Cancer 2015-2017

Technical Report

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NATIONAL QUALITY FORUM

Contents

Cancer 2015-2017

TECHNICAL REPORT

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 1,685,210 new cases of cancer will be diagnosed in the United States and 595,690 people will die from the disease in 2016.[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, appropriate treatment (including surgery, chemotherapy, and radiation therapy), and morbidity and mortality.

For this project, the Cancer Standing Committee evaluated three newly submitted measures and 15 measures undergoing maintenance review against NQF's standard evaluation criteria. Thirteen measures were endorsed, two measures received inactive endorsement with reserve status, and the Committee did not endorse three measures. The Standing Committee endorsed the following 13 measures:

- 0219 Post Breast Conservation Surgery Irradiation (American College of Surgeons)
- 0220 Adjuvant Hormonal Therapy (American College of Surgeons)
- 0223 Adjuvant Chemotherapy 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 (American College of Surgeons)
- 0225 At Least 12 Regional Lymph Nodes Are Removed and Pathologically Examined for Resected Colon Cancer (American College of Surgeons)
- 0377 Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow (American Society of Hematology)
- 0378 Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy (American Society of Hematology)
- 0389 Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (AMA-PCPI)
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- 0508 Diagnostic Imaging: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms (American College of Radiology)
- 0509 Diagnostic Imaging: Reminder System for Screening Mammograms (American College of Radiology)

- 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 (American College of Surgeons)
- 2930 Febrile Neutropenia Risk Assessment Prior to Chemotherapy (RAND Corporation)
- 2963 Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients - Legacy eMeasure (AMA-PCPI)

Two measures received inactive endorsement with reserve status:

- 1878 HER2 Testing for Overexpression or Gene Amplification in Patients with Breast Cancer (American Society of Clinical Oncology)
- 1857 HER 2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies (American Society of Clinical Oncology)

The Committee did not endorse the following measures:

- 0459 Risk-Adjusted Length of Stay >14 Days after Elective Lobectomy for Lung Cancer (Society of Thoracic Surgeons)
- 0460 Risk-Adjusted Morbidity and Mortality for Esophagectomy for Cancer (Society of Thoracic Surgeons)
- 2936 Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy (Centers for Medicare & Medicaid)

Brief summaries of the measures are included in the body of the report; detailed summaries of the Committee's discussion and ratings of the criteria for each measure are in Appendix A.

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 1,685,210 new cases of cancer will be diagnosed in the United States and 595,690 people will die from the disease in 2016.[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. In 2011, it was estimated that the direct medical costs for cancer in the U.S. were $88.7 billion.[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, to name a few. 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.

Trends and Performance

The total cancer death rate rose for most of the 20th century because of the tobacco epidemic, peaking in 1991 at 215 cancer deaths per 100,000 people. However, from 1991 to 2012, the rate dropped 23 percent because of reductions in smoking, as well as improvement in early detection and treatment.[9] Death rates are declining for all four of the most common cancer types: lung, colorectal, breast, and prostate.

The American Cancer Society provides basic statistics for the most commonly diagnosed cancers[10]:

- From 2003 to 2012, breast cancer incidence rates were stable in white women and increased by 0.3 percent per year in black women. However, breast cancer death rates declined 1.9 percent per year in white women and 1.4 percent per year in black women due to improvements in early detection and treatment.
- Colorectal cancer is the third most common cancer in both men and women. Incidence rates differ by age. From 2008 to 2012, incidence rates declined by 4.5 percent per year among adults 50 years of age and older, but increased by 1.8 percent per year among those younger than age 50. Due to improvements in early detection and treatment, colorectal cancer death rates declined 2.8 percent per year from 2003 to 2012.
- Kidney cancer incidence rates increased over the past several decades, mostly due to incidental diagnoses during abdominal imaging, but stabilized from 2008-2012. Kidney cancer death rates have been decreasing by 0.7 percent per year since 1995.
- The incidence of leukemia has slowly increased over the decades with an increase of 1.3 percent per year from 2003 to 2012. Despite an increase in the incidence of leukemia, death rates have dropped 18 percent since 1980, with a steady decline of 1.0 percent per year from 2001 to 2012.
- From 2008 to 2012, the rates of liver cancer increased by 3.5 percent per year among those 50 and older, but decreased by 3.9 percent per year among adults younger than 50 years of age. Overall, death rates due to liver cancer have been increasing since 1980; from 2003 to 2012, rates increased 2.7 percent per year.

- The incidence of lung cancer has been decreasing since the mid-2000s. From 2008 to 2012, lung cancer incidence rates decreased by 3.0 percent per year in men and by 1.9 percent per year in women. Death rates have declined by 38 percent since 1990 in men and by 12 percent in women due to the drop in smoking prevalence. From 2008 to 2012, death rates decreased by 2.9 percent per year in men and 1.9 percent per year in women.
- Pancreatic cancer incidence rates increased by 1.2 percent per year from 2000 to 2012. Death rates have increased by 0.4 percent per year since 2000.
- Prostate cancer rates decreased by 4.0 percent per year from 2003 to 2012. Prostate cancer deaths have also been decreasing since the 1990s in men of all races/ethnicities, however, these deaths remain twice as high in blacks as in any other group. Overall, prostate cancer death rates decreased by 3.5 percent per year from 2003 to 2012.
- Thyroid cancer is the most rapidly increasing cancer in the U.S. partly due to increased detection because of more sensitive diagnostic procedures, likely resulting in some over diagnoses. The incidence rates increased 5.1 percent per year from 2003 to 2012; the death rates remained stable during the same timeframe.

Despite advances in early detection and treatment, disparities in cancer care among racial and ethnic minorities persist[11]:

- Non-Hispanic black men have higher overall cancer incidence (592.3 per 100,000) and death rates (267.7) than any other major racial or ethnic group, 12 percent and 27 percent higher, respectively, than non-Hispanic whites (528.9 and 210.6). Black women have 14 percent higher cancer death rates than non-Hispanic white women despite 6 percent lower incidence rates.
- Hispanics have lower rates of the cancers that are most common in the U.S. (female breast, colorectum, lung, and prostate), but among the highest rates of cancers associated with infectious agents. Compared to non-Hispanic whites, cervical cancer incidence rates are 44 percent higher, and liver and stomach cancer incidence rates are about twice as high.
- American Indian and Alaska Natives have the highest cancer incidence and death rates of any racial or ethnic population.

NQF Portfolio of Performance Measures for Cancer Conditions

The Cancer Standing Committee (see Appendix D) oversees NQF's portfolio of cancer measures that includes measures for breast cancer, colon cancer, hematology, lung and thoracic cancer, prostate cancer, and other general cancer measures (see Appendix B). This portfolio contains 34 measures: 31 process/structure measures and 3 outcome measures (see table below).

Table 1. NQF Cancer Care Portfolio of Measures

	Process/Structure	Outcome	Composite
Breast Cancer	11	0	0
Colon Cancer	6	0	0
Hematology	4	0	0
Lung/Thoracic Cancer	1	3	0
Prostate Cancer	3	0	0
General Cancer Measures	6	0	0
Total	31	3	0

Additional measures related to cancer care are assigned to the Palliative and End-of-Life Care and the Health and Well-Being projects. The additional measures include several appropriateness of care measures, cancer screening, screening for pain, and pain related to chemotherapy or radiation therapy.

National Quality Strategy

NQF-endorsed measures for cancer care support the National Quality Strategy (NQS). NQS serves as the overarching framework for guiding and aligning public and private efforts across all levels (local, state, and national) to improve the quality of healthcare in the U.S. The NQS establishes the "triple aim" of better care, affordable care, and healthy people/communities, focusing on six priorities to achieve those aims: *Safety, Person and Family Centered Care, Communication and Care Coordination, Effective Prevention and Treatment of Illness, Best Practices for Healthy Living, and Affordable Care.*

Quality measures for cancer care align with several of the NQS priorities, including:

- **Making care safer by reducing harm caused in the delivery of care.** Adherence to evidence-based practice guidelines prevent inappropriate treatments and promote effective and safe practices that improve the quality of care and patient outcomes.
- **Working with communities to promote wide use of best practices to enable healthy living.** Early detection of breast cancer with screening mammography means that treatment can be started earlier, possibly before it has spread.

Use of Measures in the Portfolio

Endorsement of measures by NQF is valued not only because the evaluation process itself is both rigorous and transparent, but also because evaluations are conducted by multistakeholder committees comprised of clinicians and other experts from the full range of healthcare providers, employers, health plans, public agencies, community coalitions, and patients—many of whom use measures on a daily basis to ensure better care. Moreover, NQF-endorsed measures undergo routine "maintenance" (i.e., re-evaluation) to ensure that they are still the best-available measures and reflect the current science. Importantly, federal law requires that preference be given to NQF-endorsed measures for use in federal public reporting and performance-based payment programs. NQF measures also are used by various stakeholders in the private sector, including hospitals, health plans, and communities.

Many of the cancer measures in the portfolio are among NQF's most long-standing measures, several of which have been endorsed since 2007. Many of the measures are in use in at least one federal program. Also, several of the cancer measures have been included in the PPS-Exempt Cancer Hospital Core Measure Set by the NQF-convened Measure Applications Partnership (MAP). See Appendix C for details of federal program use for the measures in the portfolio.

Improving NQF's Cancer Portfolio

Measurement Framework

In its early work on cancer care quality measures, NQF applied the patient-focused episode-of-care framework to cancer.[12] The episode-of-care framework evaluates efficiency across episodes of care while taking into consideration various settings and providers, and most importantly the treatment and outcome preferences of the patient (see Appendix B).

The episode-of-care framework presents several pathways by which patients diagnosed with cancer might navigate their diagnosis, treatment, and follow-up with multiple providers and settings, and includes consideration of several patient-reported outcomes.

The first phase includes prevention of and screening for cancer and occurs prior to diagnosis. Once patients are diagnosed with cancer, there are four typical pathways they may follow, depending on the type of cancer and treatment plan. Patients may move from treatment, to maintenance, and on to surveillance once they are in remission. The surveillance phase may include measures looking at late effects of treatment, continued screening, and health-related quality of life. Other patients may progress to palliative care and end-of-life phases.

The episode-of-care framework is also helpful in identifying gaps in measurement. NQF's cancer portfolio addresses some of the phases in the framework. Gaps in the portfolio include outcome measures addressing survival, health-related quality of life, symptom management, risk-adjusted total cost of care, and reintegration into society.

Improving NQF's Cancer Portfolio

Committee Input on Gaps in the Portfolio

NQF staff compiled an extensive list of gaps identified in previous projects dating back to 2008 (see Appendix H). During the post-comment call, the Committee identified areas where additional measure development is needed, including:

- Prostate and thoracic cancer measures that range from screening to advanced disease
- Oral chemotherapy compliance measures
- Outcome measures including risk-adjusted morbidity and mortality measures

During the discussion, the Committee offered potential opportunities to reconvene and continue discussing gaps, refine the cancer framework, and provide feedback to measure developers as they develop new measures, including ad-hoc reviews and off-cycle quarterly webinars.

Cancer Care Measure Evaluation

On May 18-19, 2016, the Cancer Standing Committee evaluated three new measures and 15 measures undergoing maintenance review against NQF's standard evaluation criteria. To facilitate the evaluation, the Committee divided the candidate standards among four workgroups for preliminary review of the measures against the evaluation subcriteria prior to consideration by the entire Committee.

Comments Received Prior to Committee Evaluation

NQF solicits comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). In addition, NQF solicits comments prior to the evaluation of the measures via an online tool located on the project webpage. For this evaluation cycle, the pre-evaluation comment period was open April 13-26, 2016, for 18 of the 18 measures under review. A total of two pre-evaluation comments were received (Appendix G).

All submitted comments were provided to the Committee prior to its initial deliberations during the workgroup calls.

Refining the NQF Measure Evaluation Process

To streamline and improve the periodic evaluation of currently endorsed measures, NQF has updated the evaluation of measures for maintenance of endorsement. This change took effect beginning October 1, 2015. NQF's endorsement criteria have not changed, and all measures continue to be evaluated using the same criteria. However, under the new approach, there is a shift in emphasis for evaluation of currently endorsed measures:

- **Evidence:** If the developer attests that the evidence for a measure has not changed since its previous endorsement evaluation, there is a decreased emphasis on evidence, meaning that the Committee may accept the prior evaluation of this criterion without further discussion or need for a vote. This applies only to measures that previously passed the evidence criterion without an exception. If a measure was granted an evidence exception, the evidence for that measure must be revisited.
- **Opportunity for Improvement (Gap):** For re-evaluation of endorsed measures, there is increased emphasis on current performance and opportunity for improvement. Endorsed measures that are "topped out" with little opportunity for further improvement are eligible for inactive endorsement with reserve status.
- **Reliability:**
    - Specifications: There is no change in the evaluation of the current specifications.
    - Testing: If the developer has not presented additional testing information, the Committee may accept the prior evaluation of the testing results without further discussion or need for a vote.
- **Validity:** There is less emphasis on this criterion if the developer has not presented additional testing information, and the Committee may accept the prior evaluation of this subcriterion without further discussion and vote. However, the Committee will still consider whether the specifications are consistent with the evidence. Also, for outcome measures, the Committee discusses questions required for the SDS Trial even if no change in testing is presented.
- **Feasibility:** The emphasis on this criterion is the same for both new and previously endorsed

measures, as feasibility issues might have arisen for endorsed measures that have been implemented.

- **Usability and Use:** For re-evaluation of endorsed measures, there is increased emphasis on the use of the measure, especially use for accountability purposes. There also is an increased emphasis on improvement in results over time and on unexpected findings, both positive and negative.

Committee Evaluation

Of the 15 maintenance and three new measures reviewed by the Cancer Standing Committee at its May 18-19, 2016, meeting, nine were recommended for endorsement and two for inactive endorsement with reserve status. The Committee did not reach consensus on six measures and did not recommend one measure.

On August 23, 2016, the Committee reconvened to discuss comments and reevaluate the six measures where consensus was not reached. Of these six measures, the Committee recommended four measures for endorsement. The Committee did not recommend two measures for endorsement.

On October 11, 2016, the CSAC voted to recommend 13 measures for endorsement and 2 measures for inactive endorsement with reserve status. The CSAC's recommendations did not differ from the Standing Committee's recommendations.

Table 2 summarizes the results of the Committee's evaluation.

Table 2. Cancer Measure Evaluation Summary

	Maintenance	New	Total
Measures under consideration	15	3	18
Measures endorsed	11	2	13
Measures with inactive endorsement with reserve status	2	N/A	2
Measures not endorsed	2	1	3
Measures withdrawn from consideration	1	3	4
Reasons for not recommending	Importance – 1 Scientific Acceptability – 1 Overall – 0 Competing Measure – 0	Importance – 0 Scientific Acceptability – 1 Overall – 0 Competing Measure – 0	

Overarching Issues

During the Standing Committee's discussion of the measures, several overarching issues emerged and were factored into the Committee's ratings and recommendations for multiple measures; these issues are not repeated in detail for each individual measure.

Insufficient Testing

Several of the measures included mean performance rates for reliability testing results. NQF reliability testing requirements include statistical analysis of the computed measure score or the individual patient-level data for the measured entities to determine the proportion of variation due to true differences versus noise or random variation. Overall performance rates do not meet the reliability criterion. Percentage agreement rates were provided for some, but not all, of the data elements for validity. Validity testing of all the critical data elements (including kappa scores, sensitivity, or specificity statistics) is required to meet the validity criterion. In the absence of more comprehensive testing, the Committee considered whether each measure and its specifications were consistently implemented within the respective registries to determine reliability and validity.

New Treatments

Cancer treatments have evolved significantly over time including the use of oral chemotherapy. However, due to limitations in data sources and measure specifications, the Committee recognized that capturing the use of oral chemotherapy is not always feasible.

New eMeasure Versions of Endorsed Measures

One of the measures evaluated in this project was submitted for endorsement as a re-specified eMeasure. NQF considers eMeasures to be distinct from previously endorsed measures and assigns them different NQF measure numbers (this includes "legacy" eMeasures[13]). The eMeasure was evaluated separately from the original measure for all criteria except evidence and gap.

Although these eMeasures are used in the federal electronic health record (EHR) Incentive Program (Meaningful Use), this program does not generate a dataset that can be tested for reliability and—the majority of participants have been reporting by attestation rather than submitting data. Current NQF criteria require testing eMeasures in more than 1 EHR system; however, during this evolution toward greater use of eMeasures, NQF accepts testing in a simulated dataset (e.g., use of the Bonnie tool) as an alternative approach for "legacy" eMeasures used in federal programs.

Outcome Measures

The majority of the measures in the cancer portfolio are process measures. The Committee encouraged the measurement community to develop outcome measures, specifically for those processes further removed from the outcome. The Committee also encouraged the development of outcome measures related to process measures whose performance has "topped out" or is close to "topping out."

Summary of Measure Evaluation

The following brief summaries of the measure evaluation highlight the major issues that the Committee considered. Details of the Committee's discussion and ratings of the criteria for each measure are in included in Appendix A.

Breast Cancer Screening

0508 Diagnostic Imaging: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms (American College of Radiology): Endorsed

Description: Percentage of final reports for screening mammograms that are classified as "probably benign"; **Measure Type**: Process; **Level of Analysis**: Clinician: Individual; **Setting of Care**: Ambulatory Care: Clinician Office/Clinic, Imaging Facility; **Data Source**: Administrative claims, Electronic Clinical Data: Registry

Inappropriate designation of findings as "probably benign" can result in unnecessary follow-up of lesions that could have been quickly classified or delayed diagnosis and treatment of cancerous lesions. The "probably benign" assessment category is reserved for findings that have a high probability (equal to 98 percent) of being benign and should not be used as a category for indeterminate findings. Immediate completion of a diagnostic imaging evaluation for abnormal screening mammograms eliminates potential anxiety that women would endure with the short interval follow-up that is recommended for "probably benign" findings. This facility-level measure, originally endorsed in 2008, calculates the percentage of screening mammograms classified as "probably benign." Based on NQF criteria, the evidence was insufficient due to lack of empirical evidence provided to support this process of care. The Committee agreed that the evidence was insufficient but also believed that it is beneficial to hold providers accountable for performance in the absence of empirical evidence of benefits to patients. The Committee agreed that based on the performance data provided by the developer, providers were still using the "probably benign" assessment category 0.49 percent of the time in 2014; therefore, an opportunity for improvement still exists.

0509 Diagnostic Imaging: Reminder System for Screening Mammograms (American College of Radiology): Endorsed

Description: Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram; **Measure Type**: Process; **Level of Analysis**: Clinician: Individual; **Setting of Care**: Hospital/Acute Care Facility, Imaging Facility; **Data Source**: Administrative claims, Electronic Clinical Data: Registry

Screening mammograms can reduce breast cancer mortality by 20-35 percent in women age 40 years and older. However, recent evidence shows that only 72 percent of women are receiving mammograms based on current guideline recommendations. This clinician-level measure, originally endorsed in 2008, calculates the percentage of patients undergoing a screening mammogram whose target due date for the next mammogram is entered into a reminder system. The Committee agreed that based on the performance data provided by the developer, an opportunity for improvement still exists. The exclusion, 'medical reason documentation' was added in 2014; however, the developer did not conduct an analysis to determine the impact of this exclusion on the validity of the measure. The developer explained that the exclusion should not be a threat to validity because it was only used three times during 2014. Committee members questioned why the exclusions were so low considering that the developer was reporting Medicare data from the Physician Quality Reporting System (PQRS) and expected the number of exclusions to be higher in the older Medicare population. This raised concerns about the exclusion not being used properly by physicians and/or the need for the exclusion. During the post-comment call,

the developer stated that it would analyze the 2015 PQRS data and determine if the exclusion was in fact needed. The Committee agreed that the validity of the measure was sufficient and voted to recommend the measure for endorsement.

