Cancer, Spring 2018 Cycle: CDP Report

FINAL REPORT

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NATIONAL QUALITY FORUM

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Executive Summary

Cancer is the second most common cause of death in the U.S., exceeded only by heart disease.¹ The National Cancer Institute estimates that in 2018, an estimated 1.7 million new cases of cancer will be diagnosed in the United States, and over 600,000 people will die from the disease.² Furthermore, nearly half of all men and one-third of all women in the U.S. will develop cancer during their lifetime.³ In addition, diagnosis and treatment of cancer has great economic impact on patients, their families, and society. The National Cancer Institute estimated that in 2010 the costs for cancer care in the U.S. totaled nearly \$157 billion and could reach \$174 billion in 2020.⁴

The National Quality Forum's (NQF) portfolio of measures for cancer includes measures addressing cancer screening and appropriate treatment (including surgery, chemotherapy, and radiation therapy).

For this project, the Standing Committee evaluated one newly submitted measure against NQF's standard evaluation criteria. Measure #3365e *Treatment of Osteopenia or Osteoporosis in Men with Non-Metastatic Prostate Cancer on Androgen Deprivation Therapy*. Following evaluation and discussion of the measure, particularly concerns raised about the measure specifications, the measure developer withdrew the measure from consideration and agreed to clarify the measure specifications. The measure developer intends to resubmit the measure for consideration by the Cancer Committee in a future measure evaluation cycle.

A brief summary of the measure under review is included in the body of the report; a detailed summary of the Committee's discussion and ratings of the criteria for each measure are in <u>Appendix A</u>.

Introduction

Cancer is the second most common cause of death in the U.S., exceeded only by heart disease.⁵ The National Cancer Institute estimates that in 2018, an estimated 1.7 million new cases of cancer will be diagnosed in the United States, and over 600,000 people will die from the disease.⁶ Furthermore, nearly half of all men and one-third of all women in the U.S. will develop cancer during their lifetime.⁷ In addition, diagnosis and treatment of cancer has great economic impact on patients, their families, and society. The National Cancer Institute estimated that in 2010 the costs for cancer care in the U.S. totaled nearly \$157 billion and could reach \$174 billion in 2020.⁸

Cancer care is complex and provided in multiple settings—hospitals, outpatient clinics, ambulatory infusion centers, radiation oncology treatment centers, radiology departments, palliative and hospice care facilities—and by multiple providers including surgeons, oncologists, nurses, pain management specialists, and social workers. Due to the complexity of cancer, as well as the numerous care settings and providers, there is a need for quality measures that address the value and efficiency of care for patients and their families.

NQF Portfolio of Performance Measures for Cancer Conditions

The Cancer Standing Committee (see <u>Appendix C</u>) oversees NQF's portfolio of cancer measures that includes measures for breast cancer, colon cancer, hematology, prostate cancer, and other general cancer measures (see <u>Appendix B</u>). This portfolio contains 26 process/structure measures (see table below).

	Process/Structure	Outcome	Composite
Breast Cancer	11	0	0
Colon Cancer	6	0	0
Hematology	2	0	0
Lung/Thoracic Cancer	1	0	0
Prostate Cancer	3	0	0
General Cancer	3	0	0
Measures			
Total	26	0	0

Table 1. NQF Cancer Portfolio of Measures

Additional measures related to cancer care are assigned to the **Geriatrics** and Palliative Care, Surgery, and the **Prevention** and Population Health projects. The additional measures include several appropriateness of care measures, cancer screening, screening for pain, pain related to chemotherapy or radiation therapy, **and surgery measures**.

Cancer Measure Evaluation

On July 13, 2018 the Cancer Standing Committee evaluated one new measure against <u>NQF's standard</u> evaluation criteria.

Table 2. Spring 2018 Cancer Measure Evaluation Summary

	New
Measures under consideration	1
Measure recommendation deferred	0
Measures withdrawn from consideration	1

Comments Received Prior to Committee Evaluation

NQF solicits comments on endorsed measures on an ongoing basis through the <u>Quality Positioning</u> <u>System (QPS)</u>. In addition, NQF solicits comments for a continuous 16-week period during each evaluation cycle via an online tool located on the project webpage. For this evaluation cycle, the commenting period opened on May 8, 2018. No comments were submitted prior to the measure evaluation meeting. The commenting period was closed following the withdrawal of the measure under review.

