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
– Meaningful Measure Area: Management of Chronic Conditions

2021 COLLECTION TYPE:
MIPS CLINICAL QUALITY MEASURES (CQMS)

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 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 Merit-based Incentive Payment System (MIPS) eligible clinicians who perform external beam radiotherapy to the prostate will submit this measure.

Measure Submission Type:
Measure data may be submitted by individual MIPS eligible clinicians, groups, or third party intermediaries. The listed denominator criteria are used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions as allowed by the measure. The quality-data codes listed do not need to be submitted by MIPS eligible clinicians, groups, or third party intermediaries that utilize this modality for submissions; however, these codes may be submitted for those third party intermediaries that utilize Medicare Part B claims data. For more information regarding Application Programming Interface (API), please refer to the Quality Payment Program (QPP) website.

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 to 20 ng/mL; OR Gleason score 7/Gleason grade group 2-3; OR clinical stage T2b to T2c.
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
- Diagnosis for prostate cancer (ICD-10-CM): C61
- Patient encounter during the performance period (CPT): 77427, 77435
- High or very high risk of recurrence of prostate cancer: G8465

**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

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

**Numerator Options:**
- **Performance Met:** Androgen deprivation therapy prescribed/administered in combination with external beam radiotherapy to the prostate (G9894)
- **Denominator Exception:** Documentation of medical reason(s) for not prescribing/administering androgen deprivation therapy in combination with external beam radiotherapy to the prostate (e.g., salvage therapy) (G9895)
- **Denominator Exception:** Documentation of patient reason(s) for not prescribing/administering androgen deprivation therapy in combination with external beam radiotherapy to the prostate (G9896)
- **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, Caroll, 2010). This suggests greater outreach and education are needed to improve outcomes in care.

CLINICAL RECOMMENDATION STATEMENTS:
Clinicians should recommend radical prostatectomy or radiotherapy plus androgen deprivation therapy as standard treatment options for patients with high-risk localized prostate cancer. (Strong Recommendation; Evidence Level: Grade A) (AUA/ASTRO/SUO, 2017)

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 above]. 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. (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. (NCCN, 2017)

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2021 Clinical Quality Measure Flow for Quality ID #104 (NQF 0390):
Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer

Disclaimer: Refer to the measure specification for specific coding and instructions to submit this measure.

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%

Performance Rate = Performance Met (a=40 episodes) = 40 episodes = 66.67%

Data Completeness Numerator (70 episodes) – Denominator Exception (b₁+b₂=10 episodes) = 60 episodes

*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.
2021 Clinical Quality Measure Flow Narrative for Quality ID #104 (NQF 0390):
Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer

Disclaimer: Refer to the measure specification for specific coding and instructions to submit this measure.

1. Start with Denominator

2. Check Any male patient, regardless of age:
   a. If Any male patient, regardless of age equals No, do not include in Eligible Population/Denominator. Stop Processing.
   b. If Any male patient, regardless of age equals Yes, proceed to check Patient diagnosis for prostate cancer as listed in Denominator.

3. Check Diagnosis for prostate cancer as listed in Denominator*:
   a. If Diagnosis for prostate cancer as listed in Denominator* equals No, do not include in Eligible Population/Denominator. Stop Processing.
   b. If Diagnosis for prostate cancer as listed in the Denominator* equals Yes, proceed to check Patient encounter during the performance period as listed in the Denominator.

4. Check Patient encounter during the performance period as listed in the Denominator*:
   a. If Patient encounter during the performance period as listed in the Denominator* equals No, do not include in Eligible Population/Denominator. Stop Processing.
   b. If Patient encounter during the performance period as listed in the Denominator* equals Yes, proceed to check High or very high risk of recurrence of 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 Population/Denominator. Stop Processing.
   b. If High or very high risk of recurrence of prostate cancer equals Yes, proceed to check Diagnosis of metastatic cancer as listed in Denominator*.

6. Check Diagnosis for metastatic cancer as listed in Denominator*:
   a. If Diagnosis for metastatic cancer as listed in Denominator* equals Yes, do not include in Eligible Population/Denominator. Stop Processing.
   b. If Diagnosis for metastatic cancer as listed in Denominator* equals No, include in the Eligible Population.

7. Denominator Population:
   • 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
a. Check Androgen deprivation therapy prescribed/administered in combination with external beam radiotherapy to the prostate:

b. 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.
   - 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 check Documentation of medical reason(s) for not prescribing/administering androgen deprivation therapy in combination with external beam radiotherapy to the prostate.

9. 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 Performance Met.
      - Data Completeness Met and Performance Met is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter b^1 equals 10 episodes in the Sample Calculation.

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

10. 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 Data Completeness Met and Denominator Exception.
       - 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 b^2 equals 0 episodes in the Sample Calculation.

    b. 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 check Patients who were not prescribed/administered androgen deprivation therapy in combination with external beam radiotherapy to the prostate, reason not given.

11. 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.
       - Data Completeness Met and Performance Not Met letter is represented in the Data Complete...
Completeness in the Sample Calculation listed at the end of this document. Letter c equals 20 episodes in the Sample Calculation.

b. 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 check Data Completeness Not Met.

12. Check Data Completeness Not Met:

a. If Data Completeness Not Met, the Quality Data Code or equivalent was not submitted. 10 episodes have been subtracted from the Data Completeness Numerator in the Sample Calculation.

**Sample Calculations**

Data Completeness equals Performance Met (a equals 40 episodes) plus Denominator Exception (b^1 plus b^2 equals 10 episodes) plus Performance Not Met (c equals 20 episodes) divided by Eligible Population / Denominator (d equals 80 episodes). All equals 70 episodes divided by 80 episodes. All equals 87.50 percent.

Performance Rate equals Performance Met (a equals 40 episodes) divided by Data Completeness Numerator (70 Episodes) minus Denominator Exception (b^1 plus b^2 plus b^3 equals 10 episodes). All equals 40 episodes divided by 60 episodes. All equals 66.67 percent.

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

NOTE: Submission Frequency: Episode

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