Breast Cancer

0219 Post breast conservation surgery irradiation (Commission on Cancer, American College of Surgeons): Endorsed

Description: Percentage of female patients, age 18-69, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage I, II, or III, receiving breast conserving surgery who receive radiation therapy within 1 year (365 days) of diagnosis.; **Measure Type**: Process; **Level of Analysis**: Facility; **Setting of Care**: Hospital/Acute Care Facility; **Data Source**: Paper Medical Records, Electronic Clinical Data: Registry

Studies have demonstrated a 75 percent reduction in the risk of local breast cancer recurrence with radiation therapy compared to no radiation. This facility-level measure, originally endorsed in 2007, calculates the percentage of breast cancer patients who undergo breast conservation surgery (i.e., lumpectomy) and receive radiation therapy within one year of diagnosis. The Committee agreed that based on the performance and disparities data provided by the developer, a gap in care continues to exist for the use of radiation after breast conservation surgery for breast cancer. Although validity testing of all the critical data elements (including kappa scores, sensitivity or specificity statistics) was not provided, the Committee agreed that the measure specifications were consistently implemented within the cancer registry and met the reliability and validity criteria.

0220 Adjuvant hormonal therapy (Commission on Cancer, American College of Surgeons): Endorsed

Description: Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage T1cN0M0,IB to III, whose primary tumor is progesterone or estrogen receptor positive with tamoxifen or third generation aromatase inhibitor (recommended or administered) within 1 year (365 days) of diagnosis.; **Measure Type**: Process; **Level of Analysis**: Facility; **Setting of Care**: Hospital/Acute Care Facility; **Data Source**: Paper Medical Records, Electronic Clinical Data: Registry

Studies have demonstrated a 25 percent reduction in the risk of distant cancer recurrence and death in patients who receive adjuvant hormonal therapy for progesterone or estrogen receptor positive primary breast cancer tumors. This facility-level measure, originally endorsed in 2007, calculates the percentage of breast cancer patients with a primary tumor that is progesterone or estrogen receptor positive who receive hormone therapy within one year of diagnosis. The Committee agreed that based on the performance and disparities data provided by the developer, a gap in care continues to exist in the administration of adjuvant hormonal therapy for breast cancer patients. However, the Committee noted that the performance data provided was from Commission on Cancer (CoC) accredited centers only; therefore, the gaps in care and disparities may be larger if the measure were implemented in non-CoC-accredited centers. The developer provided percent agreement results for 2 of the data elements included in the numerator. Validity testing of all the critical data elements (including kappa scores, sensitivity, or specificity statistics) was not provided. The Committee noted that the measure

specifications for this measure are not consistently implemented due to various patient factors such as the physician recommending hormone therapy, the patient obtaining a prescription, declining hormone therapy, and then ultimately starting hormone therapy.

After the comment period, the Committee reconsidered this measure. The Committee noted that the developer did not provide additional data element testing needed to satisfy concerns discussed during the in-person meeting. However, the developer submitted recent performance results from the Rapid Quality Reporting System (RQRS) during the comment period. The additional data demonstrated that gaps in performance continue to exist with the lowest performance seen in Hispanics. Considering the additional information provided, the Committee agreed that this measure continues to be an important indicator of cancer care. On re-vote, the Committee recommended the measure for endorsement.

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. (Commission on Cancer, American College of Surgeons): Endorsed

Description: Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage T1cN0M0 (tumor greater than 1 cm), or Stage IB -III, whose primary tumor is progesterone and estrogen receptor negative recommended for multiagent chemotherapy (recommended or administered) within 4 months (120 days) of diagnosis; **Measure Type**: Process; **Level of Analysis**: Facility; **Setting of Care**: Hospital/Acute Care Facility; **Data Source**: Paper Medical Records, Electronic Clinical Data: Registry

Studies have demonstrated approximately a 33 percent reduction in the risk of distant cancer recurrence and death in patients who receive combination chemotherapy for progesterone and estrogen receptor negative breast cancer. This facility-level measure, originally endorsed in 2007, calculates the percentage of breast cancer patients with a primary tumor that is progesterone or estrogen receptor negative who receive combination chemotherapy within 4 months (120 days) of diagnosis. The Committee agreed that based on the performance and disparities data provided by the developer, a gap in care continues to exist in the administration of combination chemotherapy for breast cancer patients. The developer provided percent agreement results for two of the data elements included in the numerator. Validity testing of all the critical data elements (including kappa scores, sensitivity, or specificity statistics) was not provided. The Committee noted the same concerns about reliability and validity that were expressed while discussing #0220, and therefore, agreed to carry forward the votes for reliability and validity.

After the comment period, the Committee reconsidered this measure. Again, the Committee noted the same concerns about reliability and validity that were expressed while discussing #0220, and therefore, agreed to carry forward the votes for reliability and validity. The Committee agreed this was an important indicator. On re-vote, the Committee recommended the measure for endorsement.

Colon Cancer

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 (Commission on Cancer, American College of Surgeons): Endorsed

Description: Percentage of patients under the age of 80 with AJCC III (lymph node positive) colon cancer for whom adjuvant chemotherapy is recommended and not received or administered within 4 months (120 days) of diagnosis; **Measure Type**: Process; **Level of Analysis**: Facility; **Setting of Care**: Hospital/Acute Care Facility; **Data Source**: Paper Medical Records, Electronic Clinical Data: Registry

Studies have demonstrated approximately a 25 percent reduction in the risk of death for colon cancer patients treated with adjuvant chemotherapy. This facility-level measure, originally endorsed in 2007, calculates the percentage of patients with colon cancer who are treated with adjuvant chemotherapy within 4 months (120 days) of diagnosis. The Committee agreed that based on the performance and disparities data provided by the developer, a gap in care continues to exist in the administration of combination chemotherapy for colon cancer patients. The developer provided percent agreement results for two of the data elements included in the numerator. Although validity testing of all the critical data elements (including kappa scores, sensitivity, or specificity statistics) was not provided, the Committee agreed that the measure specifications were consistently implemented within the cancer registry and met the reliability and validity criteria.

0225 At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer. (Commission on Cancer, American College of Surgeons): Endorsed

Description: Percentage of patients >18yrs of age, who have primary colon tumors (epithelial malignancies only), at AJCC stage I, II or III who have at least 12 regional lymph nodes removed and pathologically examined for resected colon cancer; **Measure Type**: Process; **Level of Analysis**: Facility; **Setting of Care**: Hospital/Acute Care Facility; **Data Source**: Paper Medical Records, Electronic Clinical Data: Registry

This facility-level measure, originally endorsed in 2007, calculates the percentage of patients with colon cancer who undergo colorectal surgery and at least 12 lymph nodes are removed and pathologically examined. To date, there has been a lack of consensus in the literature as to the minimal number of lymph nodes that have to be examined to accurately stage colon cancer. Studies have also concluded that an “adequate” lymph node examination is not associated with patient outcomes. The Committee echoed the previous Committee’s concern that the practice of examining 12 lymph nodes is not evidence-based but rather an arbitrary number that is not connected to patient outcomes. The developer stated that the National Cancer Data Base (NCDB) will be publishing a study demonstrating the relationship between compliance on this measure and outcomes over time. According to recent studies, the developer stated, there is a correlation between the number of lymph nodes examined and patient survival. Based on this information, the Committee agreed that the current evidence was sufficient. The Committee agreed that there was room for improvement though it is unlikely that the percentage will increase much more in high performers since variation in surgical technique or pathology examination is likely to account for a significant number of patients that do not get to the 12 lymph node goal compared to that of poor performance. Though validity of all the critical data elements

(including kappa scores, sensitivity or specificity statistics) was not provided, the Committee agreed that the measure specifications were consistently implemented within the cancer registry and accepted the previous reliability and validity evaluation.

Hematology

0377 Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow (Physician Consortium for Performance Improvement): Endorsed

Description: Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow; **Measure Type**: Process; **Level of Analysis**: Clinician: Group/Practice, Clinician: Individual, Clinician: Team; **Setting of Care**: Ambulatory Care: Clinician Office/Clinic; **Data Source**: Electronic Clinical Data: Registry

Cytogenetic testing should be performed on the bone marrow of patients with myelodysplastic syndrome (MDS) in order to guide treatment options, determine prognosis, and predict the likelihood of disease evolution to leukemia. This clinician-level measure, originally endorsed in 2008, calculates the percentage of MDS/acute leukemia patients who had a baseline analysis of their bone marrow using cytogenetic testing. Based on the performance data from the Physician Quality Reporting System (PQRS), rates increased to 88.0 percent until 2012 and then decreased to 87.0 percent in 2013. Additionally, a recently published study by Dr. Gregory Abel demonstrated a 74 percent performance gap for this measure using Surveillance, Epidemiology, and End Results (SEER) Medicare data. The Committee agreed that an opportunity for improvement persists in performing baseline cytogenetic testing on bone marrow for MDS/acute leukemia patients. The Committee noted that the use of newer molecular cytogenetic studies using fluorescence in situ (FISH) is growing and encouraged the developer to include these additional studies in future iterations of the measure. The developer agreed that as new evidence supporting additional studies continues to evolve and the guideline is revised, the measure will also be revised.

0378 Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy (PCPI): Endorsed

Description: Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) who are receiving erythropoietin therapy with documentation of iron stores within 60 days prior to initiating erythropoietin therapy; **Measure Type**: Process; **Level of Analysis**: Clinician: Group/Practice, Clinician: Individual, Clinician: Team; **Setting of Care**: Ambulatory Care: Clinician Office/Clinic; **Data Source**: Electronic Clinical Data: Registry

To be effective, erythropoietin requires that adequate iron stores be present due to iron's importance in red-blood-cell synthesis. Iron deficiency presents a major limitation to the efficacy of erythropoietin therapy. This clinician-level measure, originally endorsed in 2008, calculates the percentage of myelodysplastic syndrome (MDS) patients who have documentation of iron stores within 60 days prior to initiating erythropoietin therapy. Based on the performance data from the Physician Quality Reporting System (PQRS), rates increased from 94.7 percent in 2010 to 95.3 percent in 2012, but ultimately dropped to 83.1 percent in 2013. The developer explained that beginning in 2015, PQRS

began imposing payment penalties for nonparticipants based on 2013 performance. For 2013, 6.5 percent of eligible professionals reported on this measure. As a result, performance rates may not be nationally representative. The Committee agreed there is an opportunity for improvement.

Lung/Thoracic Cancer

0459 Risk-Adjusted Length of Stay >14 Days after Elective Lobectomy for Lung Cancer (The Society of Thoracic Surgeons): Not Endorsed

Description: Percentage of patients aged 18 years and order undergoing elective lobectomy for lung cancer who had a prolonged length of stay >14 days; **Measure Type**: Outcome; **Level of Analysis**: Facility, Clinician: Group/Practice; **Setting of Care**: Hospital/Acute Care Facility; **Data Source**: Electronic Clinical Data: Registry

It is important for surgeons to be able to compare their surgical outcomes to those of peer institutions as a means of assessing results and improving quality of care. Knowing their rate of risk-adjusted length of stay (LOS) after elective lobectomy for lung cancer gives lower performing thoracic programs the opportunity to design quality improvement initiatives to improve patient outcomes and decrease resource use. This facility/clinician-level measure, originally endorsed in 2008, calculates the percentage of patients who remain in the hospital for more than 14 days (prolonged length of stay) after undergoing an elective lobectomy for lung cancer. The Committee questioned whether 14 days was still an appropriate threshold for defining prolonged length of stay (PLOS) since LOS can be significantly affected by surgical approach (open thoracotomy vs. minimally-invasive thoracotomy) as indicated in the article by Wright et al. 2010. Furthermore, PLOS has decreased from a mean of 5.1 percent to 4.3 percent from 2009 to 2015. The Committee also noted that the number of patients per surgeon ranged widely by region, yet the mean PLOS was about 4.0 percent for each region. The Committee was concerned that low-volume providers may affect overall performance rates making it difficult to distinguish high-performers from low-performers and determine if a gap in care exists based on the data provided. The Committee discussed the measure on the post-comment call and re-voted on the performance gap criterion. The measure did not pass the performance gap subcriterion and was not recommended for endorsement.

0460 Risk-Adjusted Morbidity and Mortality for Esophagectomy for Cancer (The Society of Thoracic Surgeons): Not Endorsed

Description: Percentage of patients aged 18 years and older undergoing elective esophagectomy for esophageal cancer who developed any of the following postoperative conditions: bleeding requiring reoperation, anastomosis leak requiring medical or surgical treatment, reintubation, ventilation >48 hours, pneumonia, or discharge mortality; **Measure Type**: Outcome; **Level of Analysis**: Facility, Clinician: Group/Practice; **Setting of Care**: Hospital/Acute Care Facility; **Data Source**: Electronic Clinical Data: Registry

It is important for surgeons to be able to compare their surgical outcomes to those of peer institutions as a means of assessing results and improving quality of care. Knowing their rate of risk-adjusted morbidity and mortality after an esophagectomy for esophageal cancer gives thoracic programs the opportunity to design quality improvement initiatives to improve patient outcomes. This

facility/clinician-level measure, originally endorsed in 2008, calculates the percentage of patients with esophageal cancer who develop any one of the following conditions after undergoing an elective esophagectomy: bleeding requiring reoperation, anastomosis leak requiring medical or surgical treatment, reintubation, ventilation >48 hours, pneumonia, or discharge mortality. The Committee agreed that based on the performance data provided by the developer, there is opportunity for improvement in care for patients undergoing elective esophagectomy. The Committee noted that more than 55 percent of registry participants performed fewer than five procedures per year. It also expressed concerns with the reliability of this low-volume procedure and that the measure was not specified for ≥5 procedures per year to exclude low-volume providers. The Committee also expressed concerns with combining morbidity and mortality and asked the developer if there were plans for differential weighting of these outcomes. These same concerns were expressed by the previous Committee in 2012.The developer indicated that they were developing a new measure that more heavily weights mortality than morbidity and it would be complete by the next maintenance review. The Committee discussed the measure on the post-comment call and re-voted on the reliability and validity subcriteria. The measure did not pass the reliability and validity subcriteria and was not recommended for endorsement.

Prostate Cancer

0389 Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (PCPI): Endorsed

Description: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer; **Measure Type**: Process ; **Level of Analysis**: Clinician: Group/Practice, Clinician: Individual, Clinician: Team; **Setting of Care**: Ambulatory Care: Ambulatory Surgery Center (ASC), Ambulatory Care: Clinician Office/Clinic, Other; **Data Source**: Electronic Clinical Data, Electronic Clinical Data: Registry

Although clinical practice guidelines do not recommend bone scans in low-risk prostate cancer patients, overuse is common. An analysis of prostate cancer patients in the Surveillance, Epidemiology, and End Results (SEER)-Medicare database diagnosed from 2004-2007 found that 43 percent of patients for whom a bone scan was not recommended received one. The analysis also found that the use of bone scans in low-risk patients leads to an annual cost of $4 million dollars to Medicare. This clinician-level measure, originally endorsed in 2008, calculates the percentage of men receiving treatment for prostate cancer with a low or very low risk of recurrence, who have not received a bone scan since the time of their prostate cancer diagnosis. The average performance rate from the Physician Quality Reporting System (PQRS) experience report was 71.6 percent in 2010 and 88.5 percent in 2013. The Committee agreed that performance has improved over time, but there is still an opportunity for improvement in decreasing bone scans in low-risk prostate cancer patients. The Committee noted that a potential consequence of decreasing bone scan testing rates would be undiagnosed metastatic disease; however, this is unlikely based on the evidence for low-risk prostate cancer patients.

2963 Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients – *Legacy eMeasure* (PCPI): Endorsed

Description: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer; **Measure Type**: Process; **Level of Analysis**: Clinician: Group/Practice, Clinician: Individual, Clinician: Team; **Setting of Care**: Ambulatory Care: Ambulatory Surgery Center (ASC), Ambulatory Care: Clinician Office/Clinic, Other; **Data Source**: Electronic Clinical Data: Electronic Health Record

This "legacy" eMeasure is the eCQM version of the registry measure #0389, currently used in federal programs. The Committee discussed #0389 first, and because the information provided for evidence and opportunity for improvement is identical for the two measures, the Committee agreed to assign the ratings for these criteria to #2963. The developer provided reliability results from the registry measure (#0389) and stated that once data from the eCQM are available for analysis it is expected that reliability test results will be comparable for the two measures. The Committee questioned extrapolating the reliability of the eCQM based on the registry measure without testing results. The Committee asked the developer if it had tested the correlation of the eCQM and registry measure. The developer clarified that although the eCQM is currently used in Meaningful Use (MU), CMS has not released performance data from MU. The Committee noted its concerns with providers' ability to consistently implement the Health Quality Measure Format (HQMF) specifications for the eCQM and the potential impact on the numerator, denominator, and exclusions/exceptions. The Committee acknowledged the importance of eMeasures and the challenges associated with respecifying registry and claims measures and encouraged CMS to release MU performance data. The Standing Committee did not reach consensus on the reliability criteria during the in-person meeting.

After the comment period, the Committee reconsidered this measure. The Committee emphasized its concerns with the lack of data from the measure as specified. The developer stated that since the in-person meeting it attempted to obtain Meaningful Use (MU) data from CMS, but it is not available. The developer also conducted additional analyses with the current Physician Quality Reporting System (PQRS) data, but it was not sufficient. The developer agreed to provide the Standing Committee with additional data during the measure's scheduled annual review (within one year). The Standing Committee will review the additional data through an ad-hoc review. The Standing Committee agreed that the measure met the minimum criterion for reliability required for legacy eMeasures at this time.

0390 Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients (American Urological Association): Endorsed

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); **Measure Type**: Process; **Level of Analysis**: Clinician: Group/Practice, Clinician: Individual, Clinician: Team; **Setting of Care**: Ambulatory Care: Ambulatory Surgery Center (ASC), Ambulatory Care: Clinician Office/Clinic, Other; **Data Source**: Electronic Clinical Data, Electronic Clinical Data: Registry

High-quality clinical trials have shown that high-risk prostate cancer patients considering external beam radiotherapy, the use of hormonal therapy combined with conventional radiotherapy may prolong survival. This facility-level measure, originally endorsed in 2008, calculates the percentage of high-risk prostate cancer patients undergoing radiotherapy who are also prescribed adjuvant hormonal therapy. Physician Quality Reporting System (PQRS) performance rates have increased from 79.6 percent in 2010 to 95.4 percent in 2013. The Committee agreed that there was a sufficient gap in care. There were a total of 204 exclusions/exceptions among 20 physicians with an overall rate of 32.2 percent. The Committee questioned the validity of the measure due to the high rate of exclusions/exceptions, but ultimately agreed that the measure met the criterion for validity.

Febrile Neutropenia

2930 Febrile Neutropenia Risk Assessment Prior to Chemotherapy (RAND Corporation): Endorsed

Description: Percentage of patients with a solid malignant tumor or lymphoma who had a febrile neutropenia (FN) risk assessment completed and documented in the medical record prior to the first cycle of intravenous chemotherapy; **Measure Type**: Process; **Level of Analysis**: Clinician: Group/Practice; **Setting of Care**: Ambulatory Care: Clinician Office/Clinic, Other; **Data Source**: Electronic Clinical Data: Electronic Health Record, Paper Medical Records

Having information about a patient's febrile neutropenia (FN) risk allows the identification of patients at higher risk of FN who are more likely to benefit from treatment with prophylactic colony-stimulating factor (CSF). CSF stimulates the production of white blood cells and lowers the risk of FN and its complications. This newly submitted clinician-level measure calculates the percentage of patients with a solid malignant tumor or lymphoma who had documentation of a FN risk assessment in their medical record prior to the first administration of intravenous chemotherapy. The Committee agreed that the evidence the developer provided to support the use of a FN assessment tool demonstrated a decrease in the incidence of FN and related complications. The developer provided performance rates from April 2011 to February 2016 that included 192 patient records from 5 community oncology clinics. The mean performance rate was 12.0 percent, the median was 16.0 percent, and the maximum was 27.0 percent. The Committee suggested that the low performance rates may be due to the adoption of computerized physician order entry (CPOE) and standard order sets that include supportive care treatments appropriate for the regimen, including prophylactic CSF. The Committee concluded that the inter-rater reliability testing results were sufficient, but encouraged the developer to conduct a statistical analysis of the computed measure score in the future. The Committee emphasized that a febrile neutropenia outcome measure would further the goal of high-quality, efficient healthcare more effectively than a process measure.