Summary of Measure Evaluation

The following brief summary of the measure evaluation highlights the major issues that the Committee considered. Details of the Committee's discussion and ratings of the criteria for the measure are included in <u>Appendix A</u>.

3365e Treatment of Osteopenia or Osteoporosis in Men with Non-Metastatic Prostate Cancer on Androgen Deprivation Therapy (Large Urology Group Practice Association [LUGPA]): Withdrawn from Consideration

Description: Men with non-metastatic prostate cancer and current or recent use of androgen deprivation therapy (ADT) and who also have a diagnosis of osteopenia or osteoporosis. The patient has been prescribed or is taking a bisphosphonate or denosumab. The patient is taking Calcium and Vitamin D supplementation, after an initial Calcium and Vitamin D level measurement. The measure scoring is proportion. The measure focuses on this population because androgen suppression, as a treatment for prostate cancer, can cause osteoporosis. It increases bone turnover, decreases bone mineral density, and increases the risk of bone fractures in men with prostate cancer. Denosumab reduces the risk of vertebral fractures in men with prostate cancer treated with androgen deprivation therapy. Bisphosphonates increase bone mineral density, a surrogate for fracture risk, during ADT. The Endocrine Society recommends that men at high risk of fracture be treated with medication approved by regulatory agencies; at this time, alendronate, risedronate, zoledronic acid, teriparatide and denosumab for men receiving ADT for prostate cancer. **Measure Type**: Process; **Level of Analysis**: Clinician: Group/Practice, Clinician: Individual; **Setting of Care**: Outpatient Services; **Data Source**: Electronic Health Records

Men treated with androgen deprivation therapy (ADT) for non-metastatic prostate cancer are at increased risk of osteopenia or osteoporosis. Androgen suppression increases bone turnover, decreases bone mineral density, and increases the risk of bone fractures. The Endocrine Society and International Osteoporosis Foundation Practice Guidelines recommend that men at high risk of bone fracture be treated with approved medications. This new clinician-level measure calculates the percentage of men

treated with ADT for non-metastatic prostate cancer and a diagnosis of osteopenia or osteoporosis who receive appropriate treatment to prevent and/or reverse bone loss. The Committee agreed that based on the performance data provided by the developer, a gap in care exists in the treatment of osteopenia or osteoporosis in men receiving ADT for non-metastatic prostate cancer. The Committee had a lengthy discussion about the precision of the measure specifications. The measure developer withdrew the measure from the Spring 2018 cycle and indicated it intends to clarify the specifications and resubmit the measure for consideration by the Cancer Committee during the fall 2018 measure evaluation cycle.

Measures Withdrawn from Consideration

Four measures previously endorsed by NQF have not been re-submitted for maintenance of endorsement. Endorsement for these measures will be removed. In addition, the only measure under review during this endorsement evaluation cycle was withdrawn.

Table 3. Measures	Withdrawn from	Consideration
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Measure	Reason for withdrawal
3365e Treatment of osteopenia or osteoporosis in men with non-metastatic prostate cancer on androgen deprivation therapy (Large Urology Group Practice Association [LUGPA])	The measure was withdrawn from the measure evaluation process by the developer following the Standing Committee's discussion of the precision of measure specifications.
0379 Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry	Developer chose to withdraw the measure
0380 Hematology: Multiple Myeloma: Treatment with Bisphosphonates	Developer chose to withdraw the measure
0381 Oncology: Treatment Summary Communication – Radiation Oncology	Developer chose to withdraw the measure
0382 Oncology: Radiation Dose Limits to Normal Tissues	Developer chose to withdraw the measure
1822 External Beam Radiotherapy for Bone Metastases	Developer chose to withdraw the measure

References

¹ American Cancer Society. Economic Impact of cancer website. <u>http://www.cancer.org/cancer/cancerbasics/economic-impact-of-cancer</u>. Last accessed August 2018.

² National Cancer Institute. Cancer statistics website. <u>https://www.cancer.gov/about-cancer/understanding/statistics</u>. Last accessed June 2018.

³ American Cancer Society. *Cancer Facts & Figures 2016*. Atlanta: National Cancer Society; 2016. <u>http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2016/index</u>. Last accessed August 2018.

⁴ National Cancer Institute. Cancer prevalence and cost of care projections website. <u>https://costprojections.cancer.gov/</u>. Last accessed August 2018.

⁵ American Cancer Society. Economic impact of cancer. <u>http://www.cancer.org/cancer/cancerbasics/economic-impact-of-cancer</u>. Last accessed August 2018.

