C79.81, C79.82, C79.89, C79.9

NUMERATOR:

Patients who were prescribed adjuvant hormonal therapy (GnRH [gonadotropin-releasing hormone] agonist or antagonist)

Definition:

Prescribed – Includes patients who are currently receiving medication(s) that follow the treatment plan recommended at an encounter during the reporting period, even if the prescription for that medication was ordered prior to the encounter.

Numerator Options:

Performance Met:

Adjuvant (ie, in combination with external beam radiotherapy to the prostate for prostate cancer) hormonal therapy (gonadotropin-releasing hormone[GnRH] agonist or antagonist) prescribed/administered (4164F)

OR

Denominator Exception:

Documentation of medical reason(s) for not prescribing/administering adjuvant hormonal therapy (eg, salvage therapy) (4164F *with* 1P)

OR

Denominator Exception:

Documentation of patient reason(s) for not prescribing/administering adjuvant hormonal therapy (4164F *with* 2P)

OR

Performance Not Met:

Patients who were not prescribed/administered adjuvant hormonal therapy, reason not otherwise specified (4164F *with* 8P)

RATIONALE:

The use of adjuvant hormonal therapy following external beam radiotherapy is a well-established standard of care for high-risk prostate cancer patients. Multiple large studies have shown that men who receive adjuvant hormonal therapy following external beam radiation therapy can live longer and have a lower risk of recurrence than men who receive radiation therapy alone. In addition, a cost-analysis conducted found that the use of adjuvant hormonal therapy and external beam radiation therapy is cost-effective and adds quality-adjusted life years for patients (Satish et al., 2006).

Data from several sources indicates that while utilization rates of adjuvant hormonal therapy and external beam radiation therapy have increased, they still remain suboptimal. One study analyzing the CaPSURE database, a provider-based registry, found that the utilization of adjuvant hormonal therapy and external beam radiation therapy for high-risk patients has increased to 80% throughout the past two decades, yet utilization rates have plateaued since 2000 (Cooperberg et al., 2008). There is rising concern about undertreatment of high-risk prostate cancer patients (Cooperberg, Broering, Carroll, 2010). This suggests greater outreach and education are needed to improve outcomes in care.

CLINICAL RECOMMENDATION STATEMENTS:

When counseling patients regarding treatment options, physicians should consider the following:

Based on results of two randomized controlled clinical trials, the use of adjuvant and concurrent hormonal therapy may prolong survival in the patient who has opted for radiotherapy. (AUA, 2007)

High risk patients who are considering specific treatment options should be informed of findings of recent high quality clinical trials, including that: for those considering external beam radiotherapy, use of hormonal therapy combined with conventional radiotherapy may prolong survival. (Standard) (AUA, 2007)

Men with prostate cancer that is clinical stage T3a, Gleason score 8 to 10, or PSA level greater than 20 ng/mL are categorized by the panel as high risk. Patients with multiple adverse factors may be shifted to the very high-risk category. [See detailed risk strata below]. The preferred treatment is EBRT [external beam radiation therapy] in conjunction with 2 to 3 years of neoadjuvant/concurrent/adjuvant ADT [androgen deprivation therapy] (category 1); ADT alone is insufficient. In particular, patients with low-volume, high-grade tumor warrant aggressive local radiation combined with typically 2 or 3 years of neoadjuvant/concurrent/adjuvant ADT. Fit men in the high-risk group can consider 6 cycles of docetaxel without prednisone after EBRT is completed and while continuing ADT. The combination of EBRT and brachytherapy with or without neoadjuvant/concurrent/adjuvant ADT, is another primary treatment option. However, the optimal duration of ADT in this setting remains unclear. (Category 1) (NCCN, 2016)

Patients at very high risk (locally advanced) are defined by the NCCN Guidelines as men with clinical stages T3b to T4, primary Gleason pattern 5, or more than 4 biopsy cores with Gleason score 8 to 10. The options for this group include: 1) EBRT and long-term ADT (category 1); 2) EBRT plus brachytherapy with or without long-term ADT; 3) EBRT plus ADT and docetaxel; 4) radical prostatectomy plus PLND in selected patients with no fixation to adjunct organs; or 5) ADT for patients not eligible for definitive therapy. (Category 1) (NCCN, 2016).

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