Breast Cancer

1878 HER2 testing for overexpression or gene amplification in patients with breast cancer (American Society of Clinical Oncology): Inactive Endorsement with Reserve Status

Description: Proportion of female patients (aged 18 years and older) with breast cancer who receive human epidermal growth factor receptor 2 (HER2) testing for overexpression or gene amplification;

Measure Type: Process; **Level of Analysis**: Clinician: Group/Practice; **Setting of Care**: Ambulatory Care: Clinician Office/Clinic; **Data Source**: Electronic Clinical Data: Registry

All patients with invasive breast cancer should be tested for human epidermal growth factor receptor 2 (HER2) status, and only those who test positive for HER2 status should receive HER2 targeted therapies. Results of HER2 testing are imperative to receive guideline concordant treatment. This clinician-level measure, originally endorsed in 2012, calculates the percentage of breast cancer patients who are tested for HER2 status. Based on the performance data provided by the developer from the Quality Oncology Practice Initiative (QOPI®) registry, the Committee agreed that there was little to no room for improvement; therefore, the measure failed the performance gap criterion but was recommended for endorsement with reserve status because performance outside of the QOPI® registry might not be as high.

1857 HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies (American Society of Clinical Oncology): Inactive Endorsement with Reserve Status

Description: Proportion of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2)/neu negative who are not administered HER2-targeted therapies; **Measure Type**: Process; **Level of Analysis**: Clinician: Group/Practice; **Setting of Care**: Ambulatory Care: Clinician Office/Clinic; **Data Source**: Electronic Clinical Data: Registry

The contraindicated administration of HER2 targeted therapy to patients with HER2 negative breast cancer can propagate potentially toxic, costly, and adverse effects as well as decrease a patient's overall quality of life. This clinician-level measure, originally endorsed in 2012, calculates the percentage of patients with HER2 negative breast cancer (or HER2 undocumented) that do not receive HER2 targeted therapy. Based on the performance data provided by the developer from the QOPI® registry, the Committee agreed that there was little to no room for improvement; therefore, the measure failed the performance gap criterion but was recommended for endorsement with reserve status because performance outside of the QOPI® registry might not be as high.

Inpatient Admissions and Emergency Department Visits

2936 Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy (Mathematica Policy Research): Not Endorsed

Description: Measure estimates hospital-level, risk-adjusted rates of inpatient admissions or ED visits for cancer patients >18 years of age for at least one of the following diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of hospital outpatient chemotherapy treatment. The two rates are calculated and reported separately. **Measure Type**: Outcome; **Level of Analysis**: Facility; **Setting of Care**: Hospital/Acute Care Facility; **Data Source**: Administrative claims

Chemotherapy treatment can have severe, predictable side effects, and hospital admissions and ED visits among patients receiving treatment in a hospital outpatient setting are often caused by manageable side effects and complications. Admissions and ED visits for eligible diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—may be due to

patients receiving treatment in a hospital outpatient setting having unmet needs, which, if addressed, could reduce admissions and ED visits and increase patients' quality of life. Treatment plans and guidelines exist to support the management of these conditions. Hospitals that provide outpatient chemotherapy should implement appropriate care to minimize the need for acute hospital care for these adverse events. This newly submitted hospital-level outcome measure calculates the percentage of patients receiving hospital outpatient chemotherapy that are admitted to the hospital or have an ED visit within 30 days of their chemotherapy treatment for one of the 10 eligible diagnoses. The Committee agreed that the interventions outlined by the developer to prevent and manage some of the conditions improve patients' quality of life. However, evidence linking these interventions with decreased hospitalizations and ED visits was not provided. The Committee did not reach consensus on the evidence of a linkage between the broad range of side effects and reduced ED visits and hospitalizations. The Committee questioned whether sufficient data were provided to determine if a gap in care existed due to the significantly small difference between the 25th and 75th percentile on the ED visit rate and ultimately did not reach consensus on performance gap. The Committee discussed various concerns regarding reliability including the small sample size used for reliability testing, low reliability scores for inpatient (0.41) and ED visits (0.27), the numerator limiting admissions/rates to inpatient and ED (some facilities have urgent care), attribution, and the inclusion of patients receiving chemoradiotherapy in the denominator. Based on these concerns, the Committee concluded that the measure did not meet the reliability criterion.

References

[1] American Cancer Society. Economic impact of cancer website. http://www.cancer.org/cancer/cancerbasics/economic-impact-of-cancer. Last accessed June 2016.

[2] National Cancer Institute. Cancer statistics. https://www.cancer.gov/about-cancer/understanding/statistics. Updated March 2016. Last accessed January 2017.

[3] American Cancer Society. *Cancer Facts & Figures 2016.* Atlanta: American Cancer Society; 2016. Available at http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2016/index. Last accessed June 2016.

[4] National Cancer Institute. Cancer Prevalence and Cost of Care Projections. https://costprojections.cancer.gov/.

[5] American Cancer Society. Economic impact of cancer website. http://www.cancer.org/cancer/cancerbasics/economic-impact-of-cancer. Last accessed June 2016.

[6] National Cancer Institute. Cancer prevalence and cost of care projections. https://costprojections.cancer.gov/. Last accessed January 2017.

[7] American Cancer Society. *Cancer Facts & Figures 2016.* Atlanta: American Cancer Society; 2016. Available at http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2016/index. Last accessed June 2016.

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[9] American Cancer Society. *Cancer Facts & Figures 2016.* Atlanta: American Cancer Society; 2016. Available at http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2016/index. Last accessed June 2016.

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[11] American Cancer Society. *Cancer Facts & Figures 2016.* Atlanta: American Cancer Society; 2016. Available at http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2016/index. Last accessed June 2016.

[12] National Quality Forum (NQF). *Towards a Comprehensive Cancer Measure Set: Value-Based Episodes of Care* [workshop summary]. Washington, DC: NQF; May 20, 2008. http://www.qualityforum.org/Publications/2008/05/Workshop_Summary,_Toward_a_Comprehensive_Cancer_Measure_Set__Value-Based_Episodes_of_Care.aspx.

[13] Legacy eMeasures are "respecified" eMeasures that are currently used in federal programs.

Appendix A: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable; **Y**=Yes; **N**=No

Endorsed Measures

0219 Post breast conservation surgery irradiation

Submission | Specifications

Description: Percentage of female patients, age 18-69, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage I, II, or III, receiving breast conserving surgery who receive radiation therapy within 1 year (365 days) of diagnosis.

Numerator Statement: Radiation therapy to the breast is initiated within 1 year (365 days) of the date of diagnosis

Denominator Statement: Include, if all of the following characteristics are identified:

Women

Age 18-69 at time of diagnosis

Known or assumed to be first or only cancer diagnosis

Primary tumors of the breast

Epithelial malignancy only,

AJCC Stage I, II, or III

Surgical treatmen

Exclusions: Exclude, if any of the following characteristics are identified:

Men

Under age 18 at time of diagnosis

Over age 69 at time of diagnosis

Second or subsequent cancer diagnosis

Tumor not originating in the breast

Non-epithelial malignancies

Phyllodes tumor histology

Stage 0, in-situ tumor

Stage IV, metastatic tumor

None of 1st course therapy performed at reporting facility

Died within 12 months (365 days) of diagnosis

Patient participating in clinical trial that directly impacts delivery of the standard of care

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Paper Medical Records, Electronic Clinical Data : Registry

Measure Steward: Commission on Cancer, American College of Surgeons

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STANDING COMMITTEE MEETING [5/18-19/2016]

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

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

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-8**; **M-9**; **L-3**; **I-0;**

Rationale:

- For the 2012 endorsement evaluation, the developer provided a clinical practice guideline from National Comprehensive Cancer Network (NCCN) Practice Guidelines as evidence to support post breast conservation surgery irradiation. The developer also included a systematic review of multiple randomized clinical trials (RCTs) demonstrating a 75 percent reduction in the risk of local recurrence with radiation compared to no radiation in the hospital or acute care setting.
- The Committee agreed that the evidence basis for the measure has not changed and there was no need to repeat the discussion and vote on evidence.
- For the current evaluation, the developer provided national trend data from the National Cancer Data Base (NCDB) from 2008 and 2012. The mean performance rate for 2008 was 88.1% and 90.7% for 2012. The developer explained that more recent performance data was not available at the time of measure submission because participating programs have not yet had time to collect the 2013 information required for this measure.
- The Committee agreed that based on the performance and disparities data provided by the developer, a gap in care continues to exists for the utilization of radiation with breast conservation surgery for breast cancer.

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2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

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

2a. Reliability: **M-16**; **L-2**; **I-2** 2b. Validity: **M-18**; **L-0**; **I-1**

Rationale:

- For the 2012 endorsement evaluation, the developer provided mean performance rates that included 1,400 Commission on Cancer (CoC) accredited cancer programs and approximately 55,700 cases from 2007 (84.1) and 2008 (84.7).
- For the current evaluation, the developer provided updated mean performance rates (90.7) from 2012. NQF reliability testing requirements include statistical analysis of the computed measure score or the individual patient-level data for the measured entities to determine the proportion of variation due to true differences versus noise or random variation. Overall performance rates do not meet the reliability criterion, which was provided by the developer. Data element validity testing was performed and counted for data element reliability.
- For the 2012 endorsement evaluation, validity was assessed by randomly selecting charts and reviewing them by site surveyors to determine completeness and validity of data reported to registry. The measure denominator and numerator were viewed by the clinical constituency within these cancer programs as valid and an appropriate reflection of the standard of care described in NCCN clinical guidelines.
- For the current evaluation, the developer provided additional details on data element validity testing conducted in 2009 and 2010 by comparing registry data to data that were re-abstracted

from the medical records by CoC site surveyors, which was considered the gold standard. The developer provided percentage agreement results for one of the data elements included in the numerator (timing of radiation therapy (91.4, 92.2). The developer also stated that there were 494 cases during 2006 and 2007 in which there was 59 percent agreement with missing radiation therapy. The Committee noted their concern with the large percentage of missing data required to calculate this measure as a threat to validity. The developer responded that they provide reports to the participating programs on missing data elements required to calculate the measures and verify whether or not the information is available. The developer also stated that they have seen a decrease in the percent of missing data since 2007 but did not provide updated testing information.

- One Committee member questioned why the measure only includes adults up to age 69. The developer responded that the age cutoff is based on the RCTs and that radiation therapy is generally considered necessary in women under age 69 versus a treatment preference in older women.
- Although validity testing of all the critical data elements (including kappa scores, sensitivity or specificity statistics) was not provided, the Committee agreed that the measure specifications were consistently implemented within the registry and met the reliability and validity criteria. The Committee encouraged the developer to provide updated reliability and validity testing at the next maintenance review of the measure. The developer confirmed that they are planning to update their validity and reliability testing for the 5 measures submitted in this project (#0219, #0220, #0223, #0225, and #0559).

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3. Feasibility: H-13; M-5; L-1; I-0

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

Rationale:

- The Committee agreed that, while a small level of burden exists, the measure is easily available in medical records and the data elements are routinely captured by national cancer registries.

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4. Usability and Use: H-12; M-6; L-1; I-0

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

Rationale:

- The measure is currently used in the Pennsylvania Health Care Quality Alliance, the Commission on Cancer, and the National Cancer Data Base reporting programs.
- The developer provided improvement results showing increases in the overall facility level compliance rates and across all patient demographics.
- The Committee agreed that the measure meets the usability and use criterion.

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5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-19**; **N-1**

6. Public and Member Comment

- No comments were received.

7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-16; N-0

Decision: Approved for continued endorsement

8. Board of Directors Vote: Yes (October 25, 2016)

Decision: Ratified for continued endorsement

9. Appeals: No appeals were received.

0220 Adjuvant hormonal therapy

Submission | Specifications

Description: Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage T1cN0M0,IB to III, who's primary tumor is progesterone or estrogen receptor positive with tamoxifen or third generation aromatase inhibitor (recommended or administered) within 1 year (365 days) of diagnosis.

Numerator Statement: Hormone therapy is administered within 1 year (365 days) of the date of diagnosis or it is recommended but not received

Denominator Statement: Include if all of the following characteristics are identified:

Women

Age >=18 at time of diagnosis

Known or assumed to be first or only cancer diagnosis

Epithelial malignancy only

Primary tumors of the breast

AJCC T1cN0M0 or Stage IB - III

Primary tumor

Exclusions: Exclude, if any of the following characteristics are identified:

Men

Under age 18 at time of diagnosis

Second or subsequent cancer diagnosis

Tumor not originating in the breast

Non-epithelial malignancies, exclude malignant phyllodes tumors, 8940 - Mixed tumor, malignant, NOS, 8950 - Mullerian mixed tumor , 8980 - Carcinosarcoma,8981 - Carcinosarcoma, embryona

Stage 0, in-situ tumor

AJCC T1mic, or T1a tumor

Stage IV, metastatic tumor

Primary tumor is estrogen receptor negative and progesterone receptor negative
None of 1st course therapy performed at reporting facility
Died within 1 year (365 days) of diagnosis,
Patient enrolled in a clinical trial that directly impacts delivery of the standard of care
Adjustment/Stratification: No risk adjustment or risk stratification
Level of Analysis: Facility
Setting of Care: Hospital/Acute Care Facility
Type of Measure: Process
Data Source: Paper Medical Records, Electronic Clinical Data : Registry
Measure Steward: Commission on Cancer, American College of Surgeons

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STANDING COMMITTEE MEETING [05/18-19/2016]

1. Importance to Measure and Report: The measure meets the Importance criteria
(1a. Evidence, 1b. Performance Gap)
1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-10**; **M-10; L-0**; **I-0**
Rationale:

- For the 2012 endorsement evaluation, the developer provided a clinical practice guideline from the National Comprehensive Cancer Network (NCCN) as evidence to support the administration of tamoxifen or third generation aromatase inhibitor to breast cancer patients whose primary tumor is progesterone or estrogen receptor positive. The developer also included results of a systematic review of several randomized control trials (RCTs) and meta-analyses demonstrating a 25% reduction in risk of distant cancer recurrence and death.
- The Committee agreed that the evidence basis for the measure has not changed and there was no need to repeat the discussion and vote on evidence.
- For the current evaluation, the developer provided national trend data from the National Cancer Data Base (NCDB) from 2008 and 2012. The mean performance rate for 2008 was 78.7% and 85.5% for 2012. The developer stated that the performance rate for 2013 was 90.1% (the most current data was not available at the time submission and will be submitted during the commenting period). The Committee noted that the performance data provided by the developer is from CoC-accredited centers only; therefore, the gaps in care and disparities may be larger if the measure was implemented in non-CoC-accredited centers.
- The Committee agreed that based on the performance and disparities data provided by the developer, a gap in care continues to exist in the administration of adjuvant hormonal therapy for breast cancer patients.

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2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability Criteria
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
Initial 2a. Reliability: **M-9**; **L-9**; **I-2** 2b. Validity: **M-9**; **L-9**; **I-2**
Re-vote on 2a. Reliability: **H-2; M-12** 2b. Validity: **H-2; M-12**
Rationale:

- The developer clarified that the definition for "hormone therapy is administered" included documentation of a prescription and the date the prescription was filled or the date the treatment was started. The Committee noted that during the previous review of the measure, the previous Committee recommended that in future iterations, the measure capture that patients are receiving the appropriate dose of hormonal therapy, appropriateness of hormonal therapy based upon menopausal state of the patient, and patient adherence to the hormonal therapy through filled prescriptions. The developer did not update the measure specifications with any of these recommendations.
- For the 2012 endorsement evaluation, the developer provided mean performance rates that included 1,400 CoC-accredited cancer programs and approximately 65,200 cases from 2007 (76.6) and 2008 (77.1).
- For the current evaluation, the developer provided updated mean performance rates (85.5) from 2012. NQF reliability testing requirements include statistical analysis of the computed measure score or the individual patient-level data for the measured entities to determine the proportion of variation due to true differences vs. noise or random variation. Overall performance rates do not meet the reliability criterion, which was provided by the developer. Data element validity testing was performed and counted for data element reliability.
- For the 2012 endorsement evaluation, validity was assessed by randomly selecting charts and reviewing them by site surveyors to determine completeness and validity of data reported to registry. The measure denominator and numerator were viewed by the end-users within these cancer programs as valid and as an appropriate reflection of the standard of care described in NCCN clinical guidelines.
- For the current evaluation, the developer provided additional details on data element validity testing conducted in 2009 and 2010 by comparing registry data to data that were re-abstracted from the medical records by CoC site surveyors, which was considered the gold standard. The developer provided percentage agreement results for 2 of the data elements included in the numerator, timing for hormone therapy (84.3, 79.1) and hormone therapy which was recommended but not administered (77.9, 91.1). Validity testing of all the critical data elements (including kappa scores, sensitivity, or specificity statistics) was not provided. The Committee noted that the measure specifications for this measure are not consistently implemented due to various patient factors such as the physician recommending hormone therapy, the patient obtaining a prescription, declining hormone therapy, and then possibly starting hormone therapy. The Committee also noted that the performance gap may not be accurate due to the variability in percent agreement of the data elements between the data submitted to the registry and the re-abstracted data. The Committee suggested this would lead to hospitals spending their resources to improve their performance rates on the measure rather than improving the overall quality of care for patients.
- The Committee encouraged the developer to provide updated reliability and validity testing at the next maintenance review of the measure. The developer confirmed that they are planning to update their validity and reliability testing for the 5 measures submitted in this project (#0219, #0220, #0223, #0225, and #0559).

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3. Feasibility: H-1; M-15; L-4; I-0

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

Rationale:

- Although the data are readily available through medical records, the Committee recognized the data collection burden for manual chart abstraction that could result in various interpretations.
- The Committee agreed this measure meets the feasibility criterion.

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4. Usability and Use: H-10; M-6; L-4; I-0

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

Rationale:

- The measure is publicly reported through the Pennsylvania Health Care Quality Alliance, the PPS-Exempt Cancer Hospital Quality Reporting program, the Commission on Cancer, various compliance benchmarking programs through the National Cancer Data Base, and Quality Oncology Practice Initiative programs.
- The developer provided improvement results showing increases in the overall facility level compliance rates and across all census regions.
- The Committee agreed that despite some centers, including some of the PPS-exempt cancer hospitals, "topping out", gaps persist among other hospitals, therefore, the performance results from this measure can continue to be used to further the goal of high-quality and efficient healthcare.

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5. Related and Competing Measures

This measure is related to:

- #0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer (AMA-PCPI)
    - The developer stated that the measures are not harmonized because they assess different levels of analysis and different data systems are used to determine eligibility and compliance. Measure #0387 assesses whether hormone therapy was prescribed, whereas #0220 assesses whether hormone therapy was administered within one year of diagnosis or if it was recommended but not received based on patient refusal, medical co-morbidity, or other valid reasons. Measure #0220 assesses compliance at the facility level while #0387 assesses individual physician or practice level performance and the measures use different data sources as well.

