

Quality ID #104 (NQF 0390): Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer – National Quality Strategy Domain: Effective Clinical Care

2018 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 androgen deprivation therapy in combination with external beam radiotherapy to the prostate

INSTRUCTIONS:

This measure is to be submitted **once per episode** of radiation therapy for all male patients with prostate cancer who receive external beam radiotherapy to the prostate during the performance period. Each episode of radiation therapy in an eligible patient receiving external beam radiotherapy to the prostate occurring during the performance 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 Submission:

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 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/Gleason grade group 1; 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/Gleason grade group 1; AND clinical stage T1 to T2a.

Intermediate Risk – PSA 10 to 20 ng/mL; OR Gleason score 7/Gleason grade group 2-3; 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/Gleason grade group 4-5; 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/Gleason grade group 4-5. (NCCN, 2017)

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 performance 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 androgen deprivation therapy in combination with external beam radiotherapy to the prostate

NUMERATOR NOTE: *Denominator Exception(s) are determined on the date of the denominator eligible encounter.*

Definition:

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

Numerator Options:

Performance Met:

Androgen deprivation therapy prescribed/administered in combination with external beam radiotherapy to the prostate (**G9894**)

OR

Denominator Exception:

Documentation of medical reason(s) for not prescribing/administering androgen deprivation therapy in combination with external beam radiotherapy to the prostate (eg, salvage therapy) (**G9895**)

OR

Denominator Exception:

Documentation of patient reason(s) for not prescribing/administering androgen deprivation therapy in combination with external beam radiotherapy to the prostate (**G9896**)

OR

Performance Not Met:

Patients who were not prescribed/administered androgen deprivation therapy in combination with external beam radiotherapy to the prostate, reason not given (**G9897**)

RATIONALE:

The use of androgen deprivation therapy in combination with 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 androgen deprivation therapy in combination with 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 androgen deprivation 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 androgen deprivation 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 androgen deprivation 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/Gleason grade group 4-5, 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, 2017)

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/Gleason grade group 4-5. 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) radical prostatectomy plus PLND in younger, healthier patients with no tumor fixation to the pelvic side wall; or 4) ADT or observation for patients not candidates for definitive therapy. (Category 1) (NCCN, 2017)

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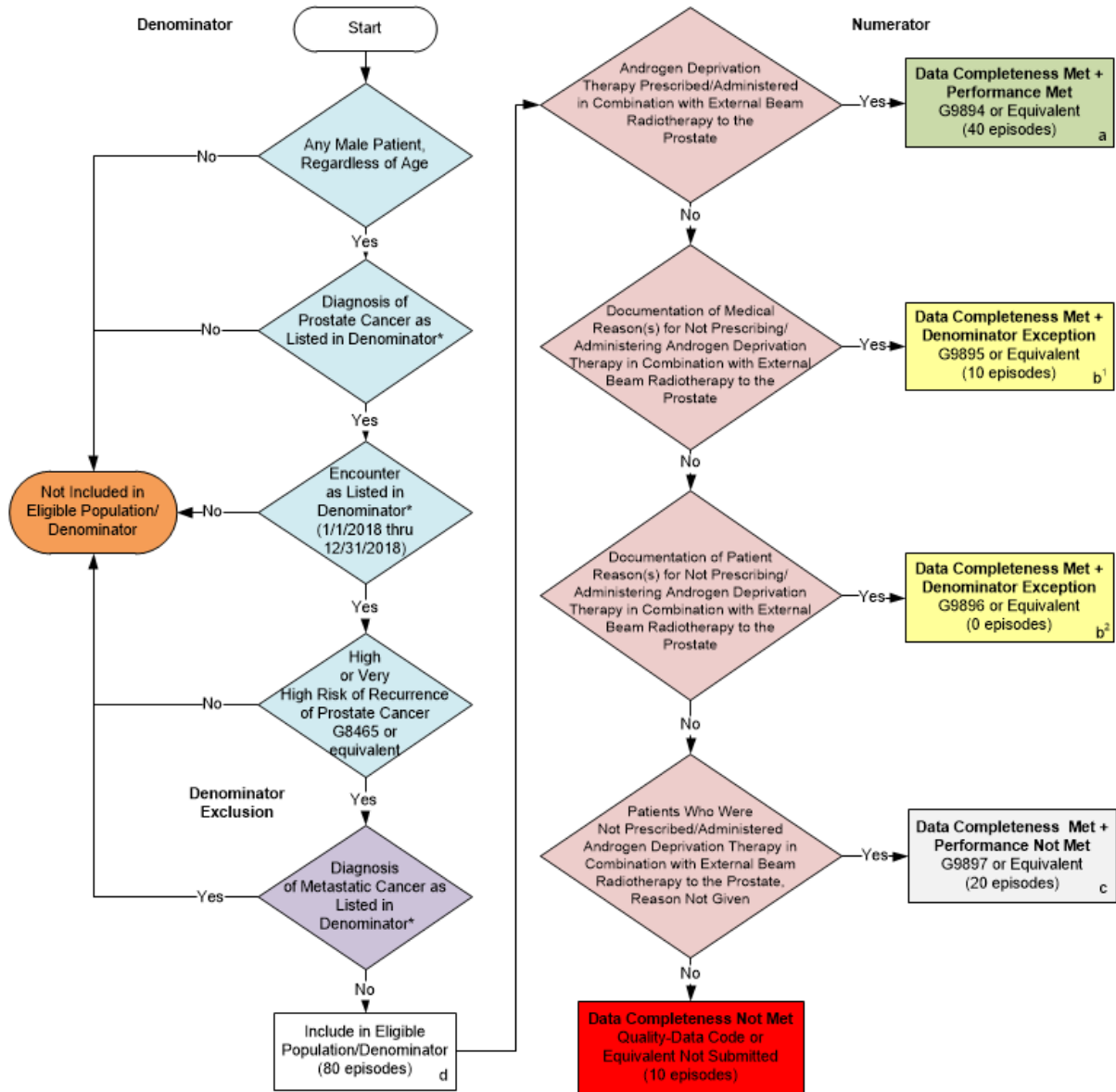
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2018 Registry Flow for Quality ID #104 NQF #0390: Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer



SAMPLE CALCULATIONS:

Data Completeness =
 Performance Met (a=40 episodes) + Denominator Exception (b¹+b²=10 episodes) + Performance Not Met (c=20 episodes) = 70 episodes = 87.50%
 Eligible Population / Denominator (d=80 episodes) = 80 episodes

Performance Rate=

$$\frac{\text{Performance Met (a=40 episodes)}}{\text{Data Completeness Numerator (70 episodes) - Denominator Exception (b¹+b²=10 episodes)}} = \frac{40 \text{ episodes}}{60 \text{ episodes}} = 66.67\%$$

*See the posted Measure Specification for specific coding and instructions to submit this measure.

NOTE: Submission Frequency: Episode

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 The measure diagrams were developed by CMS as a supplemental resource to be used in conjunction with the measure specifications. They should not be used alone or as a substitution for the measure specification.

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**2018 Registry Flow for Quality ID #104 (NQF #0390): Prostate Cancer:
Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer**

Please refer to the specific section of the specification to identify the denominator and numerator information for use in submitting this Individual Specification. This flow is for registry data submission.

1. Start with Denominator
2. Check Patient Gender:
 - a. If Male Gender equals No, do not include in Eligible Patient Population. Stop Processing.
 - b. If Male Gender equals Yes, proceed to check Patient Diagnosis.
3. Check Patient Diagnosis:
 - a. If Diagnosis of Prostate Cancer as Listed in Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
 - b. If Diagnosis of Prostate Cancer as Listed in the Denominator equals Yes, proceed to check Encounter Performed.
4. Check Encounter Performed:
 - a. If Encounter as Listed in the Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
 - b. If Encounter as Listed in the Denominator equals Yes, proceed to check High or Very High Risk of Recurrence, Prostate Cancer.
5. Check High or Very High Risk of Recurrence of Prostate Cancer:
 - a. If High or Very High Risk of Recurrence of Prostate Cancer equals No, do not include in Eligible Patient Population. Stop Processing.
 - b. If High or Very High Risk of Recurrence of Prostate Cancer equals Yes, proceed check Patient Diagnosis.
6. Check Patient Diagnosis:
 - a. If Diagnosis of Metastatic Cancer as Listed in Denominator equals Yes, do not include in Eligible Patient Population. Stop Processing.
 - b. If Diagnosis of Metastatic Cancer as Listed in the Denominator equals No, include in the Eligible Population.
7. Denominator Population:
 - a. Denominator Population is all Eligible Patients in the Denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d equals 80 episodes in the Sample Calculation.
8. Start Numerator