⁶ National Cancer Institute. Cancer statistics website. <u>https://www.cancer.gov/about-cancer/understanding/statistics</u>. Last accessed June 2018.

⁷ American Cancer Society. *Cancer Facts & Figures 2016.* Atlanta: American Cancer Society; 2016. <u>http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2016/index</u>. Last accessed August 2018.

⁸ National Cancer Institute. Cancer Prevalence and cost of care projections website. <u>https://costprojections.cancer.gov/</u>. Last accessed August 2018.

Appendix A: Details of Measure Evaluation

Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

Measures Withdrawn from Consideration

3365e Treatment of Osteopenia or Osteoporosis in Men with Non-Metastatic Prostate Cancer on Androgen Deprivation Therapy

Submission

Description: Men with non-metastatic prostate cancer and current or recent use of androgen deprivation therapy (ADT) and who also have a diagnosis of osteopenia or osteoporosis. The patient has been prescribed or is taking a bisphosphonate or denosumab. The patient is taking Calcium and Vitamin D supplementation, after an initial Calcium and Vitamin D level measurement. The measure scoring is proportion.

Numerator Statement: Patients with an order for or taking bisphosphonates or denosumab and who had a Vitamin D and Calcium level completed prior to the start of treatment. Patients are also taking Calcium and Vitamin D.

Denominator Statement: The denominator equals the initial population. That is, male patients with a diagnosis of prostate cancer and osteoporosis or osteopenia. Patients with prior and/or current androgen deprivation therapy with an office visit during the measurement period. This is also the initial population. There is no age cut off for this measure as prostate cancer can affect younger men, although it is a disease that normally occurs after the age of 40. According to the NCCN Prostate Cancer Early Detection guidelines, a cut off at 40 could miss those unfortunate patients who developed the disease in their late 20's and 30's. At the upper end, very healthy men over age 75 may choose to seek more aggressive treatment. Cancer genetics show an increased risk if the patient is a BRCA1/2 pathogenic mutation carrier which can lead to earlier detection of prostate cancers (and other cancers as well). When a family member is diagnosed with prostate cancer, another first degree relative is recommended to be screened at age 40 or 10 years prior to the age of the relative when prostate cancer was discovered, whichever is soonest.

Exclusions: Denominator Exclusions are prostate cancer with secondary metastasis to the bone and patients on comfort measures such as hospice and end of life care. The NQF document does not include a Denominator Exception, but there is one exception which is listed in the MAT - Patient refusal of the recommendation for bisphosphonates or denosumab after the start of ADT therapy and known osteoporosis diagnosis.

Adjustment/Stratification:

Level of Analysis: Clinician : Group/Practice, Clinician : Individual

Setting of Care: Outpatient Services

Type of Measure: Process

Data Source: Electronic Health Records

Measure Steward: Large Urology Group Practice Association (LUGPA)

STANDING COMMITTEE MEETING [07/13/2018]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: H-0; M-13; L-0; I-1; 1b. Performance Gap: H-6; M-7; L-1; I-0;

Rationale:

- The developer cites the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology Prostate Cancer version 2.2017. MS-27, MS-28 as evidence to support the measure. (Level of Evidence: Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.)
- The NCCN Guidelines Panel recommends screening and treatment for osteoporosis according to guidelines for the general population from the National Osteoporosis Foundation:
 - supplemental calcium (1200 mg daily) and vitamin D3 (800-1000 IU daily) for all men older than age 50 years; and
 - additional treatment for men when the 10-year probability of hip fracture is >=3% or the 10-year probability of a major osteoporosis-related fracture is >=20%. Fracture risk can be assessed using the algorithm FRAX [®], recently released by WHO. ADT should be considered "secondary osteoporosis" using the FRAX [®] algorithm. Treatment with Denosumab (60mg every 6 months), zoledronic acid (5mg IV annually, or alendronate (70mgPO weekly) is recommended when the absolute fracture risk warrants drug therapy. A baseline dual-energy x-ray absorptiometry (DEXA) scan before start of therapy and a follow-up DEXA scan after one year of therapy is recommended by the International Society of Clinical Densitometry to monitor response.
- The committee noted that there was ample evidence that androgen deprivation therapy (ADT) contributes to loss of bone density, which in turn increases risk of bone fracture. The committee also noted that the evidence underlying the NCCN guideline and citations submitted with the measure appear sufficient to support the measure and link to preferred patient outcomes, i.e. a relationship between initiation of osteoporosis/osteopenia treatment and the bone health of patients with prostate cancer undergoing ADT.
- The committee noted that urologists typically treat early stage prostate cancer patients, who may be less familiar with giving chronic therapies to their early stage patients than physicians who have more experience providing long term care treatment to patients who present at a general oncology office
- The Committee agreed that the measure meets the Evidence criterion.
- The developer provided data from a literature review as indication of an opportunity for improvement on the treatment of osteopenia or osteoporosis in men with non-metastatic prostate cancer on ADT.
- The data from the literature demonstrated that men on ADT have between a 9-53% risk of osteoporosis and that testing and/or treatment of osteoporosis/osteopenia ranges from 9-59%. On average, less than 25% of the patients received appropriate care. The committee noted that the provided figures suggest a high incidence of patients not receiving recommended care and a high incidence of poor performance.
- The developer also presented an analysis of two large databases (one urology group, LUGPA, and the other a radiation oncology group). Group 1 demonstrated an average performance rate of 47.91% with a range from 0-87% among 11 clinicians. Group 2 had only one clinician reviewed with 0% compliance.