Standing Committee Recommendation for Endorsement: **Y-17**; **N-3**

6. Public and Member Comment

- One commenter stated that it would be beneficial to have the measure stipulate administered vs. prescribed and to address who might not receive the treatment via the exclusions.
- Developer response: The language of "recommended or administered" in these measures was specifically selected after discussion with clinicians and users and is based directly on the FORDs data item definitions used to calculate these measures. We agree with that when assessing overall quality, cancer programs should review patients in which treatment is administered and those in which treatment is recommended but not administered. Therefore, in the our reporting systems where compliance with these measures is assessed, cancer programs are able to view cases stratified by if; a) treatment is administered, b) treatment is

recommended but not administered and c) the case is non-compliant with the measure. This allows programs to assess patients which cases are compliant with the measure but for which adjuvant therapy was not administered during internal quality improvement efforts.

- During the Comment period, the developer submitted additional performance data from the Rapid Quality Reporting System (RQRS). The developer stated that the RQRS performance rates were similar to the performance rates from the NCDB.
- The Committee considered the additional performance data from the Rapid Quality Reporting System (RQRS) and agreed this was an important indicator for cancer. On re-vote, the Committee recommended the measure for endorsement.

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7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-16; N-0

Decision: Approved for continued endorsement

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8. Board of Directors Vote: Yes (October 25, 2016)

Decision: Ratified for continued endorsement

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9. Appeals: No appeals were received

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

Submission | Specifications

Description: Percentage of patients under the age of 80 with AJCC III (lymph node positive) colon cancer for whom adjuvant chemotherapy is recommended and not received or administered within 4 months (120 days) of diagnosis.

Numerator Statement: Chemotherapy is administered within 4 months (120 days) of diagnosis or it is recommended and not received

Denominator Statement: Include, if all of the following characteristics are identified:

Age 18-79 at time of diagnosis

Known or assumed to be first or only cancer diagnosis

Primary tumors of the colon

Epithelial malignancy only

At least one pathologically examined regional lymph node positive for cancer (AJCC Stage III)

All or part of 1st course of treatment performed at the reporting facility

Known to be alive within 4 months (120 days) of diagnosis

Exclusions: Exclude, if any of the following characteristics are identified:

Age <18 and >=80; not a first or only cancer diagnosis; non-epithelial and non-invasive tumors; no regional lymph nodes pathologically examined; metastatic disease (AJCC Stage IV); not treated surgically; died within 4 months (120 days) of diagnosis; Patient participating in clinical trial which directly impacts receipt of standard of care.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Paper Medical Records, Electronic Clinical Data : Registry

Measure Steward: Commission on Cancer, American College of Surgeons

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STANDING COMMITTEE MEETING [5/18-19/2016]

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

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

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-6**; **M-14**; **L-0**; **I-0**

Rationale:

- For the 2012 endorsement evaluation, the developer provided a clinical practice guideline from the National Comprehensive Cancer Network (NCCN) recommending chemotherapy with Stage III colon cancer and a systematic review of the body of evidence demonstrating approximately 25% reduction in risk of death. The developer did not provide updates to the evidence for the current endorsement evaluation. The Committee agreed the evidence basis for the measure has not changed and accepted the previous evidence evaluation without further discussion.
- For the current evaluation, the developer provided national trend data from the National Cancer Data Base (NCDB) from 2008 and 2012. The mean performance rate for 2008 was 82.0% and 86.5% for 2012. The developer stated that the performance rate for 2014 was 86.2% (the most current data was not available at the time submission and will be submitted during the commenting period).
- A Committee member noted that the previous Committee questioned whether Stage 2b colon cancers should be included in the measure. At the time the developer responded that the evidence for the appropriateness of adjuvant chemotherapy for Stage 2b colon cancers was not complete. According to the developer, since the previous review, a German study concluded that Stage 2b colon cancers benefit slightly from adjuvant chemotherapy. The NCCN and American Society of Clinical Oncology (ASCO) guidelines recommend that adjuvant chemotherapy is considered for Stage 2b colon cancers but the number in the study was considered insufficient for the recommendations for be implemented nationally.
- The Committee agreed the developer provided sufficient data on disparities based on race, ethnicity, age, insurance status, income, facility type, and sex and that a gap in care remains and there is opportunity for improvement.

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2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

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

2a. Reliability: **M-13**; **L-6**; **I-1** 2b. Validity: **M-14**; **L-5**; **I-1**

Rationale:

- For the 2012 endorsement evaluation, the developer provided mean performance rates that included 1,400 CoC-accredited cancer programs and approximately 65,200 cases from 2007 (88.1) and 2008 (88.3).

- For the current evaluation, the developer provided updated mean performance rates (86.5) from 2012. NQF reliability testing requirements include statistical analysis of the computed measure score or the individual patient-level data for the measured entities to determine the proportion of variation due to true differences versus noise or random variation. Overall performance rates do not meet the reliability criterion, which was provided by the developer. Data element validity testing was performed and counted for data element reliability.
- For the 2012 endorsement evaluation, validity was assessed by randomly selecting charts and reviewing them by site surveyors to determine completeness and validity of data reported to registry. The measure numerator and denominator were viewed by the clinical constituency within these cancer programs as valid and an appropriate reflection of the standard of care described in NCCN clinical guidelines.
- For the current evaluation, the developer provided additional details on data element validity testing conducted in 2009 and 2010 by comparing registry data to data that were re-abstracted from the medical records by CoC site surveyors, which was considered the gold standard. The developer provided percentage agreement results for two of the data elements included in the numerator (timing of chemotherapy (88.9, 81.8) and therapy recommended but not received (88.5, 92.4)). Although validity of all the critical data elements (including kappa scores, sensitivity or specificity statistics) was not provided, the Committee agreed that the measure specifications were consistently implemented within the registry.
- The Committee agreed that the validity and reliability of the measure was sufficient but encouraged the developer to provide updated reliability and validity testing at the next maintenance review of the measure. The developer confirmed that they are planning to update their validity and reliability testing for the 5 measures submitted in this project (#0219, #0220, #0223, #0225, and #0559).

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3. Feasibility: H-8; M-11; L-1; I-0

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

Rationale:

- The Committee agreed that, while a small level of burden exists, the measure is easily available in medical records and the data elements are routinely captured by national cancer registries.

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4. Usability and Use: H-9; M-11; L-0; I-0

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

Rationale:

- The measure is currently used in the PPS-Exempt Cancer Hospital Quality Reporting program, Pennsylvania Health Care Quality Alliance, the Commission on Cancer, and the National Cancer Data Base reporting programs.
- The developer provided improvement results showing increases in the overall facility level compliance rates and across all patient demographics.
- The Committee agreed that the measure meets the usability and use criterion.

5. Related and Competing Measures

- This measure is related to:
  - #0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients (AMA-PCPI)
- The measures assess different levels of analysis. #0223 assesses facility level performance; #0385 assesses clinical group practice performance.

Standing Committee Recommendation for Endorsement: **Y-20**; **N-0**

6. Public and Member Comment

- No comments were received.

7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-16; N-0

Decision: Approved for continued endorsement

8. Board of Directors Vote: Yes (October 25, 2016)

Decision: Ratified for continued endorsement

9. Appeals: No appeals were received

0225 At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer.

Submission | Specifications

Description: Percentage of patients >18yrs of age, who have primary colon tumors (epithelial malignancies only), at AJCC stage I, II or III who have at least 12 regional lymph nodes removed and pathologically examined for resected colon cancer.

Numerator Statement: >=12 regional lymph nodes pathologically examined.

Denominator Statement: Include, if all of the following characteristics are identified:

Age >=18 at time of diagnosis

Primary tumors of the colon

Epithelial malignancy only

AJCC Stage I, II, or III

Surgical resection performed at the reporting facility

Exclusions: Exclude, if any of the following characteristics are identified:Age <18; non-epithelial and non-invasive tumors; metastatic disease (AJCC Stage IV); not treated surgically at the reporting facility; perforation of the primary site; acute obstruction

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Paper Medical Records, Electronic Clinical Data : Registry

Measure Steward: Commission on Cancer, American College of Surgeons

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STANDING COMMITTEE MEETING [05/18-19/2016]

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

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

1a. Evidence: **H-0**; **M-13**; **L-7**; **I-0**; 1b. Performance Gap: **H-6**; **M-12**; **L-2**; **I-0**

Rationale:

- For the 2012 endorsement evaluation, the developer provided a clinical practice guideline for stage II colon cancer from the National Comprehensive Cancer Network (NCCN). The guideline, based on lower-level evidence, states that if less than 12 lymph nodes are initially identified, it is recommended that the pathologist go back to the specimen and resubmits more tissue of potential lymph nodes. If 12 lymph nodes are still not identified, a comment in the report should indicate that an extensive search for lymph nodes was undertaken. The developer also provided a systematic review of the body of evidence that concluded that there is a lack of consensus on the minimal number of lymph nodes that have to be examined to accurately identify AJCC stage III colon cancer. The systematic review also concluded that an "adequate" lymph node examination was not associated with patient survival.
- The previous Committee in 2012 had noted their concern with the quality of the evidence presented and the lack of evidence demonstrating that 12 lymph nodes be identified. The developer stated that the measure would be updated as the evidence evolved.
- The developer did not provide updates to the evidence for the current endorsement evaluation. The Committee noted that the practice of examining 12 lymph nodes is not evidence-based, but rather an arbitrary number that is not connected to patient outcomes. During the Committee workgroup call, the developer stated that the National Cancer Data Base (NCDB) will be publishing a study demonstrating the relationship between compliance on this measure and outcomes over time. According to the recent studies conducted by NCDB, the developer stated, there is a correlation between the number of lymph nodes examined and patient survival.
- Due to the low-level of evidence, the Committee decided to re-vote on the evidence criterion and agreed the evidence provided was sufficient at this time.
- For the current evaluation, the developer provided national trend data from the National Cancer Data Base (NCDB) from 2008 and 2013. The mean performance rate for 2008 was 81.7% and 89.7% for 2013. The Committee agreed that there was room for improvement though it is unlikely that the percentage will increase much more in high performers, since variation in surgical technique or pathology examination is likely to account for a significant number of patients that do not get to the 12 lymph node goal rather than poor performance.

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2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

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

2a. Reliability: **Previous Reliability Evaluation Accepted** 2b. Validity: **Previous Validity Evaluation Accepted**

Rationale:

- For the 2012 endorsement evaluation, the developer provided mean performance rates that included 1,400 CoC-accredited cancer programs and approximately 37,800 cases from 2007 (80.4) and 2008 (81.5).
- For the current evaluation, the developer provided updated mean performance rates (89.7) from 2012. NQF reliability testing requirements include statistical analysis of the computed measure score or the individual patient-level data for the measured entities to determine the proportion of variation due to true differences versus noise or random variation. Overall performance rates do not meet the reliability criterion, which was provided by the developer. Data element validity testing was performed and counted for data element reliability.
- For the 2012 endorsement evaluation, validity was assessed by randomly selecting charts and reviewing them by site surveyors to determine completeness and validity of data reported to registry. The measure denominator and numerator were viewed by the clinical constituency within these cancer programs as valid and an appropriate reflection of the standard of care described in NCCN clinical guidelines.
- For the current evaluation, the developer provided additional details on data element validity testing conducted in 2009 and 2010 by comparing registry data to data that were re-abstracted from the medical records by CoC site surveyors, which was considered the gold standard. The developer provided percentage agreement results for two of the data elements included in the numerator (timing of chemotherapy (88.9, 81.8) and therapy recommended but not received (88.5, 92.4)). Although validity of all the critical data elements (including kappa scores, sensitivity or specificity statistics) was not provided, the Committee agreed that the measure specifications were consistently implemented within the registry and accepted the previous reliability and validity evaluation.
- The Committee encouraged the developer to provide updated reliability and validity testing at the next maintenance review of the measure. The developer confirmed that they are planning to update their validity and reliability testing for the 5 measures submitted in this project (#0219, #0220, #0223, #0225, and #0559).

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3. Feasibility: H-6; M-11; L-3; I-0

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

Rationale:

- The Committee agreed that, while a small level of burden exists, the measure is easily available in medical records and the data elements are routinely captured by national cancer registries.

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4. Usability and Use: H-9; M-9; L-2; I-0

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

Rationale:

- The measure is currently used in the Pennsylvania Health Care Quality Alliance, the Commission on Cancer's accreditation program and National Cancer Data Base, and the Quality Oncology Practice Initiative (QOPI®).

- The developer provided improvement results showing increases in the overall facility level compliance rates.
- The Committee agreed that the measure meets the usability and use criterion.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-17**; **N-3**

6. Public and Member Comment

- No comments were received.

7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-16; N-0

Decision: Approved for continued endorsement

8. Board of Directors Vote: Yes (October 25, 2016)

Decision: Ratified for continued endorsement

9. Appeals: No appeals were received

0377 Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow

Submission | Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow

Numerator Statement: Patients who had baseline cytogenetic testing performed on bone marrow

Denominator Statement: All patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia

Exclusions: For Registry:

Documentation of medical reason(s) for not performing baseline cytogenetic testing (eg, no liquid bone marrow or fibrotic marrow)

Documentation of patient reason(s) for not performing baseline cytogenetic testing (eg, at time of diagnosis receiving palliative care or not receiving treatment as defined above)

Documentation of system reason(s) for not performing baseline cytogenetic testing (eg, patient previously treated by another physician at the time cytogenetic testing performed)

Adjustment/Stratification: No risk adjustment or risk stratification

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

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: American Society of Hematology

STANDING COMMITTEE MEETING [05/18-19/2016]

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

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

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-10**; **M-11**; **L-0**; **I-0**

Rationale:

- For the 2012 endorsement evaluation, the developer provided a lower-level evidence clinical practice guideline from the National Comprehensive Cancer Network (NCCN) for cytogenetic testing bone marrow of patients with myelodysplastic syndrome (MDS) and acute leukemia (AML).
- For the current evaluation, the Committee noted that the use of newer molecular cytogenetic studies using fluorescence in situ (FISH) is growing and encouraged the developer to include these additional studies. The developer agreed that as new evidence supporting additional studies continues to evolve and the guideline is revised, the measure will also be revised.
- The Committee agreed that higher-level evidence, such as randomized control trials (RCTs), supporting this measure would be limited; therefore, accepted prior evaluation of this criterion without further discussion.
- The developer provided average performance rates from the PQRS Registry from 2010 – 2013. The average performance rate was 88.8% in 2010, 94.6% in 2011, 95.6% in 2012, and 87.0% in 2013. The mean performance rate in 2014 was 95.09%, the minimum was 22.22%, and the maximum was 100.0%. The developer did not provide data on disparities from the measure as specified and stated they are not aware of any literature that addresses disparities in patients with ACL and MDS receiving baseline cytogenetic testing. The Committee agreed that performance has improved over time but there is still an opportunity for improvement.
- The developer referenced additional data from the study conducted by Dr. Gregory Abel suggesting 74% of patients had baseline cytogenetic testing performed on bone marrow indicating a performance gap (Abel, G. A., Cronin, A. M., Odejide, O. O., Uno, H., Stone, R. M. and Steensma, D. P. (2016), Influence of patient and provider characteristics on quality of care for the myelodysplastic syndromes. Br J Haematol, 173: 713–721. doi:10.1111/bjh.13987).

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2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

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

2a. Reliability: **H-2**; **M-18**; **L-1**; **I-0** 2b. Validity: **M-20**; **L-1**; **I-0**

Rationale:

- For the 2012 endorsement evaluation, inter-rater reliability was conducted on 29 acute leukemia patient records and 31 MDS patient records from 2 hematology practice sites. The percent agreement for the numerator was 98.3%, 100.0% for the denominator and the exclusions/exceptions, and 98.3% for overall reliability.

- For the current evaluation, the developer provided updated reliability testing of the measure score using a beta-binomial model to assess the signal-to-noise ratio. Reliability at the minimum level of quality reporting events (10) was 0.68 and 0.82 at the average number of quality events (21.0). A reliability of 0.70 is generally considered a minimum threshold for reliability.
- The Committee agreed that the updated reliability testing results were satisfactory and met the reliability criterion.
- For the 2012 endorsement evaluation, face validity of the measure score as an indicator of quality was systematically assessed by an expert panel. The expert panel agreed that the scores obtained from the measure as specified provide an accurate reflection of quality and can be used to distinguish good and poor quality.
- For the current evaluation, the developer conducted additional face validity testing with a panel of 23 experts representing the American Society of Hematology (ASH) Committee on Quality. Ninety-four percent of the total respondents (18) either agreed or strongly agreed that the measure can accurately distinguish good and poor quality. The Committee discussed the overall exclusion rate of 1.2% and determined that the exclusions are appropriate.
- The Committee agreed that the updated validity testing results were sufficient and met the validity criterion.

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3. Feasibility: H-3; M-17; L-1; I-0

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

Rationale:

- The Committee did not note any concerns regarding feasibility, acknowledging that the data elements used to construct this measure are based on clinical registry data and available in electronic sources.

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4. Usability and Use: H-4; M-17; L-0; I-0

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

Rationale:

- The Committee noted that this measure is used in PQRS and will be available for public reporting on Physician Compare in late 2017.

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5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-21**; **N-0**

6. Public and Member Comment

- No comments were received.

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7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-16; N-0

Decision: Approved for continued endorsement

8. Board of Directors Vote: Yes (October 25, 2016)

Decision: Ratified for continued endorsement

9. Appeals: No appeals were received

0378 Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy

Submission | Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) who are receiving erythropoietin therapy with documentation of iron stores within 60 days prior to initiating erythropoietin therapy

Numerator Statement: Patients with documentation of iron stores within 60 days prior to initiating erythropoietin therapy

Denominator Statement: All patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) who are receiving erythropoietin therapy

Exclusions: Documentation of system reason(s) for not documenting iron stores prior to initiating erythropoietin therapy

Adjustment/Stratification: No risk adjustment or risk stratification

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

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: American Society of Hematology

STANDING COMMITTEE MEETING [05/18-19/2016]

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

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

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-9**; **M-10**; **L-1**; **I-0**

Rationale:

- For the 2012 endorsement evaluation, the developer provided a lower-level evidence clinical practice guideline from the National Comprehensive Cancer Network (NCCN) that states that iron repletion be verified before instituting erythropoietin or darbepoetin therapy.
- For the current evaluation, the Committee agreed that higher-level evidence, such as randomized control trials (RCTs), supporting this measure would be limited; therefore, accepted prior evaluation of this criterion without further discussion.
- The developer provided average performance rates from the Physician Quality Reporting System (PQRS) Registry from 2010 – 2013. The average performance rate was 94.7% in 2010, 97.7% in 2011, 95.3% in 2012, and 83.1% in 2013. The mean performance rate in 2014 was 54.58%, the

minimum was 0.0%, and the maximum was 100.0%. The developer did not provide data on disparities from the measure as specified and stated they are not aware of any literature outlining disparities for the documentation of iron stores in patients receiving erythropoietin therapy.
- The Committee agreed that performance has improved over time but there is still an opportunity for improvement.
- The study, conducted by Dr. Gregory Abel, and referenced during the discussion for #0377, found that 56.0% of patients had pre-erythropoiesis-stimulating agent (ESA) assessments.

