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 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 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 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 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, Caroll, 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 our 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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2017 Registry Individual Measure Flow
#104 NQF #0390: Prostate Cancer: Adjuvant Hormonal Therapy for High Risk or Very High Risk Prostate Cancer

Start

Denominator

Any Male Patient, Regardless of Age

Yes

Diagnosis of Prostate Cancer as Listed in Denominator*

Yes

Encounter as Listed in Denominator* (1/1/2017 thru 12/31/2017)

Yes

High or Very High Risk of Recurrence of Prostate Cancer 79465 or equivalent

No

Denominator Exclusion

Yes

Include in Eligible Population/Denominator (8 episodes) d

No

Numerator

Adjuvant Hormonal Therapy Prescribed/Administered

Data Completeness Met + Performance Met 4164F or equivalent (4 episodes) a

No

Documentation of Medical Reason(s) for Not Prescribing/Administering Adjuvant Hormonal Therapy

Yes

Data Completeness Met + Denominator Exception 4164F-1P or equivalent (1 episode) b¹

No

Documentation of Patient Reason(s) for Not Prescribing/Administering Adjuvant Hormonal Therapy

Yes

Data Completeness Met + Denominator Exception 4164F-2P or equivalent (0 episodes) b²

No

Patients Who Were Not Prescribed/ Administered Adjuvant Hormonal Therapy, Reason Not Specified

Yes

Data Completeness Met + Performance Not Met 4164F-8P or equivalent (2 episodes) c

No

Diagnosis of Metastatic Cancer as Listed in Denominator*

Include in Eligible Population/Denominator (8 episodes) d

SAMPLE CALCULATIONS:

Data Completeness =
Performance Met (a=4 episodes) + Denominator Exception (b¹+b²=1 episode) + Performance Not Met (c=2 episodes) = 7 episodes = 87.50%

Eligible Population / Denominator (d=8 episodes) = 8 episodes

Performance Rate=

Data Completeness Numerator (7 episodes) / Denominator Exception (b¹+b²=1 episode) = 4 episodes = 66.67%

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

NOTE: Reporting 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.
2017 Registry Individual Measure Flow
#104 NQF #0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

Please refer to the specific section of the Measure Specification to identify the denominator and numerator information for use in reporting this Individual Measure.

1. Start with Denominator

2. Check Patients 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, 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, check Patient Diagnosis.

6. Check Patient Diagnosis:
   a. If a 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 8 episodes in the sample calculation.

8. Start Numerator
9. Check Adjuvant Hormonal Therapy Prescribed/Administered:
   a. If Adjuvant Hormonal Therapy Prescribed/Administered 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 4 episodes in Sample Calculation.
   c. If Adjuvant Hormonal Therapy Prescribed/Administered equals No, proceed to Documentation of Medical Reason(s) for Not Prescribing/Administering Adjuvant Hormonal Therapy.

10. Check Documentation of Medical Reason(s) for Not Prescribing/Administering Adjuvant Hormonal Therapy:
    a. If Documentation of Medical Reason(s) for Not Prescribing/Administering Adjuvant Hormonal Therapy 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 1 episode in the Sample Calculation.
    c. If Documentation of Medical Reason(s) for Not Prescribing/Administering Adjuvant Hormonal Therapy equals No, proceed to Documentation of Patient Reason(s) for Not Prescribing/Administering Adjuvant Hormonal Therapy.

11. Check Documentation of Patient Reason(s) for Not Prescribing/Administering Adjuvant Hormonal Therapy:
    a. If Documentation of Patient Reason(s) for Not Prescribing/Administering Adjuvant Hormonal Therapy 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 Adjuvant Hormonal Therapy equals No, proceed to Patients Who Were Not Prescribed/Administered Adjuvant Hormonal Therapy, Reason Not Otherwise Specified.

12. Check Patients Who Were Not Prescribed/Administered Adjuvant Hormonal Therapy, Reason Not Specified:
    a. If Patients Who Were Not Prescribed/Administered Adjuvant Hormonal Therapy, Reason Not Specified 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 2 episodes in the Sample Calculation.
    c. If Patients Who Were Not Prescribed/Administered Adjuvant Hormonal Therapy, Reason Not Specified 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 reported. 1 episode has been subtracted from the data completeness numerator in the sample calculation.
## SAMPLE CALCULATIONS:

<table>
<thead>
<tr>
<th></th>
<th>Calculation</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Completeness</td>
<td>Performance Met ( (a=4 \text{ episodes}) ) + Denominator Exception ( b^2+c=1 \text{ episode} ) + Performance Not Met ( (c=2 \text{ episodes}) )</td>
<td>87.50%</td>
</tr>
<tr>
<td></td>
<td>Eligible Population / Denominator ( (d=8 \text{ episodes}) )</td>
<td>6 episodes</td>
</tr>
<tr>
<td>Performance Rate</td>
<td>( \frac{\text{Performance Met} \ (a=4 \text{ episodes})}{\text{Data Completeness Numerator} \ (7 \text{ episodes}) - \text{Denominator Exception} \ (b^2+c=1 \text{ episode})} )</td>
<td>66.67%</td>
</tr>
</tbody>
</table>

\( a \): Performance Met

\( b \): Denominator Exception

\( c \): Performance Not Met

\( d \): Eligible Population/Denominator