- The committee questioned if there was more evidence that untreated osteoporosis/osteopenia prostate cancer patients on ADT is a widespread issue across urology practices in the United States.
- The Committee noted that ordering DEXA scans is not a normal practice within urology practices because urologists are treating early stage prostate cancer and are administering ADT, but they do not typically treat osteoporosis/osteopenia. The committee noted the importance of this measure, especially when paired with an osteopenia/osteoporosis screening measure.
- The committee acknowledged that unless there is a mandated consult to medical oncology--as there might be in large teaching hospital-- it is unlikely that most patients will receive appropriate care (i.e. treatment with bisphosphonates or denosumab) when treated in the community or in local urology practices. This is indicative of a large gap in performance.

2. Scientific Acceptability of Measure Properties: Vote Deferred; Measure Withdrawn

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity) Rationale:

- The Committee had a lengthy discussion about the measure specifications, including asking the measure developer to provide multiple clarifications throughout the discussion. The Committee's concerns included the complexity of the measure description, numerator, and denominator as written in the measure submission form.
- The Committee voiced their support for the measure; however, and was overwhelming
 reluctant to vote on scientific acceptability due to the confusion about the measure
 specifications. The Committee asked the measure developer to revise the measure
 specifications so they are precise and unambiguous and providers can consistently implement
 the measure.
- The measure developer agreed to withdraw the measure from the current cycle and revise the measure specifications as recommended. The measure developer indicated they will resubmit the revised measure for endorsement consideration in a future cycle.
- Therefore, since the developer withdrew the measure from endorsement consideration, the Committee did not vote on Scientific Acceptability, the remaining measure evaluation criteria, including overall suitability for endorsement.

3. Feasibility: N/A

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified; 3d. Data collection strategy can be implemented)

4. Usability and Use: N/A

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

5. Related and Competing Measures: N/A

Standing Committee Recommendation for Endorsement: N/A

Appendix	B: Cance	r Portfolio—Us	se in Federal Programs
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NQF #	Title	Federal Programs: Finalized or Implemented as of July 19, 2018 ^a
0389e	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	Merit-Based Incentive Payment System (MIPS) Program (Finalized)
0219	Post Breast Conservation Surgery Irradiation	N/A
0220	Adjuvant Hormonal Therapy	Hospital Compare (Implemented); Prospective Payment System-Exempt Cancer Hospital Quality Reporting (Implemented)
0223	Adjuvant Chemotherapy is Recommended or Administered Within 4 Months (120 Days) of Diagnosis to Patients Under the Age of 80 with AJCC III (Lymph Node Positive) Colon Cancer	Hospital Compare (Implemented); Prospective Payment System-Exempt Cancer Hospital Quality Reporting (Implemented)
0225	At Least 12 Regional Lymph Nodes Are Removed and Pathologically Examined for Resected Colon Cancer	N/A
0377	Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow	Medicare Physician Quality Reporting System (Implemented); Physician Feedback/Quality Resource Use Report (Implemented); Physician Value-Based Payment Modifier (Implemented); MIPS Program (Finalized)
0378	Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy	Medicare Physician Quality Reporting System (Implemented); Physician Feedback/Quality Resource Use Report (Implemented); Physician Value-Based Payment Modifier (Implemented); MIPS Program (Finalized)
0383	Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (paired with 0384)	Hospital Compare (Implemented); Medicare Physician Quality Reporting System (Implemented); Physician Feedback/Quality Resource Use Report (Implemented); Physician Value-Based Payment Modifier (Implemented); Prospective Payment System-Exempt Cancer Hospital Quality Reporting (Implemented); MIPS Program (Finalized)
0384	Oncology: Medical and Radiation - Pain Intensity Quantified	MIPS Program (Finalized)
0385	Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients	N/A