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2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-1**; **M-15**; **L-4**; **I-0** 2b. Validity: **M-16**; **L-3**; **I-1**

<u>Rationale</u>:

- For the 2012 endorsement evaluation, inter-rater reliability was conducted on 41 myelodysplastic syndrome (MDS) patient records from 2 hematology practice sites. The percent agreement for the numerator was 90.2%, 100.0% for the denominator and the exclusions/exceptions, and 90.2% for overall reliability.
- For the current evaluation, the developer provided updated reliability testing of the measure score using a beta-binomial model to assess the signal-to-noise ratio. Reliability at the minimum level of quality reporting events (10) was 0.88 and 0.93 at the average number of quality events (18.4). A reliability of 0.70 is generally considered a minimum threshold for reliability.
- The developer clarified that to meet a portion of the denominator; the provider must attest that a qualifying patient is receiving erythropoietin therapy.
- The Committee encouraged the developer to consider including periodic monitoring of iron stores (in addition to baseline iron stores), to reduce the need for ESAs, maximize symptomatic improvement for patients, and determine the reason for failure to respond adequately to ESA therapy as currently indicated in the NCCN practice guideline.
- The Committee agreed that the updated reliability testing results were satisfactory and met the reliability criterion.
- For the 2012 endorsement evaluation, face validity of the measure score as an indicator of quality was systematically assessed by an expert panel. The expert panel agreed that the scores obtained from the measure as specified provide an accurate reflection of quality and can be used to distinguish good and poor quality.
- For the current evaluation, the developer conducted additional face validity testing with a panel of 23 experts representing the American Society of Hematology (ASH) Committee on Quality. Eighty-nine percent of the total respondents (18) either agreed or strongly agreed that the measure can accurately distinguish good and poor quality.
- The Committee questioned the developer about the seemingly excessive exclusion/exception rate of 97 exclusions/exceptions per 28 providers with an overall rate of 15.8%. The developer explained that they recommend providers document the specific reasons for exclusion/exception in patients' medical records for purposes of optimal patient management and audit-readiness. However, they are not able to obtain the specific reasons for not documenting iron stores prior to initiating erythropoietin therapy from PQRS data submitted to CMS. The developer also noted that, due to the high exclusion/exception rate, they have requested additional data from CMS to ensure that the measure is being reported accurately.

- Despite the potential threat to validity due to the high rate of exclusion/exception rates, the Committee agreed that without specific information about the exclusions/exceptions, it was difficult to understand how validity of the measure overall was impacted; therefore, the updated validity testing results were sufficient and met the validity criterion.

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3. Feasibility: H-5; M-13; L-1; I-1

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

Rationale:

- The Committee did not note any concerns regarding feasibility, acknowledging that the data elements used to construct this measure are based on clinical registry data and available in electronic sources.

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4. Usability and Use: H-7; M-12; L-1; I-0

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

Rationale:

- The Committee noted that this measure is used in PQRS and will be available for public reporting on Physician Compare in late 2017.

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5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-18**; **N-2**

6. Public and Member Comment

- One commenter stated that it is unlikely that this measure will have a performance rate of 100.0%; therefore, an outcome measure based on the patient benefit of ESAs with respect to iron stores may be more appropriate.

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7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-16; N-0

Decision: Approved for continued endorsement

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8. Board of Directors Vote: Yes (October 25, 2016)

Decision: Ratified for continued endorsement

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9. Appeals: No appeals were received

0389 Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Submission | Specifications

Description: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer

Numerator Statement: Patients who did not have a bone scan performed at any time since diagnosis of prostate cancer

Denominator Statement: All patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence, receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy

Exclusions: Documentation of medical reason(s) for having a bone scan performed (including documented pain, salvage therapy, other medical reasons)

Documentation of system reason(s) for having a bone scan performed (including bone scan ordered by someone other than reporting physician)

Adjustment/Stratification: No risk adjustment or risk stratification

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

Setting of Care: Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Other

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry

Measure Steward: PCPI

STANDING COMMITTEE MEETING [05/18-19/2016]

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

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

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-2**; **M-15**; **L-2**; **I-0**

Rationale:

- For the 2012 endorsement evaluation, the developer provided a best practice statement, a clinical practice guideline, and a systematic review of the body of evidence to demonstrate the use of bone scans for low risk prostate cancer patients is not supported by the evidence, is extremely costly, and unnecessarily exposes patients to radiation.
- For the current evaluation, the developer updated the evidence with updates to the best practice statement and clinical practice guideline. There were no changes to the recommendations since the previous submission.
- The developer also provided new evidence from the 2012 American College of Radiology (ACR) Appropriateness Criteria: Prostate Cancer – Pretreatment Detection, Staging, and Surveillance. The ACR criteria recommends that only patients with a PSA ≥20 ng/ml (with any T stage or Gleason score), locally advanced disease (T3 or T4 with any PSA or Gleason score), or Gleason

score ≥8 (with any PSA or T stage) should be considered for a radionuclide bone scan. Patients with skeletal symptoms or advanced-stage disease should also be considered candidates for bone scans.

- The Committee agreed that the updated evidence supports the measure focus and has a stronger level of evidence. The Committee accepted the prior evaluation of this criterion without further discussion.
- The developer provided group/practice level performance data from 2014 PQRS EHR, Registry, and Part B Claims. The mean performance rate for EHR data was 90.76% and 90.24% for registry data. The developer also provided average performance rates from the PQRS Experience Report from 2010-2013. The average performance rate was 71.6% in 2010, 90.5% in 2011, 92.5% in 2012, and 88.5% in 2013. The developer did not provide data on disparities from the measure as specified but cited literature showing higher morbidity and mortality of prostate cancer in African-Americans. Another citation suggests that imaging overuse is associated with nonwhite race, education, income, and region. The Committee agreed that performance has improved over time but there is still an opportunity for improvement.

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2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **Previous Reliability Evaluation Accepted** 2b. Validity: **Previous Validity Evaluation Accepted**

<u>Rationale</u>:

- For the 2012 endorsement evaluation, inter-rater reliability was conducted on 94 patient records from 2010; chart and data auditing occurred in 2011. The percent agreement for the numerator, denominator, exclusions/exceptions, and overall was 100.0%.
- For the current evaluation, the developer provided updated reliability testing of the measure score using a beta-binomial model to assess the signal-to-noise ratio. Reliability at the minimum level of quality reporting events (10) was 0.84 and 0.96 at the average number of quality events (46.0).
- The Committee agreed that the updated reliability testing results were satisfactory and accepted the prior evaluation of this criterion without further discussion.
- For the 2012 endorsement evaluation, face validity of the measure score as an indicator of quality was systematically assessed by an expert panel. The expert panel agreed that the scores obtained from the measure as specified provide an accurate reflection of quality and can be used to distinguish good and poor quality.
- For the current evaluation, the developer conducted additional face validity testing with a panel of 17 experts representing the PCPI Measures Advisory Committee. A total of 80% (10) of the respondents either agreed or strongly agreed that the measure can accurately distinguish good and poor quality. The Committee discussed the overall exclusion rate of 14.1% and determined that the exclusions are appropriate.
- The Committee agreed that the updated validity testing results were sufficient and accepted the prior evaluation of this criterion without further discussion.

3. Feasibility: H-10; M-9; L-0; I-0

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

Rationale:

- The Committee did not note any concerns regarding feasibility, acknowledging that the data elements used to construct this measure are based on clinical registry data and available in electronic sources.

4. Usability and Use: H-13; M-6; L-0; I-0

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

Rationale:

- The Committee noted that this measure is used in PQRS and will be available for public reporting on Physician Compare in late 2017.
- No unintended consequences have been identified. Nonetheless, the Committee noted a potential consequence of decreasing bone scan testing rates would be undiagnosed metastatic disease; however, this is unlikely based on the evidence for low-risk prostate cancer patients.

5. Related and Competing Measures

- This measure is related to:
    - #0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients
    - #1853: Radical Prostatectomy Pathology Reporting
- Measures #0390 and #1853 assess different target populations and different aspects of prostate cancer care.

Standing Committee Recommendation for Endorsement: **Y-19**; **N-0**

6. Public and Member Comment

- No comments were received.

7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-16; N-0

Decision: Approved for continued endorsement

8. Board of Directors Vote: Yes (October 25, 2016)

Decision: Ratified for continued endorsement

9. Appeals: No appeals were received

0390 Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

Submission | Specifications

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)

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

Denominator Statement: 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

Exclusions: AUA methodology uses three categories of reasons for which a patient may be excluded from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For this measure, exceptions for not prescribing/administering adjuvant hormonal therapy may include medical reason(s) (eg, salvage therapy) or patient reason(s). Although this methodology does not require the external reporting of more detailed exception data, the AUA recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The AUA also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that physicians have identified as meeting the criteria for exception. Additional details by data source are as follows:

Documentation of medical reason(s) for not prescribing/administering adjuvant hormonal therapy (eg, salvage therapy)

Documentation of patient reason(s) for not prescribing/administering adjuvant hormonal therapy

Adjustment/Stratification: No risk adjustment or risk stratification

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

Setting of Care: Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Other

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Registry

Measure Steward: American Urological Association

STANDING COMMITTEE MEETING [05/18-19/2016]

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

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

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-1**; **M-13**; **L-5**; **I-1**

Rationale:

- For the 2012 endorsement evaluation, the developer provided clinical practice guidelines from the American Urological Association (AUA) and the National Comprehensive Cancer Network

(NCCN) stating physicians should consider the use of external beam radiotherapy and concurrent use of hormonal therapy in high-risk prostate cancer patients to prolong survival.

- For the current evaluation, the developer provided updates to the guidelines, and included a Cochrane Review of the body of evidence. There were no changes to the recommendations since the previous submission. The Committee agreed that the updated evidence supports the measure focus and has a stronger level of evidence. The Committee accepted the prior evaluation of this criterion without further discussion.
- The developer provided average performance rates from the Physician Quality Reporting System (PQRS) Registry from 2010 – 2013. The average performance rate was 79.6% in 2010, 93.5% in 2011, 91.1% in 2012, and 95.4% in 2013. The mean performance rate in 2014 was 93.82%, the minimum was 16.67%, and the maximum was 100.0%. The developer did not provide data on disparities from the measure as specified but provided evidence from the literature that demonstrated higher incidence rates of prostate cancer in African-American men compared to white men. The literature also showed that African-American men are more likely to receive non-surgical treatment than white men and white men were less likely than African-American men to receive radiation therapy and hormonal therapy.
- The developer also cited an analysis of data from the Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE) registry that found that the utilization of adjuvant hormonal therapy and external beam radiotherapy for high-risk patients has increased to 80.0% throughout the past two decades, yet utilization rates have plateaued since 2000.
- The Committee agreed that performance has improved over time but there is still an opportunity for improvement.

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2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **Previous Reliability Evaluation Accepted** 2b. Validity: **M-14**; **L-5**; **I-1**

<u>Rationale</u>:

- For the 2012 endorsement evaluation, inter-rater reliability was conducted on 91 patient records from 2010; chart and data auditing occurred in 2011. The percent agreement for the numerator, denominator, and exclusions/exceptions was 100.0% and 98.9% for overall reliability.
- For the current evaluation, the developer provided updated reliability testing of the measure score using a beta-binomial model to assess the signal-to-noise ratio. Reliability at the minimum level of quality reporting events (10) was 0.73 and 0.85 at the average number of quality events (21.5). A reliability of 0.70 is generally considered a minimum threshold for reliability.
- The Committee agreed that the updated reliability testing results were satisfactory and accepted the prior evaluation of this criterion without further discussion.
- For the 2012 endorsement evaluation, face validity of the measure score as an indicator of quality was systematically assessed by an expert panel. The expert panel agreed that the scores obtained from the measure as specified provide an accurate reflection of quality and can be used to distinguish good and poor quality.
- For the current evaluation, the developer conducted additional face validity testing with a panel of 21 experts representing the AUA Committee on Quality Improvement and Patient Safety. One hundred percent of the total respondents (15) either agreed or strongly agreed that this measure can accurately distinguish good and poor quality.

- The Committee discussed the seemingly excessive exclusion/exception rate of 204 exclusions/exceptions per 20 providers with an overall rate of 32.2%. One of the Committee members noted that although some patients should not receive adjuvant hormonal therapy, the exclusion/exception rate appeared relatively high. The Committee also questioned the usefulness of the measure since one-third of the patients were excluded.
- Despite the potential threat to validity due to the high rate of exclusion/exception rates, the Committee agreed that without specific information about the exclusions/exceptions, it was difficult to understand how validity of the measure overall was impacted; therefore, the updated validity testing results were sufficient and met the validity criterion.

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3. Feasibility: H-9; M-10; L-0; I-1

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

Rationale:

- The Committee did not note any concerns regarding feasibility, acknowledging that the data elements used to construct this measure are based on clinical registry data and available in electronic sources.

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4. Usability and Use: H-8; M-11; L-1; I-0

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

Rationale:

- The Committee noted that this measure is used in the Physician Quality Reporting System (PQRS) and is also used in the AUA Quality (AQUA) Registry.

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5. Related and Competing Measures

- This measure is related to:
    - 0220: Adjuvant hormonal therapy
    - 0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients
    - 1853: Radical Prostatectomy Pathology Reporting
- According to the developer the measures specifications are not completely harmonized. Measure #0220 focuses on adjuvant hormonal therapy for breast cancer patients. Measures #0389 and #1853 have different target populations and address different aspects of prostate cancer care.

Standing Committee Recommendation for Endorsement: **Y-19**; **N-1**

6. Public and Member Comment

- No comments were received.

7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-16; N-0

Decision: Approved for continued endorsement

8. Board of Directors Vote: Yes (October 25, 2016)

Decision: Ratified for continued endorsement

9. Appeals: No appeals were received

0508 Diagnostic Imaging: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms

Submission | Specifications

Description: Percentage of final reports for screening mammograms that are classified as "probably benign"

Numerator Statement: Final reports classified as "probably benign"

Denominator Statement: All final reports for screening mammograms

Exclusions: No Denominator Exclusions or Denominator Exceptions

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Imaging Facility

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data : Registry

Measure Steward: American College of Radiology (ACR)

STANDING COMMITTEE MEETING [05/18-19/2016]

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

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

1a. Evidence: **H-0**; **M-7**; **L-0**; **I-13**; 1b. Performance Gap: **H-3**; **M-14**; **L-4**; **I-0**; Evidence Exception: **Y-20; N-1**

Rationale:

- For the 2008 endorsement evaluation,[1] the developer provided a guideline recommendation from the American College of Radiology (ACR) Breast Imaging Reporting Data System (BI-RADS®) Atlas, 2003 that stated: Do not use "probably benign" (Category 3) in interpreting screening examinations (level of evidence is not graded).
- For the current evaluation, the developer provided several sources of evidence that did not support the measure focus including an updated recommendation from the ACR BI-RADS® 5th edition, 2012 that recommends overall final assessment of findings should be based on all imaging studies performed up to that day. In addition, they must be classified according to the FDA-approved final assessment categories and should follow the define categories (level of

evidence is not graded). The developer also provided a recommendation from the U.S. Preventive Services Task Force (USPSTF) that included biennial screening mammography for women within different age groups and risks. The developer did, however, provide 8 studies from the literature addressing the "probably benign" category.

- Based on NQF criteria, the evidence was insufficient due to lack of empirical evidence provided to support this process of care: "probably benign" should not be used as a category for indeterminate findings. The Committee agreed that the evidence was insufficient but that it is beneficial to hold providers accountable for performance in the absence of empirical evidence of benefits to patients.
- The developer provided physician performance rates from the CMS Physician Quality Reporting System (PQRS) from 2012 – 2014. The performance rate in 2012 was 2.09%, 5.48% in 2013, and 0.49% in 2014. The goal of this measure is a zero-reporting rate. The developer did not provide data on disparities from the measure as specified.
- The Committee agreed that based on the performance data provided by the developer, providers were still using the "probably benign" assessment category 0.49% of the time in 2014, therefore, an opportunity for improvement still exists.

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2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **Previous Reliability Evaluation Accepted** 2b. Validity: **Previous Validity Evaluation Accepted**;

<u>Rationale</u>:

- For the 2012 endorsement evaluation,[2] inter-rater reliability was conducted on 114 patient records from 3 radiology practices from 2010. The percent agreement for the numerator, denominator, and overall reliability was 100.0%.
- For the current evaluation, the developer provided updated reliability testing of the measure score using a beta-binomial model to assess the signal-to-noise ratio. The mean reliability was 0.99. A reliability of 0.70 is generally considered a minimum threshold for reliability.
- The Committee agreed that the updated reliability testing results were satisfactory and accepted the prior evaluation of this criterion without further discussion.
- For the 2012 endorsement evaluation,[3] face validity of the measure score as an indicator of quality was systematically assessed by an expert panel. The expert panel agreed that the scores obtained from the measure as specified provide an accurate reflection of quality and can be used to distinguish good and poor quality.
- For the current evaluation, the developer conducted additional face validity testing with a panel of 20 experts representing the ACR Commission on Breast Imaging and the National Mammography Database. Eleven respondents either agreed or strongly agreed that physicians who perform well on this measure demonstrate a higher level of quality than physicians who do not perform well on this measure.
- The Committee agreed that the updated validity testing results were satisfactory and accepted the prior evaluation of this criterion without further discussion.

3. Feasibility: H-19; M-1; L-1; I-0

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

Rationale:

- The Committee did not note any concerns regarding feasibility, acknowledging that the data elements used to construct this measure are based on clinical registry data and available in electronic sources.

4. Usability and Use: H-17; M-3; L-1; I-0

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

Rationale:

- The Committee noted that this measure is used in the Physician Quality Reporting System (PQRS) and Value Based Payment Modifier.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-20**; **N-1**

6. Public and Member Comment

- No comments were received.

7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-16; N-0

Decision: Approved for continued endorsement

8. Board of Directors Vote: Yes (October 25, 2016)

Decision: Ratified for continued endorsement

9. Appeals: No appeals were received

0509 Diagnostic Imaging: Reminder System for Screening Mammograms

Submission | Specifications

Description: Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram

Numerator Statement: Patients whose information is entered into a reminder system with a target due date for the next mammogram

Denominator Statement: All patients undergoing a screening mammogram

Exclusions: Documentation of medical reason(s) for not entering patient information into a reminder system [(eg, further screening mammograms are not indicated, such as patients with a limited life expectancy, other medical reason(s)]

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Clinician : Individual

Setting of Care: Hospital/Acute Care Facility, Imaging Facility

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data : Registry

Measure Steward: American College of Radiology

STANDING COMMITTEE MEETING [05/18-19/2016]

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

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

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-5; M-14**; **L-1**; **I-1**

Rationale:

- For the 2008 endorsement evaluation,[4] the developer provided a guideline recommendation from the American College of Radiology (ACR) Breast Imaging Reporting Data System (BI-RADS®) Atlas, 2003 that stated: Do not use 'probably benign' (Category 3) in interpreting screening examinations (level of evidence is not graded).
- For the current evaluation, the developer provided a recommendation from the Community Preventive Services Task Force that recommends the use of client reminders to increase screening for breast and cervical cancers on the basis of strong evidence of effectiveness.
- The Committee agreed that the updated evidence provided was stronger than the previous evidence and accepted the prior evaluation of this criterion without further discussion.
- The developer provided physician performance rates from the CMS Physician Quality Reporting System (PQRS) from 2012 – 2014. The performance rate in 2012 was 79.4%, 86.0% in 2013, and 87.6% in 2014. The developer did not provide data on disparities from the measure as specified but cited a 2010 National Health Interview Survey that demonstrated Asian race, low education status, recent immigrant status, and no regular source of medical care or no medical insurance were factors found to reduce the likelihood for a woman to receive a mammogram.
- The Committee agreed that based on the performance data provided by the developer, an opportunity for improvement still exists.