9. Check Androgen Deprivation Therapy Prescribed/Administered in Combination with External Beam Radiotherapy to the Prostate:
 - a. If Androgen Deprivation Therapy Prescribed/Administered in Combination with External Beam Radiotherapy to the Prostate equals Yes, include in Data Completeness Met and Performance Met.
 - b. Data Completeness Met and Performance Met letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a equals 40 episodes in the Sample Calculation.
 - c. If Androgen Deprivation Therapy Prescribed/Administered in Combination with External Beam Radiotherapy to the Prostate equals No, proceed to Documentation of Medical Reason(s) for Not Prescribing/Administering Androgen Deprivation Therapy in Combination with External Beam Radiotherapy to the Prostate.
10. Check Documentation of Medical Reason(s) for Not Prescribing/Administering Androgen Deprivation Therapy in Combination with External Beam Radiotherapy to the Prostate
 - a. If Documentation of Medical Reason(s) for Not Prescribing/Administering Androgen Deprivation Therapy in Combination with External Beam Radiotherapy to the Prostate equals Yes, include in Data Completeness Met and Denominator Exception.
 - b. Data Completeness Met and Denominator Exception is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter b¹ equals 10 episodes in the Sample Calculation.
 - c. If Documentation of Medical Reason(s) for Not Prescribing/Administering Androgen Deprivation Therapy in Combination with External Beam Radiotherapy to the Prostate equals No, proceed to Documentation of Patient Reason(s) for Not Prescribing/Administering Androgen Deprivation Therapy in Combination with External Beam Radiotherapy to the Prostate.
11. Check Documentation of Patient Reason(s) for Not Prescribing/Administering Androgen Deprivation Therapy in Combination with External Beam Radiotherapy to the Prostate:
 - a. If Documentation of Patient Reason(s) for Not Prescribing/Administering Androgen Deprivation Therapy in Combination with External Beam Radiotherapy to the Prostate equals Yes, include in the Data Completeness Met and Denominator Exception.
 - b. Data Completeness Met and Denominator Exception letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter b² equals 0 episodes in the Sample Calculation.
 - c. If Documentation of Patient Reason(s) for Not Prescribing/Administering Androgen Deprivation Therapy in Combination with External Beam Radiotherapy to the Prostate equals No, proceed to Patients Who Were Not Prescribed/Administered Androgen Deprivation Therapy in Combination with External Beam Radiotherapy to the Prostate, Reason Not Given.
12. Check Patients Who Were Not Prescribed/Administered Androgen Deprivation Therapy in Combination with External Beam Radiotherapy to the Prostate, Reason Not Given:
 - a. If Patients Who Were Not Prescribed/Administered Androgen Deprivation Therapy in Combination with External Beam Radiotherapy to the Prostate, Reason Not Given equals Yes, include in the Data Completeness Met and Performance Not Met.

- b. Data Completeness Met and Performance Not Met letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c equals 20 episodes in the Sample Calculation.
 - c. If Patients Who Were Not Prescribed/Administered Androgen Deprivation Therapy in Combination with External Beam Radiotherapy to the Prostate, Reason Not Given equals No, proceed to Data Completeness Not Met.
13. Check Data Completeness Not Met:
- a. If Data Completeness Not Met equals No, Quality Data Code or equivalent not submitted. 10 episodes have been subtracted from the Data Completeness Numerator in the Sample Calculation.

SAMPLE CALCULATIONS:

Data Completeness =

$$\frac{\text{Performance Met (a=40 episodes)} + \text{Denominator Exception (b}^1\text{+b}^2\text{=10 episodes)} + \text{Performance Not Met (c=20 episodes)}}{\text{Eligible Population / Denominator (d=80 episodes)}} = \frac{70 \text{ episodes}}{80 \text{ episodes}} = 87.50\%$$

Performance Rate=

$$\frac{\text{Performance Met (a=40 episodes)}}{\text{Data Completeness Numerator (70 episodes) - Denominator Exception (b}^1\text{+b}^2\text{=10 episodes)}} = \frac{40 \text{ episodes}}{60 \text{ episodes}} = 66.67\%$$