^a All measure use information reflects the information listed in the CMS Measures Inventory Tool as July 19, 2018. <u>https://cmit.cms.gov/CMIT_public/ListMeasures</u>

NQF #	Title	Federal Programs: Finalized or Implemented as of July 19, 2018 ^a
0386	Oncology: Cancer Stage Documented	N/A
0387	Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer	N/A
0389	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	MIPS Program (Finalized)
0390	Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer	Hospital Compare (Implemented); Medicare Physician Quality Reporting System (Implemented); Physician Feedback/Quality Resource Use Report (Implemented);Physician Value-Based Payment Modifier (Implemented); Prospective Payment System-Exempt Cancer Hospital Quality Reporting (Implemented); MIPS Program (Finalized)
0391	Breast Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade	Medicare Physician Quality Reporting System (Implemented); Physician Feedback/Quality Resource Use Report (Implemented); Physician Value-Based Payment Modifier (Implemented); MIPS Program (Finalized)
0392	Colorectal Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade	Medicare Physician Quality Reporting System (Implemented); Physician Feedback/Quality Resource Use Report (Implemented); Physician Value-Based Payment Modifier (Implemented); MIPS Program (Finalized)
0508	Diagnostic Imaging: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms	Medicare Physician Quality Reporting System (Implemented); Physician Feedback/Quality Resource Use Report (Implemented); Physician Value-Based Payment Modifier (Implemented); MIPS Program (Finalized)
0509	Diagnostic Imaging: Reminder System for Screening Mammograms	Medicare Physician Quality Reporting System (Implemented); Physician Feedback/Quality Resource Use Report (Implemented); Physician Value-Based Payment Modifier (Implemented); MIPS Program (Finalized)

NQF #	Title	Federal Programs: Finalized or Implemented as of July 19, 2018 ^a
0559	Combination Chemotherapy is Recommended or Administered Within 4 Months (120 Days) of Diagnosis for Women Under 70 with AJCC T1cN0M0, or Stage IB - III Hormone Receptor Negative Breast Cancer	Hospital Compare (Implemented); Prospective Payment System-Exempt Cancer Hospital Quality Reporting (Implemented)
1853	Radical Prostatectomy Pathology Reporting	Medicare Physician Quality Reporting System (Implemented); Physician Feedback/Quality Resource Use Report (Implemented); Physician Value-Based Payment Modifier (Implemented); MIPS Program (Finalized)
1854	Barrett's Esophagus	Medicare Physician Quality Reporting System (Implemented); Physician Feedback/Quality Resource Use Report (Implemented; Physician Value-Based Payment Modifier (Implemented); Merit- Based Incentive Payment System (MIPS) Program (Finalized)
1855	Quantitative HER2 Evaluation by IHC Uses the System Recommended by the ASCO/CAP Guidelines	Medicare Physician Quality Reporting System (Implemented); Physician Feedback/Quality Resource Use Report (Implemented); Physician Value-Based Payment Modifier (Implemented); MIPS Program (Finalized)
1857	HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies	MIPS Program (Finalized)
1858	Trastuzumab Administered to Patients with AJCC Stage I (T1c) – III and Human Epidermal Growth Factor Receptor 2 (HER2) Positive Breast Cancer Who Receive Adjuvant Chemotherapy	MIPS Program (Finalized)
1859	KRAS Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer Who Receive Anti- Epidermal Growth Factor Receptor Monoclonal Antibody Therapy	MIPS Program (Finalized)
1860	Patients with Metastatic Colorectal Cancer and KRAS Gene Mutation Spared Treatment with Anti-Epidermal Growth Factor Receptor Monoclonal Antibodies	MIPS Program (Finalized)
1878	HER2 Testing for Overexpression or Gene Amplification in Patients with Breast Cancer	N/A
2930	Febrile Neutropenia Risk Assessment Prior to Chemotherapy	N/A

Appendix C: Cancer Standing Committee and NQF Staff

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