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2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

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

2a. Reliability: **Previous Reliability Evaluation Accepted** Initial 2b. Validity: **M-9**; **L-7**; **I-5**

Re-vote on 2b. Validity: **M-13; L-7**

Rationale:

- For the 2012 endorsement evaluation,[5] inter-rater reliability was conducted on 114 patient records from 3 radiology practices from 2010. The percent agreement for the numerator, denominator, and overall reliability was 100.0%.
- For the current evaluation, the developer provided updated reliability testing of the measure score using a beta-binomial model to assess the signal-to-noise ratio. The mean reliability was 0.88. A reliability of 0.70 is generally considered a minimum threshold for reliability.
- The Committee agreed that the updated reliability testing results were satisfactory and accepted the prior evaluation of this criterion without further discussion.
- For the 2012 endorsement evaluation,[6] face validity of the measure score as an indicator of quality was systematically assessed by an expert panel. The expert panel agreed that the scores obtained from the measure as specified provide an accurate reflection of quality and can be used to distinguish good and poor quality.
- For the current evaluation, the developer conducted additional face validity testing with a panel of 20 experts representing the ACR Commission on Breast Imaging and the National Mammography Database. Ten respondents generally agreed that physicians who perform well on this measure demonstrate a higher level of quality than physicians who do not perform well on this measure.
- The exclusion, 'medical reason documentation' was added in 2014; however, the developer did not conduct an analysis to determine the impact of this exclusion on the validity of the measure. The developer stated that the exclusion allows physicians to report on the measure if a patient's information was not entered into a reminder system because it was determined that they did not need to return for a screening mammogram due to decreased life expectancy, history of a mastectomy, or some other medical reason. The developer explained that the exclusion should not be a threat to validity because it was only used 3 times during 2014. Committee members then questioned why the exclusions were so low considering that the developer was reporting Medicare data from PQRS and expected the number of exclusions to be higher in the Medicare population. This raised concerns about the exclusion not being used properly by physicians and the need for the exclusion. During the post-comment call, the developer stated that they would analyze the 2015 PQRS data and consider removing the exclusion. The developer will provide the additional data analysis during the measure's annual review (within one year) for the Committee's review. The Committee re-voted on the validity of the measure and recommended it for endorsement.

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3. Feasibility: H-0; M-19; L-0; I-2

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

Rationale:

- This measure is based on clinical registry data and all data elements are available in electronic sources.
- While the Committee did recommend having an age range for women in the denominator, they agreed the measure was feasible.

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4. Usability and Use: H-1; M-18; L-2; I-0

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

Rationale:

- The Committee noted that this measure is used in PQRS and is also used for quality improvement with benchmarking in the ACR NRDR Qualified Clinical Data Registry.

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5. Related and Competing Measures

- This measure is related to:
  - #2372: Breast Cancer Screening (NQCA)
- The developer stated that the measures have the same measure focus and target population. According to the developer, the measure specifications are completely harmonized.

Standing Committee Recommendation for Endorsement: **Y-18**; **N-3**

6. Public and Member Comment

- No comments were received.

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7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-16; N-0

Decision: Approved for continued endorsement

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8. Board of Directors Vote: Yes (October 25, 2016)

Decision: Ratified for continued endorsement

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9. Appeals: No appeals were received

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.

Submission | Specifications

Description: Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage T1cN0M0 (tumor greater than 1 cm), or Stage IB -III, whose primary tumor is progesterone and estrogen receptor negative recommended for multiagent chemotherapy (recommended or administered) within 4 months (120 days) of diagnosis.

Numerator Statement: Combination chemotherapy is administered within 4 months (120 days) of the date of diagnosis or it is recommended and not received.

Denominator Statement: Women under the age of 70 with AJCC T1cN0M0, or Stage IB-III hormone receptor negative breast cancer:

- Women
- Age 18-69 at time of diagnosis
- Known or assumed first or only cancer diagnosis
- Primary tumors of the breast

- Epithelial invasive malignance

Exclusions: Exclude, if any of the following characteristics are identified:

Men;

Age <18 and >=70;

not a first or only cancer diagnosis;

non-epithelial and non-invasive tumors;

phyllodes tumor histology;

rare histology not supported by clinical trials: 8940 - Mixed tumor, malignant, NOS, 8950 - Mullerian mixed tumor, 8980 – Carcinosarcoma, 8981 - Carcinosarcoma, embryonal

Tumor size <=1cm and AJCC pN=0;

ERA positive;

PRA positive;

Evidence of in situ or metastatic disease;

Not treated surgically;

Died within 4 months (120 days) of diagnosis;

Participation in a clinical trial which directly impacts the delivery of the standard of care

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Paper Medical Records, Electronic Clinical Data : Registry

Measure Steward: Commission on Cancer, American College of Surgeons

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STANDING COMMITTEE MEETING [05/18-19/2016]

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

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

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-7**; **M-12**; **L-1**; **I-0**

Rationale:

- For the 2012 endorsement evaluation, the developer provided a clinical practice guideline from the National Comprehensive Cancer Network (NCCN) as evidence to support the administration of combination chemotherapy to breast cancer patients whose primary tumor is progesterone and estrogen receptor negative. The developer also included a systematic review of the body of evidence with multiple randomized clinical trials demonstrating approximately 33.0% reduction in risk of distant cancer recurrence and death.
- The Committee agreed that the evidence basis for the measure has not changed and there was no need to repeat the discussion and vote on evidence.
- For the current evaluation, the developer provided national trend data from the National Cancer Data Base (NCDB) from 2008 and 2013. The mean performance rate for 2008 was 85.1% and 89.4% for 2013.

- The Committee agreed that based on the performance and disparities data provided by the developer, a gap in care continues to exist in the administration of combination chemotherapy for breast cancer patients.
- The Committee suggested monitoring the impact of emerging breast cancer data and new genomic assays that may potentially exclude patients with hormone receptor negative tumors from receiving chemotherapy.

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2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

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

Initial 2a. Reliability: **M-9**; **L-9**; **I-2** 2b. Validity: **M-9**; **L-9**; **I-2**

Re-vote on 2a. Reliability: **H-2; M-12** 2b. Validity: **H-2; M-12**

Rationale:

- For the 2012 endorsement evaluation, the developer provided mean performance rates that included 1,400 CoC-accredited cancer programs and approximately 14,000 cases from 2007 (86.3) and 2008 (84.9).
- For the current evaluation, the developer provided updated performance rates from 2013 showing the hospital-level performance rates from 0% to 100%. NQF reliability testing requirements include statistical analysis of the computed measure score or the individual patient-level data for the measured entities to determine the proportion of variation due to true differences vs. noise or random variation. Overall performance rates do not meet the reliability criterion, which was provided by the developer. Data element validity testing was performed and counted for data element reliability.
- For the 2012 endorsement evaluation, validity was assessed by randomly selecting charts and reviewing them by site surveyors to determine completeness and validity of data reported to registry. The measure numerator and denominator were viewed by the clinical constituency within these cancer programs as valid and an appropriate reflection of the standard of care described in NCCN clinical guidelines.
- For the current evaluation, the developer provided additional details on data element validity testing conducted in 2009 and 2010 by comparing registry data to data that were re-abstracted from the medical records by CoC site surveyors, which was considered the gold standard. The developer provided percentage agreement results for 2 of the data elements included in the numerator, timing for chemotherapy (81.1, 75.7) and chemotherapy which was recommended but not administered (88.1, 89.5). Validity testing of all the critical data elements (including kappa scores, sensitivity or specificity statistics) was not provided.
- Since the testing provided by the developer for this measure had the same issues as #0220, the Committee considered the same concerns they had for the testing of that measure and agreed to carry forward the votes from the reliability and validity criteria from #0220 and recommended the measure for endorsement
- The Committee encouraged the developer to provide updated reliability and validity testing at the next maintenance review of the measure. The developer confirmed that they are planning to update their validity and reliability testing for the 5 measures submitted in this project (#0219, #0220, #0223, #0225, and #0559).
- The Committee agreed there may be multiple providers and procedures (genetic testing, surgery, etc.) from the time of diagnosis to the start of chemotherapy that may extend beyond

the 120 day timeframe required by the measure, but facilities should aim to prevent delays in initiating treatment and improving patient outcomes.

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3. Feasibility: H-4; M-14; L-2; I-0

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

Rationale:

- Although the data are readily available through medical records, the Committee recognized the data collection burden for manual chart abstraction that could result in various interpretations.
- The Committee agreed this measure meets the feasibility criterion.

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4. Usability and Use: H-9; M-9; L-2; I-0

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

Rationale:

- The measure is publicly reported through the Pennsylvania Health Care Quality Alliance, the Commission on Cancer, various compliance benchmarking programs through the National Cancer Data Base, and Quality Oncology Practice Initiative programs.
- The developer provided improvement results showing increases in the overall facility level compliance rates and across all census regions.
- The Committee agreed this measure meets the usability and use criterion.

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5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-19**; **N-1**

6. Public and Member Comment

- One commenter stated that it would be beneficial to have the measure stipulate administered vs. prescribed and to address who might not receive the treatment via the exclusions.
- Developer response: The language of "recommended or administered" in these measures was specifically selected after discussion with clinicians and users and is based directly on the FORDs data item definitions used to calculate these measures. We agree with that when assessing overall quality, cancer programs should review patients in which treatment is administered and those in which treatment is recommended but not administered. Therefore, in our reporting systems where compliance with these measures is assessed, cancer programs are able to view cases stratified by if; a) treatment is administered, b) treatment is recommended but not administered and c) the case is non-compliant with the measure. This allows programs to assess patients which cases are compliant with the measure but for which adjuvant therapy was not administered during internal quality improvement efforts.
- During the Comment period, the developer submitted additional performance data from the Rapid Quality Reporting System (RQRS). The developer stated that the RQRS performance rates were similar to the performance rates from the NCDB.

- The Committee considered the additional performance data from the Rapid Quality Reporting System (RQRS) and agreed this was an important indicator for cancer care. On re-vote, the Committee recommended the measure for endorsement.

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7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-16; N-0

Decision: Approved for continued endorsement

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8. Board of Directors Vote: Yes (October 25, 2016)

Decision: Ratified for continued endorsement

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9. Appeals: No appeals were received

2930 Febrile Neutropenia Risk Assessment Prior to Chemotherapy

Submission | Specifications

Description: Percentage of patients with a solid malignant tumor or lymphoma who had a febrile neutropenia (FN) risk assessment completed and documented in the medical record prior to the first cycle of intravenous chemotherapy

Numerator Statement: Number of patients who had an FN risk assessment documented in the medical record prior to the first cycle of intravenous chemotherapy.

Denominator Statement: Number of patients 18 years of age or older with a solid malignant tumor or lymphoma receiving the first cycle of intravenous chemotherapy.

Exclusions: There are no denominator exclusions.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Clinician : Group/Practice

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Other

Type of Measure: Process

Data Source: Electronic Clinical Data : Electronic Health Record, Paper Medical Records

Measure Steward: RAND Corporation

STANDING COMMITTEE MEETING [05/18-19/2016]

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

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

1a. Evidence: **H-4**; **M-15**; **L-0**; **I-0**; 1b. Performance Gap: **H-3**; **M-12**; **L-2**; **I-2**

Rationale:

- The developer provided a clinical practice guideline from the 2015 American Society of Clinical Oncology (ASCO) Recommendations for the Use of WBC Growth Factors and the 2015 NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) to support the assessment of febrile neutropenia (FN) risk and administration of appropriate colony-stimulating factor (CSF)

prophylaxis prior to chemotherapy. The developer provided additional studies evaluating the effectiveness of FN risk assessment tools. The Committee noted that the developer presented strong evidence supporting the administration of CSF prophylaxis prior to chemotherapy. However, the focus of the measure is documentation of a FN risk assessment prior to chemotherapy. The developer clarified that there is no evidence supporting 1 FN risk assessment tool over another at this time. The Committee agreed the evidence the developer provided to support the use of a FN assessment tool demonstrated a decrease in the incidence of febrile neutropenia and related complications.

- The developer provided performance rates from April 2011-February 2016 that included 192 patient records from 5 community oncology clinics. The mean performance rate was 12.0%, the median was 16.0%, and the maximum was 27.0%. The performance rates were stratified by age, race/ethnicity, and gender. The developer provided data from the literature that showed disparities on the use of prophylactic CSF based on gender, race, geographic location, and lower socioeconomic status. The developer stated that there is limited published data on the frequency of risk assessment for FN but cited a study (Miller, 2010) conducted at 4 offices of a community oncology practice to assess the effect of a computer-based risk assessment tool (CBRAT) for FN. Before implementation of the CBRAT, 13 of 101 (13.0%) patients had documented risk assessments for FN. After implementation of CBRAT, documented risk assessments increased to 100.0%.
- The Committee noted that appropriately administering prophylactic CSF and preventing FN in high-risk cancer patients is important, but based on the limited data the developer provided, the Committee questioned whether a gap in care/quality problem exists related to documentation of a FN assessment. The Committee suggested that the low performance rates presented by the developer may be due to the adoption of computerized physician order entry (CPOE) and standard order sets that include supportive care treatments appropriate for the regimen, including pre-medications, hydration, CSF, and hypersensitivity medications. Providers using standardized orders sets are not likely to include additional documentation explicitly stating the FN risk or a note in the chart that reflects the rationale for either administering or not administering CSF based on patient and regimen risk factors as required by the measure.
- The Committee agreed that is it important to assess patients for FN risk and administer CSF appropriately, however, they encouraged the developer to expand the measure so that evidence-based standing orders meet the intent of the measure.

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2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **M-14**; **L-4**; **I-1** 2b. Validity: **H-17**; **M-0**; **L-1**

<u>Rationale</u>:

- The Committee agreed the data elements are clearly defined, but somewhat complex and may be difficult to calculate consistently.
- Inter-rater reliability testing was assessed using 2 abstractors who were instructed to abstract the same randomly selected 50 medical records from 5 community oncology clinics, 10 records per clinic, for a 25 percent inter-rater reliability (IRR) sample. The kappa statistic and percent agreement between the abstractors was calculated based on whether documentation of a febrile neutropenia risk assessment was in the medical record. The developer provided kappa statistics and percent agreement results for 1 data element included in the numerator

(documentation of a febrile neutropenia risk assessment in the medical record). Kappa estimates ranged from 0.783 to 1.0 for the 5 clinics; percent agreement ranged from 90-100%. NQF guidance states that testing should be done for all critical data elements. The clinics determined which patients met the denominator inclusion criteria (age at least 18 years, solid tumor or lymphoma, initiating chemotherapy, and not participating in a clinical trial). The developers excluded additional patients due to incomplete records, malignancy other than solid tumor or lymphoma, or concurrent radiation. The Committee commented that the sample used for reliability testing was relatively small, yet the reliability score was acceptable and met the reliability criterion.

- The Committee encouraged the developer to conduct a statistical analysis, in the future, of the computed measure score to assess the proportion of variability due to real differences among the measured entities.
- The developer assessed face validity of the measure score using a panel of 10 experts in clinical oncology. Eighty percent (8/10) of the respondents either agreed or strongly agreed that performance scores resulting from the measure as defined can be used to distinguish good and poor quality. One of the Committee members commented that they would like to see data showing that groups with high scores on the measure have less FN. Another Committee member suggested that missing data may be a threat to validity, although the developer stated that missing data was not identified during the medical record abstraction. The Committee concluded that the validity criterion was met.

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3. Feasibility: H-1; M-14; L-3; I-0

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

Rationale:

- Some of the data elements are easily found in electronic sources, but information about FN risk assessment may not be generated during routine care delivery and require manual chart abstraction. The Committee suggested incorporating the FN risk assessment into CPOE and standard orders to increase the feasibility of the measure in the future.

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4. Usability and Use: H-1; M-16; L-1; I-0

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

Rationale:

- The developer stated that because the measure is being submitted to NQF for initial endorsement, they do not yet have plans to submit it for use in a specific federal, state or local program. However, the measure would be appropriate for use in a CMS reporting program for outpatient care provided to oncology patients.
- The Committee emphasized that a febrile neutropenia outcome measure would further the goal of high-quality, efficient healthcare rather than this process measure. The Committee requested that, if endorsed, the developer provide data on the performance of the measure and include patients who were administered CSF prophylaxis and patients with febrile neutropenia to understand the impact of the measure. Another Committee member questioned the impact this measure will have on the appropriate use of CSF but acknowledged that additional data will be useful to improve quality.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-16**; **N-2**

6. Public and Member Comment

- One commenter noted that an outcome measure will assist in determining more than appropriate use of colony-stimulating factor (CSF), specifically resource utilization related to urgent care due to febrile neutropenia (FN). The commenter also noted the challenges of documenting FN risk assessment in electronic health records (EHR).
- Developer response: We agree that measuring febrile neutropenia (FN) outcomes is important, but view an outcome measure as a complement to our proposed measure rather than a substitute.

7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-16; N-0

Decision: Approved for endorsement

8. Board of Directors Vote: Yes (October 25, 2016)

Decision: Ratified for endorsement

9. Appeals: No appeals received

2963 Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients – Legacy eMeasure

Submission | Specifications

Description: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer

Numerator Statement: Patients who did not have a bone scan performed at any time since diagnosis of prostate cancer

Denominator Statement: All patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence, receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy

Exclusions: Documentation of medical reason(s) for having a bone scan performed (including documented pain, salvage therapy, other medical reasons)

Documentation of system reason(s) for having a bone scan performed (including bone scan ordered by someone other than reporting physician)

Adjustment/Stratification: No risk adjustment or risk stratification

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

Setting of Care: Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Other

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry

Measure Steward: PCPI

STANDING COMMITTEE MEETING [05/18-19/2016]

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

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

1a. Evidence: **Measure #0389 Evidence Criteria Evaluation Accepted**; 1b. Performance Gap: **Measure #0389 Performance Gap Criteria Evaluation Accepted**

Rationale:

- This "legacy" eMeasure is the eCQM version of the registry measure #0389, currently used in federal programs. The Committee discussed #0389 first, and because the information provided for evidence and opportunity for improvement is identical for the 2 measures, the Committee agreed to assign the ratings for these criteria to #2963.

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2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

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

Initial 2a. Reliability: **M-10**; **L-6**; **I-4** 2b. Validity: **M-16**; **L-2**; **I-2**

Re-vote on 2a. Reliability: **M-14**; **L-2**; **I-1**

Rationale:

- The developer conducted data element validity testing using 34 synthetic patients created in the Bonnie testing system simulating the year 2012. This testing method is appropriate for Legacy eMeasures and satisfies the reliability testing requirement. The Bonnie testing tool was used to test the numerator, denominator, exceptions, measure logic, and value sets to ensure the measure performs as expected. The Bonnie testing results demonstrated 100% coverage and 100% passing rate confirming there was a test case for each pathway of logic and each test case performed as expected.
- The developer provided reliability results from the registry measure (#0389) and stated that once data from the eCQM are available for analysis it is expected that reliability test results will be comparable for the 2 measures. The Committee questioned extrapolating the reliability of the eCQM based on the registry measure without testing results. The Committee questioned if the developer had tested the correlation of the eCQM and registry measure. The developer clarified that although the eCQM is currently used in Meaningful Use (MU), CMS has not released performance data from MU. The Committee noted their concerns with providers' ability to consistently implement the Health Quality Measure Format (HQMF) specifications for the eCQM and the potential impact on the numerator, denominator, and exceptions.

- The Committee acknowledged the importance of eMeasures and the challenges associated with respecifying registry and claims measures and encouraged CMS to release MU performance data.
- The developer conducted face validity testing with a panel of 17 experts representing the PCPI Measures Advisory Committee. Eighty percent of the total respondents (10) either agreed or strongly agreed that the measure can accurately distinguish good and poor quality. The Committee agreed the validity testing results were sufficient.

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3. Feasibility: H-5; M-13; L-1; I-1

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

Rationale:

- The developer provided information on feasibility testing in the eMeasure Feasibility Score Card for 2 implementation sites and an explanation for scores below 2 on a scale from 1 to 3. Bonnie testing verified that the measure logic is functional, but not all of the required data elements exist as structured data in the unidentified EHRs that were used for testing feasibility. The Committee agreed that the developer provided sufficient information to demonstrate feasibility.

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4. Usability and Use: H-9; M-11; L-0; I-0

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

Rationale:

- The measure is currently used in Meaningful Use Stage 2 (EHR Incentive Program).
- No unintended consequences have been identified, but similar to #0389, the Committee noted a potential consequence of decreasing bone scan testing rates would be higher rates of undiagnosed metastatic disease. However, this is unlikely based on the evidence for low-risk prostate cancer patients.

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5. Related and Competing Measures

- This measure is related to:
    - #0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients (AMA-PCPI)
    - #1853: Radical Prostatectomy Pathology Reporting (CAP)
- The developer stated that the measure specifications are not completed harmonized; #0390 and #1853 address different target populations and different aspects of prostate cancer care.

Standing Committee Recommendation for Endorsement: **Y-20**; **N-0**

6. Public and Member Comment

- After the comment period, the Committee emphasized their concerns with the lack of data from the measure as specified. The developer agreed to provide the Standing Committee with additional data during the measure's scheduled annual review (within one year). The Standing

Committee will review the additional data through an ad-hoc review. The Standing Committee agreed that the measure met the minimum criterion for reliability required for legacy eMeasures at this time.

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7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-16; N-0

Decision: Approved for endorsement

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8. Board of Directors Vote: Yes (October 25, 2016)

Decision: Ratified for endorsement

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9. Appeals: No appeals received

Measures with Inactive Endorsement with Reserve Status

1878 HER2 testing for overexpression or gene amplification in patients with breast cancer

Submission | Specifications

Description: Proportion of female patients (aged 18 years and older) with breast cancer who receive human epidermal growth factor receptor 2 (HER2) testing for overexpression or gene amplification

Numerator Statement: HER2 testing performed

Denominator Statement: Adult women with breast cancer

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Clinician : Group/Practice

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: American Society of Clinical Oncology

STANDING COMMITTEE MEETING [05/18-19/2016]

1. Importance to Measure and Report: The measure did not meet the Importance criteria

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

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-1**; **M-3**; **L-15**; **I-1**

Rationale:

- For the 2012 endorsement evaluation, the developer provided a clinical practice guideline from the American Society of Clinical Oncology (ASCO) and the College of American Pathologists (CAP) recommending that human epidermal growth factor receptor 2 (HER2) status should be determined for all invasive breast cancer.
- For the current evaluation, the developer provided updated citations to the clinical practice guideline but the recommendations did not change.
- The Committee agreed that the evidence basis for the measure has not changed and there was no need to repeat the discussion and vote on evidence.
- The developer provided performance rates from the ASCO Quality Oncology Practice Initiative (QOPI®) Registry from 2013 – 2015. The mean performance rate in 2013 was 98.53%, 98.77% in 2014, and 98.63% in 2015. The developer provided disparities data aggregated by race and/or ethnic groups. The developer also noted that studies show that tumors of older female patients (15.7 %) and Hispanics (20.7 %) as well as other race/ethnicities (18.8 %) are less likely to be tested for HER2.
- The Committee discussed the high performance rates of this measure, noting that there is no longer a gap in performance among the practices being measured. There was discussion about participants in the QOPI Registry being self-selected and voluntarily reporting on this measure and the possibility for practices outside of the registry having lower performance rates. Another Committee member cited Surveillance, Epidemiology, and End Results (SEER) data, which is

more nationally representative, from 2007 demonstrating 96.5% of eligible patients had HER2 testing performed.

- Ultimately, the measure did not pass performance gap. However, despite the high rate of performance there was evidence that disparities exist; therefore, the Committee voted to continue reviewing the measure against the rest of the criteria with the possibility of recommending the measure for inactive endorsement with reserve status.

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2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **Previous Reliability Evaluation Accepted** 2b. Validity: **Previous Validity Evaluation Accepted**;

<u>Rationale</u>:

- For the 2012 endorsement evaluation, data element validity testing was performed and counted for data element reliability. The dataset included 264 patient records from 44 QOPI practices submitted in spring 2007. Trained, independent nurse abstractors served as the "gold standard" against which practice abstractions were compared for accuracy. Kappa statistics were used to analyze the validity of the audited patient records compared to the submitted patient records. By convention, a kappa > 0.70 is considered acceptable. The developer provided a kappa score of 0.85 and an overall percent agreement of 98.0%. While this kappa score is above what is considered acceptable, the developer did not state which of the data elements this kappa score represented; no additional results were provided. NQF guidance states that testing should be done for all critical data elements. The developer responded that they were unable to find the additional data from the testing previously conducted but based on the kappa score and overall agreement rate they did not have any concerns with the performance of the measure in the registry.
- Although the developer did not provide updated reliability and validity testing, the Committee agreed that the measure specifications were consistently implemented within the registry and accepted the previous reliability and validity evaluation.

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3. Feasibility: H-3; M-15; L-1; I-1

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

<u>Rationale</u>:

- This measure is based on clinical registry data and all data elements are available in electronic sources. The Committee agreed the measure is feasible.
- The Committee noted that eventual use of this measure through EHRs would lessen the data collection burden.

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4. Usability and Use: H-4; M-13; L-3; I-0

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

<u>Rationale</u>:

- The developer shared that this measure was recently selected for inclusion in a Medical Oncology Core Measure Set supported by AHIP and CMS. The measure was also recently approved for use in the Medicare Access & CHIP Reauthorization Act's (MACRA) Merit-Based Incentive Payment System (MIPS).
- The Committee noted that this measure is used in Quality Oncology Practice Initiative (QOPI®), the QOPI® Certification Program, and the PQRS Qualified Clinical Data Registry.

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5. Related and Competing Measures

- This measure is related to:
  - #1855: Quantitative HER2 Evaluation by IHC uses the System Recommended by the ASCO/CAP Guidelines (CAP)
- Measure #1855 and #1878 address 2 complimentary components and are related to appropriate identification and treatment of breast cancer patients. Measure #1855 and #1878 differ by data source. Measure #1878 is suited for registry data. Measure #1855 is suited for administrative claims and paper medical records data sources. The developer indicates the measures have been harmonized.

Standing Committee Recommendation for Inactive Endorsement with Reserve Status : **Y-19**; **N-1**

6. Public and Member Comment

- No comments were received.

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7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-15; N-0

Decision: Approved for continued endorsement

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8. Board of Directors Vote: Yes (October 25, 2016)

Decision: Ratified for continued endorsement

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9. Appeals: No appeals were received.

1857 HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies

Submission | Specifications

Description: Proportion of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2)/neu negative who are not administered HER2-targeted therapies

Numerator Statement: HER2-targeted therapies not administered during the initial course of treatment.

Denominator Statement: Adult women with breast cancer that are HER2 negative or HER2 undocumented.

Exclusions: Patient transfer to practice during or after initial course.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Clinician : Group/Practice

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: American Society of Clinical Oncology

STANDING COMMITTEE MEETING [05/18-19/2016]

1. Importance to Measure and Report: The measure did not meet the Importance criteria

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

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-0**; **M-1**; **L-19**; **I-0**

Rationale:

- For the 2012 endorsement evaluation, the developer provided clinical practice guidelines from the American Society of Clinical Oncology (ASCO) and the Cancer Care Ontario (CCO) recommending trastuzumab to patients with HER2-positive node or node-negative breast cancer.
- For the current evaluation, the developer provided updated clinical practice guidelines from ASCO and CCO and an additional joint guideline from ASCO and the College of American Pathologists recommending HER2-targeted therapy for only for patients with HER2-positive breast cancer.
- The Committee agreed that the evidence is sufficient and there was no need to repeat the discussion and vote on evidence.
- The developer provided performance rates from the ASCO Quality Oncology Practice Initiative (QOPI®) Registry from 2013 – 2015. The mean performance rate in 2013 was 99.25%, 99.26% in 2014, and 99.54% in 2015. The developer provided 2013-2015 data stratified by race and/or ethnic groups that demonstrated little variation. Performance rates for Hispanics were 99.26% - 100.0% and 98.47% - 99.66% for black patients. The developer did not provide additional data on disparities.
- The Committee discussed the same issues related to performance gap that were discussed for #1878.
- Like #1878, the measure did not pass performance gap. Despite the high rate of performance other disparities may exist; therefore, the Committee voted to continue reviewing the measure against the rest of the criteria with the possibility of recommending the measure for inactive endorsement with reserve status.

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2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

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

2a. Reliability: **Previous Reliability Evaluation Accepted** 2b. Validity: **Previous Validity Evaluation Accepted**

Rationale:

- For the 2012 endorsement evaluation, data element validity testing was performed and counted for data element reliability. The dataset included 264 patient records from 44 QOPI practices submitted in spring 2007. Trained, independent nurse abstractors served as the "gold standard" against which practice abstractions were compared for accuracy. Kappa statistics were used to analyze the validity of the audited patient records compared to the submitted patient records. By convention, a kappa > 0.70 is considered acceptable. The developer provided a kappa score of 0.74 and an overall percent agreement of 96.0%. While this kappa score is above what is considered acceptable, the developer did not state which of the data elements this kappa score represented; no additional results were provided. NQF guidance states that testing should be done for all critical data elements. Like #1878, the developer responded that they were unable to find the additional data from the testing previously conducted but based on the kappa score and overall agreement rate they did not have any concerns with the performance of the measure in the registry.
- Although the developer did not provide updated reliability and validity testing, the Committee agreed that the measure specifications were consistently implemented within the registry and accepted the previous reliability and validity evaluation.

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3. Feasibility: H-0; M-20; L-0; I-0

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

Rationale:

- This measure is based on clinical registry data and all data elements are available in electronic sources. The Committee agreed the measure is feasible.
- The Committee noted that eventual use of this measure through EHRs would lessen the data collection burden.

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4. Usability and Use: H-5; M-11; L-4; I-0

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

Rationale:

- The developer shared that this measure was recently selected for inclusion in a Medical Oncology Core Measure Set supported by AHIP and CMS. The measure was also recently approved for use in the Medicare Access & CHIP Reauthorization Act's (MACRA) Merit-Based Incentive Payment System (MIPS).
- The Committee noted that this measure is used in Quality Oncology Practice Initiative (QOPI®).

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5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Inactive Endorsement with Reserve Status : **Y-19**; **N-1**

6. Public and Member Comment

- No comments were received.

7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-15 ; N-0
Decision: Approved for continued endorsement

8. Board of Directors Vote: Yes (October 25, 2016)
Decision: Ratified for continued endorsement

9. Appeals: No appeals were received

Measures Not Endorsed

0459 Risk-Adjusted Length of Stay >14 Days after Elective Lobectomy for Lung Cancer

Submission | Specifications

Description: Percentage of patients aged 18 years and older undergoing elective lobectomy for lung cancer who had a prolonged length of stay >14 days

Numerator Statement: Number of patients aged 18 years and older undergoing elective lobectomy for lung cancer who had a prolonged length of stay >14 days

Denominator Statement: Number of patients aged 18 years and older undergoing elective lobectomy for lung cancer

Exclusions: None

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Electronic Clinical Data : Registry

Measure Steward: The Society of Thoracic Surgeons

STANDING COMMITTEE MEETING [05/18-19/2016]

1. Importance to Measure and Report: The measure did not meet the Importance Criteria

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

1a. Evidence: **Previous Evidence Evaluation Accepted**; Initial 1b. Performance Gap: **H-0**; **M-10**; **L-5**; **I-6**

Re-vote on 1b. Performance Gap: M-11; L-8; I-1

Rationale:

- For the 2008 endorsement evaluation,[7] the developers stated that prolonged length of stay after pulmonary lobectomy is both a surrogate marker of morbidity and a direct marker of increased resource utilization. Lower performing thoracic programs have the opportunity to design quality improvement initiatives when they know their rate of risk adjusted prolonged length of stay. The Committee accepted the previous evidence evaluation.
- For the current evaluation, the developers did not provide data on disparities from the measure as specified, but the Committee noted that there are studies demonstrating disparities based on the size of the program, the number of operations performed per year, insurance status, and general surgeons vs. board-certified thoracic surgeons.
- For the current evaluation, the developer provided performance data from the STS General Thoracic Surgery Database (GTSD) for patients that underwent elective lobectomy for lung cancer between July 1, 2012 and June 30, 2015 that demonstrated a mean prolonged length of stay (PLOS) (>14 days) occurred in 4.3% of eligible patients. After the workgroup call the developer calculated the overall mean and median PLOS from 2009-2012, 2010-2013, 2011-2014, and 2012-2015. The PLOS decreased from a mean of 5.1% to 4.3% and the median decreased from 4.9% to 4.2% for all four time intervals. The Committee questioned whether 14 days was still an appropriate threshold for defining PLOS since LOS can be significantly impacted

by surgical approach such as an open thoracotomy or a minimally-invasive thoracotomy as indicated in Wright et al 2010.

- The Committee noted that the number of patients per region ranged from 2,996 per 40 surgeons to 7,756 patients per 73 surgeons, yet the mean PLOS was ~4.0% for each region. The Committee was concerned that low-volume providers may affect overall performance rates making it difficult to distinguish high-performers from low-performers and determining if a gap in care exists based on the data provided.
- The Committee noted several concerns with the performance data provided by the developer. The Committee requested that the developer provide performance data on 10 days vs. 14 days PLOS and the correlation between the number of procedures performed (volume) and PLOS at the next maintenance review of the measure.
- The Committee discussed the measure during the post-comment call and re-voted on the performance gap subcriterion. The Committee determined that the data provided did not demonstrate a gap in performance.

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2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

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

2a. Reliability: **Previous Reliability Evaluation Accepted** 2b. Validity: **M-15**; **L-6**; **I-0**

<u>Rationale</u>:

- For the 2012 endorsement evaluation,[8] the developer assessed test-retest reliability by comparing the results of estimated hospital rates of prolonged stay between 2 consecutive 6-month time intervals during 2009. The Pearson correlation between hospital-specific rates of prolonged stay in the first versus second half of 2009 was 0.31, which Evans (1996) suggests as "very weak" (0.20-0.39).
- For the current evaluation, the developer provided updated reliability testing of the measure score using the Pearson correlation coefficient to assess the signal-to-noise ratio. The reliability of the measure score increased as the volume of minimum procedures per year for participants increased. The reliability for all 244 participants in the registry and 23,174 operations was 37.6%, 44.5% for ≥10 procedures per year, and 63.8% for ≥ 40 procedures per year.
- The Committee agreed that the reliability scores of the measure were sufficient and accepted the previous reliability evaluation.
- For the 2012 endorsement evaluation,[9] the developer assessed face validity by an expert panel of thoracic surgeons assembled by the STS General Thoracic Surgery Database Task Force, the STS Task Force on Quality Initiatives and the STS Workforce on National Databases. The developer also stated than in 2010 they would conduct patient-level data element validity testing.
- For the current evaluation, the developer conducted data element validity testing using 10% of randomly selected STS GTSD participants from 2013 to 2015. Twenty cases (at least 15 lobectomies and up to 5 esophagectomies) that were previously submitted to the STS data warehouse were re-abstracted and compared to the "gold standard". Agreement rates for the individual data elements ranged from 84.15% (diabetes control) to 100.0% (esophageal cancer, date of surgery, gastric outlet, and discharge date). The Committee agreed that the threats to validity were adequately assessed including the variables used in the risk-adjustment model. The Committee also agreed with the developer's rationale that given the lack of consistent, compelling evidence regarding sociodemographic (SDS) factors and length of stay, there is no

conceptual basis for adjusting the measure for SDS factors at this time, but noted that it is an important future state of development.

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3. Feasibility: H-17; M-4; L-0; I-0

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

Rationale:

- The Committee did not note any concerns regarding feasibility, acknowledging that some but not all of the data elements used to construct this measure are in defined fields in electronic sources.

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4. Usability and Use: H-8; M-11; L-2; I-0

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

Rationale:

- The measure is currently used for quality improvement by the STS General Thoracic Surgery Database which includes 273 participants. STS is planning to launch the general thoracic surgery component of STS Public Reporting Online in 2017.
- The developer did not provide any unintended consequences but the developer confirmed that if a patient was discharged to a LTAC (long-term acute care) facility on a ventilator on day 13 they would meet the measure.

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5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-17**; **N-4**

- The initial vote was taken during the in-person meeting. However, since the measure did not pass Performance Gap, a must-pass criterion, during the post-comment call, the measure was not recommended for endorsement.

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6. Public and Member Comment

- One commenter suggests a measure addressing the discharge outcomes may provide better insight into variations of care due to low patient volume in the current measure. The commenter also noted the new measure(s) might be similar to measure #0460 with a different surgical procedure/patient diagnostic group.
- The developer response: Although length of stay is a surrogate for morbidity, measure #0459 is intended to be used to measure health care resource utilization. #1790 Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer, an outcomes measure also stewarded by STS addresses the commenter's suggestion. In addition, STS recently developed a two-domain, outcomes only composite measure for lobectomy for lung cancer.

7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-0; N-16

Decision: Measure not recommended for continued endorsement

0460 Risk-Adjusted Morbidity and Mortality for Esophagectomy for Cancer

Submission | Specifications

Description: Percentage of patients aged 18 years and older undergoing elective esophagectomy for esophageal cancer who developed any of the following postoperative conditions: bleeding requiring reoperation, anastomosis leak requiring medical or surgical treatment, reintubation, ventilation >48 hours, pneumonia, or discharge mortality

Numerator Statement: Number of patients aged 18 years and older undergoing elective esophagectomy for esophageal cancer who developed any of the following postoperative conditions: bleeding requiring reoperation, anastomosis leak requiring medical or surgical treatment, reintubation, ventilation >48 hours, pneumonia, or discharge mortality.

Denominator Statement: Number of patients aged 18 years and older undergoing elective esophagectomy for esophageal cancer

Exclusions: None

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility, Clinician : Group/Practice

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Electronic Clinical Data : Registry

Measure Steward: The Society of Thoracic Surgeons

STANDING COMMITTEE MEETING [05/18-19/2016]

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

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

1a. Evidence: **Previous Evidence Evaluation Accepted**; 1b. Performance Gap: **H-6**; **M-12**; **L-2**; **I-1**

Rationale:

- In the 2008 endorsement evaluation,[10] the developer stated that measuring risk adjusted morbidity and mortality of patients undergoing esophagectomy for cancer provides surgeons and institutions the opportunity to evaluate outcomes and subsequently design quality improvement initiatives to address identified deficits. The Committee accepted the previous evidence evaluation.
- For the current evaluation, the developers did not provide data on disparities from the measure as specified. However, an analysis (Sammon et al, 2015) cited by the developer that was used to select patient factors for the risk model, suggested that age, gender, and race are relevant to esophagectomy outcomes. The Committee noted that race (African-Americans) was one of the variables included in the in the risk-model, therefore, taking into account race when computing the performance measure score.

- For the current evaluation, the developer provided performance data from the STS General Thoracic Surgery Database (GTSD) for patients that underwent elective esophagectomy for primary esophageal cancer between July 1, 2012 and June 30, 2015. The Committee noted that the median ranged from 27.7% to 28.6% and the 10th percentile and the 90th percentile ranged from 20.6% to 42.6%. The Committee agreed there is opportunity for improvement in care for patients undergoing elective esophagectomy.

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2. Scientific Acceptability of Measure Properties: The measure does not meet the Scientific Acceptability

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

Initial 2a. Reliability: **H-0**; **M-11**; **L-9**; **I-1** 2b. Validity: **M-12**; **L-9**; **I-0**

Revote on 2a. Reliability: H-2; M-9; L-8; I-1 2b. Validity: M-10; L-9; I-1

Rationale:

- For the 2012 endorsement evaluation,[11] the developer assessed test-retest reliability by comparing the results of estimated hospital rates mortality or major morbidity between 2 consecutive 6-month time intervals during 2009. The Pearson correlation between hospital-specific rates of mortality or major morbidity in the first versus second half of 2009 was 0.50, which Evans (1996) suggests as "weak" (0.40-0.59).
- For the current evaluation, the developer provided updated reliability testing of the measure score using the Pearson correlation coefficient to assess the signal-to-noise ratio. The reliability of the measure score increased as the volume of minimum procedures per year for participants increased. The reliability scores for all 169 participants and 4,557 operations were 44.4%, 67.9% for ≥5 procedures per year, and 80.6% for ≥20 procedures per year. The Committee noted that more than 55.0% of participants (94) in the registry did fewer than 5 procedures a year. The Committee expressed their concerns with the reliability of this low-volume procedure and that the measure was not specified for ≥5 procedures per year. The Committee also expressed their concerns with combining morbidity and mortality and asked the developer if there were plans for differential weighting of these outcomes. The developer responded that they were developing a new measure that more heavily weights mortality than morbidity and it would be complete by the next maintenance review. The previous Committee also noted the same concerns in 2012.
- Due to the concerns regarding the reliability of the measure as specified, the Committee and did not reach consensus on this criterion.
- For the 2012 endorsement evaluation,[12] the developer assessed face validity by an expert panel of thoracic surgeons assembled by the STS General Thoracic Surgery Database Task Force, the STS Task Force on Quality Initiatives and the STS Workforce on National Databases. The developer also stated than in 2010 they would conduct patient-level data element validity testing.
- For the current evaluation, the developer conducted data element validity testing using 10% of randomly selected STS GTSD participants from 2013 to 2015. Twenty cases (at least 15 lobectomies and up to 5 esophagectomies) that were previously submitted to the STS data warehouse were re-abstracted and compared to the "gold standard". Agreement rates for the individual data elements ranged from 84.15% (diabetes control) to 100.0% (esophageal cancer, date of surgery, gastric outlet, and discharge date). The Committee agreed that the risk-model variables were appropriate.

- The Committee determined that the data element validity testing was adequate but the data provided demonstrated a threat to validity due to low-volume providers. On re-vote the Committee did not pass the reliability and validity subcriteria.

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3. Feasibility: H-9; M-12; L-0; I-0

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

Rationale:

- The Committee did not note any concerns regarding feasibility, acknowledging that some but not all of the data elements used to construct this measure are in defined fields in electronic sources.

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4. Usability and Use: H-4; M-15; L-2; I-0

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

Rationale:

- The measure is currently used for quality improvement by the STS General Thoracic Surgery Database which includes 273 participants. STS is planning to launch the general thoracic surgery component of STS Public Reporting Online in 2017.
- The Committee noted that it would be important to determine how to publicly report the performance rates of this measure for the layperson (i.e., low-volume versus low performance).

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5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-20**; **N-1**

- The initial vote was taken during the in-person meeting. However, since the measure did not pass Reliability and Validity, must-pass criteria, during the post-comment call, the measure was not recommended for endorsement.

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6. Public and Member Comment

- No comments were received.

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7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-0; N-16

Decision: Measure not recommended for continued endorsement

2936 Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy

Submission | Specifications

Description: Measure estimates hospital-level, risk-adjusted rates of inpatient admissions or ED visits for cancer patients >18 years of age for at least one of the following diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of hospital outpatient chemotherapy treatment. The two rates are calculated and reported separately.

Numerator Statement: This measure involves calculating two mutually exclusive outcomes: one or more inpatient admissions or one or more ED visits for any of the following diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of chemotherapy treatment among cancer patients receiving treatment in a hospital outpatient setting. These 10 conditions are potentially preventable through appropriately managed outpatient care. The qualifying diagnosis on the admission or ED visit claim must be (1) the principal diagnosis or (2) a secondary diagnosis accompanied by a principal diagnosis of cancer.

Denominator Statement: The measure cohort includes Medicare FFS patients aged 18 years and older as of the start of the performance period with a diagnosis of any cancer who received at least one hospital outpatient chemotherapy treatment at the reporting hospital during the performance period.

Exclusions: We established the following exclusion criteria after reviewing the literature, examining existing measures, reviewing feedback from a public comment period, and discussing alternatives with the Cancer Working Group and TEP members (see Section Ad.1. for description of group and membership). The goal was to be as inclusive as possible; we excluded only those patient groups for which hospital visits were not typically a quality signal or for which risk adjustment would not be adequate. The exclusions, based on clinical rationales, prevent unfair distortion of performance results.

1) Patients with a diagnosis of leukemia at any time during the performance period.

Rationale: Patients with leukemia are excluded due to the high toxicity of treatment and recurrence of disease so that admissions do not reflect poorly managed outpatient care for this population. Patients with leukemia have an expected admission rate due to relapse, so including leukemia patients in the cohort could be conceptualized as a planned admission, which does not align with the intent of the measure.

2) Patients who were not enrolled in Medicare FFS Parts A and B in the year prior to the first outpatient chemotherapy treatment during the performance period.

Rationale: We exclude these patients to ensure complete patient diagnosis data for the risk-adjustment model, which uses the year prior to the first chemotherapy treatment during the period to identify comorbidities.

3) Patients who do not have at least one outpatient chemotherapy treatment followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the procedure.

Rationale: We exclude these patients to ensure full data availability for outcome assessment.

Adjustment/Stratification: Statistical Risk Model

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Administrative claims

Measure Steward: Centers for Medicare & Medicaid Services (CMS)

STANDING COMMITTEE MEETING [05/18-19/2016]

1. Importance to Measure and Report: Consensus was not reached on the Importance criteria

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

1a. Evidence: **Y-12**; **N-9**; 1b. Performance Gap: **H-2**; **M-9**; **L-3**; **I-7**

Rationale:

- According to the developer, chemotherapy treatment can have severe, predictable side effects, and hospital admissions and ED visits among patients receiving treatment in a hospital outpatient setting are often caused by manageable side effects and complications. Admissions and ED visits for eligible diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—may be due to patients receiving treatment in a hospital outpatient setting having unmet needs and gaps in care, which, if addressed, could reduce admissions and ED visits and increase patients' quality of life. Treatment plans and guidelines exist to support the management of these conditions. Hospitals that provide outpatient chemotherapy should implement appropriate care to minimize the need for acute hospital care for these adverse events.
- The Committee acknowledged this outcome measure encourages care coordination and symptom management in an effort to minimize the side effects of chemotherapy administration, improve the quality of cancer care, and patients' overall quality of life. While the Committee agreed that the interventions outlined by the developer to prevent and manage anemia, dehydration, diarrhea, nausea/emesis, neutropenic fever, pain, and pneumonia/sepsis improves patients' quality of life, some members stated that evidence linking these interventions with decreased hospitalizations and ED visits was not provided. Committee members agreed there are higher levels of evidence to support some of the clinical interventions the developer listed versus non-clinical interventions like care coordination. Some Committee members expressed concern with the complexity of the measure and the broad range of diagnoses that it would be difficult for a facility to determine where to focus their quality improvement efforts. Other Committee members agreed that list of side effects are broad but determined that the developer provided sufficient evidence to support the interventions to prevent and manage the side effects and symptoms of chemotherapy and decrease the risk of ED visits and hospital admissions.
- The Committee did not reach consensus on the evidence of a linkage between the broad range of side effects and reduced ED visits and hospitalizations.
- The developer provided inpatient admission rates and ED visit rates from July 1, 2012 - June 30, 2013 using Medicare FFS claims for 252,408 patients and 3,765 hospitals. The risk-standardized inpatient admission rate ranged from 6.0% to 24.9% (median 10.2, 25th and 75th percentiles were 9.8 and 10.8, respectively). The risk-standardized ED visit rate ranged from 2.1% to 7.5% (median 4.1, 25th and 75th percentiles are 4.0 and 4.4, respectively). Additionally, the developer cited several studies that demonstrated a significant number of cancer patients experience inpatient admissions and ED visits each year related to the frequently reported side effects of chemotherapy. Other studies cited by the developer suggest that there is substantial institutional and geographic variation in hospital admissions and ED visits among chemotherapy patients.
- The developer did not provide disparities data from the measure as specified but did examine associations between outcomes and sociodemographic (SDS) factors. The developer analyzed dual-eligibility, race, and AHRQ SES Composite Index to determine if these factors affected whether patients receiving hospital-based outpatient chemotherapy were more likely to have

an inpatient admission and emergency department visit within 30 days than "non-low SDS" patients. On the patient level, the developer's analysis found disparities based on the 3 variables examined. However, theses disparities were no longer significant when evaluated at the hospital level. One of the Committee members noted that disparities may have not been significant at the hospital level due to volume or other statistical issues. The member suggested stratifying the measure since disparities were significant at the patient level.

- The Committee noted the narrow interquartile range (IQR) for both rates indicating little variability in performance among most of the facilities. On the other hand, the Committee noted the overall range of inpatient admission rates demonstrated a gap in care and an opportunity for improvement, especially for the facilities in the 25th percentile. A Committee member questioned that sufficient data was provided to determine if a gap in care existed due to the significantly small difference in percentage points between the 25th and 75th percentile on the ED visit rate. The Committee asked the developer if they could provide the 10th and 90th percentile rates for the ED visit rates; the developer did not have the data available at the in-person meeting.
- The Committee did not reach consensus on the performance gap criterion.
- Prior to the Committee's vote on performance gap, NQF staff recommended that the Committee consider the measure as 2 separate measures and NQF would categorize it as a "paired measure" due to the developer's wish that the 2 rates be reported together. As stated in previous conversations with NQF staff, the developer expressed the intent of the measure to calculate 2 rates and report them separately. However, 90% of the Committee voted to keep the measure as it was submitted; and only 10% voted to separate the measure into a paired measure, so the measure was not split.

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2. Scientific Acceptability of Measure Properties: <u>The measure did not meet the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-0**; **M-4**; **L-10**; **I-6** 2b. Validity: **N/A**

<u>Rationale</u>:

- The developer used 2012-2013 Medicare data from 3,765 hospitals and 240,446 patients. A total of 942 hospitals with ≥ 60 patients in the cohort were included in the sample. A split-sample methodology was used to test the measure score reliability. The developers randomly assigned half of the patients in each hospital to 2 separate groups, calculated the performance measure score for each hospital in each of the 2 groups, and calculated the Pearson correlation between the performance rates in each half-year sample; the higher the correlation, the higher the reliability of the measure.
- The developers also used the intraclass correlation coefficient (ICC) signal-to-noise method to determine the recommended minimum number of cases needed to maintain a reliability level of 0.4 or higher. The ICC reflects the percentage of variance in score results that is due to "true" or real variance between the hospitals.
- The reliability score for inpatient admissions was 0.41 and 0.27 for ED visits. To achieve reliability (ICC) of 0.4, a minimum of 25 patients are required to calculate the inpatient admissions rate and a minimum of 20 patients for the ED visit rate per performance period. The developer recommended a performance period long enough to accumulate a sufficient number of patients per hospital for improved reliability.

- During the workgroup call and the in-person meeting, the Committee questioned the developer about the strength of the reliability score for the ED measure (Pearson correlation = 0.27). The developer responded that they had access to only 1 year of data at the time the analyses were conducted. As mentioned previously, the methodology requires a random-split of data into 2 distinct samples to calculate a test-retest reliability score. Therefore, the test-retest reliability calculation was based on correlation between 2 half-year samples, or roughly half the data that will be used to calculate outcome rates for public reporting. Calculating reliability estimates on samples analogous in size to those in public reporting would require 2 years of data, to which developers currently do not have access, but is expected to increase the measure reliability. The developer also noted that given the reliability calculation split a year of data into 2 half-year samples, they were further limited by low facility volume and the low rate of the ED measure (median rate of 4.1 per 100 patient visits for hospital-based outpatient chemotherapy). The reliability score measures the consistency within two split samples, and diminishing sample size in the presence of low rates makes it less likely that the two split samples are similar. For example, a facility with 30 cases would be expected to have approximately one ED visit case. When this facility is randomly split the observed event would only be attributed to 1 of the 2 split-year samples, resulting in a discrepancy in the rates of 0% versus 6.7%. These large discrepancies reduce the strength of the reliability estimate.
- To determine what effect a 2-year sample of data would have on reliability estimates, the developers conducted additional reliability analyses with the same split-year samples used in the original analyses. Specifically, the developers recalculated the reliability score using the Intraclass Correlation Coefficient (ICC) and adjusted the ICC estimate using the Spearman-Brown prophecy formula to determine the range of ICC values if calculated in a split-sample with 2 years of data instead of 1. The Spearman-Brown prophecy formula provides an estimate of an ICC if the number of items in a test increases by a certain factor. Using the Spearman-Brown formula, assuming a 2-year split sample, the adjusted ICC was estimated to be 0.47 (95% confidence interval: 0.40/0.53). Accordingly, the developers expect reliability estimates will improve when calculated in a data sample analogous in size to that used for implementation and public reporting.
- During the workgroup call, one of the Committee members inquired about the distribution of hospital case count, since the number of hospitals included in the reliability analysis declined from over 3,000 to less than 1,000 once the minimum patient threshold was imposed on the split-halves analysis. The developer conducted additional analyses and found that 41.0% of hospitals had a minimum case count of ≥25 patients (the typical threshold for public reporting) over the 1-year period from July 2012 through June 2013.
- Some Committee members continued to express their concern with the complexity of the measure and questioned a facility's ability to consistently implement the measure and the potential impact on reliability. The developer clarified that the measure does not require facilities to calculate their rates; rather the rates are calculated by CMS using Medicare FFS administrative claims.
- Another Committee member expressed their concerns with the numerator limiting admissions/rates to inpatient and ED. Many facilities and cancer centers, the member reasoned, have affiliated urgent care centers or 24-hour clinics rather than emergency departments. If a patient was seen at an urgent care centers or clinics for one of the eligible diagnoses, they would not be counted in the numerator. Additionally, if they were admitted to the hospital for observation, they would not be included in the numerator unless they crossed the two-midnight rule.[13]

- Committee members also voiced their concerns about attribution. One member suggested that if a patient receives chemotherapy from more than 1 facility in the 30-day timeframe, the facility that administered the chemotherapy prior to the inpatient admission or ED visit should bear more attribution. The developer pointed to the analysis they conducted to see how many patients received chemotherapy from more than 1 hospital and found that only 5%of patients in the sample (n=240,446) received chemotherapy at more than 1 hospital.
- Other Committee members noted that patients receiving concurrent chemoradiotherapy should be excluded from the denominator.
- Overall, the Committee concluded that the measure did not meet the reliability criterion due to the concerns discussed, specifically the small sample size used for reliability testing and the low reliability scores.

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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)

Rationale:

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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)

Rationale:

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5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **N/A**

Rationale

- The measure did not pass reliability.

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6. Public and Member Comment

- No comments were received.

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7. Consensus Standards Approval Committee (CSAC) Vote: (October 11, 2016): Y-0; N-16

Decision: Measure not recommended for endorsement

Measures Withdrawn from Consideration

Five measures previously endorsed by NQF were not re-submitted for maintenance of endorsement. Endorsement for these measures has been removed. Maintenance of endorsement was deferred for one measure and three new measures were withdrawn from consideration during the endorsement evaluation process.

Measure	Reason for withdrawal
0221 Image or Palpation-Guided Needle Biopsy (core or FNA) of the Primary Site is Performed to Establish Diagnosis of Breast Cancer (American College of Surgeons)	Measure was not submitted for maintenance review. Developer determined they were not able conduct additional testing needed based on changes to measure specifications.
0455 Recording of Clinical Stage Prior to Surgery for Lung Cancer or Esophageal Cancer Resection (The Society of Thoracic Surgeons)	Measure was not submitted for maintenance review. No reason provided by developer.
0457 Recording of Performance Status prior to Lung or Esophageal Cancer Resection (The Society of Thoracic Surgeons)	Measure was not submitted for maintenance review. No reason provided by developer.
0562 Overutilization of Imaging Studies in Melanoma (American Academy of Dermatology)	Measure was not submitted for maintenance review. The melanoma guideline is now in update and the developer anticipates developing new melanoma measures once the updated guideline is available.
0650 Melanoma: Continuity of Care – Recall System (American Academy of Dermatology)	Measure was not submitted for maintenance review. The melanoma guideline is now in update and the developer anticipates developing new melanoma measures once the updated guideline is available.
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 (American Society of Clinical Oncology)	Due to recent changes in guidelines, developer requested deferral of maintenance review.
2938 Lung Cancer Reporting (Biopsy/Cytology Specimens) (The College of American Pathologists)	Measure withdrawn from consideration; additional testing needed.
2931 Melanoma Reporting (The College of American Pathologists)	Measure withdrawn from consideration; additional testing needed.
2929 Lung Cancer Reporting (Resection Specimens) (The College of American Pathologists)	Measure withdrawn from consideration; additional testing needed.

Endnotes

[1] Measure #0508 was initially endorsed in 2008 with time-limited endorsement.

[2] In 2012, #0508 underwent time-limited reliability testing review and received full endorsement.

[3] In 2012, #0508 underwent time-limited validity testing review and received full endorsement.

[4] Measure #0509 was initially endorsed in 2008 with time-limited endorsement.

[5] In 2012, #0509 underwent time-limited reliability testing review and received full endorsement.

[6] In 2012, #0509 underwent time-limited validity testing review and received full endorsement.

[7] Measure #0459 was initially endorsed in 2008 with time-limited endorsement.

[8] In 2012, #0459 underwent time-limited reliability testing review and received full endorsement.

[9] In 2012, #0459 underwent time-limited validity testing review and received full endorsement.

[10] Measure #0460 was initially endorsed in 2008 with time-limited endorsement.

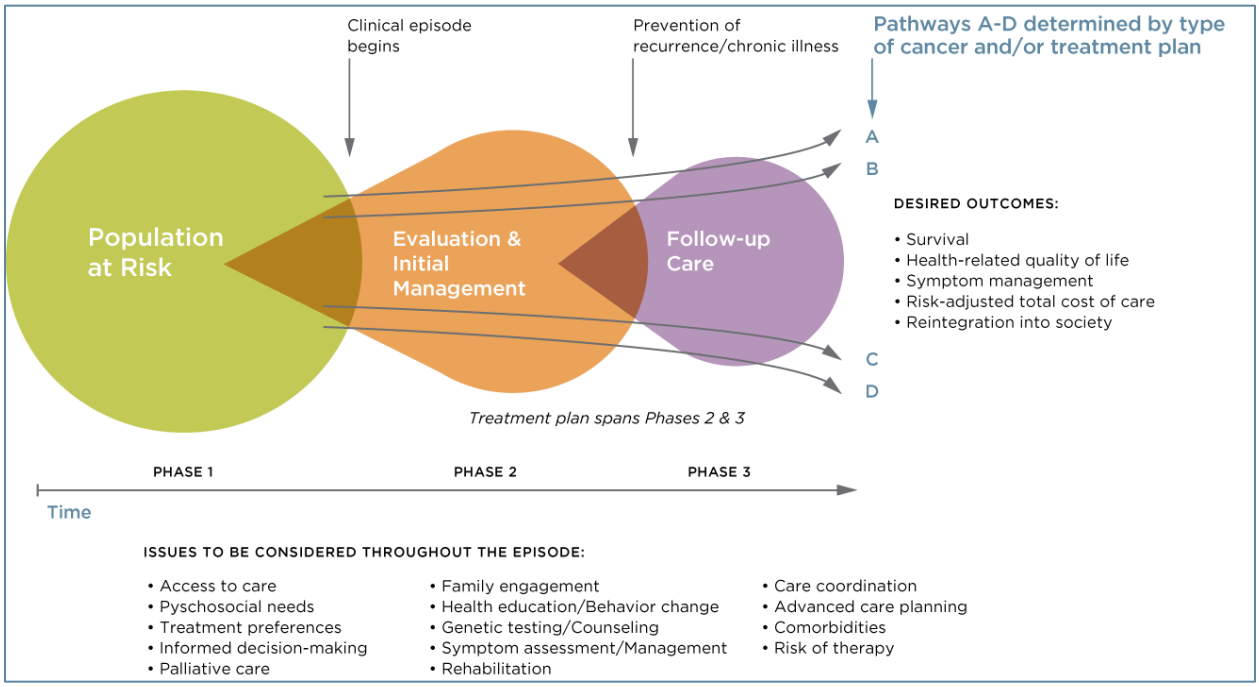
[11] In 2012, #0460 underwent time-limited reliability testing review and received full endorsement.

[12] In 2012, #0460 underwent time-limited validity testing review and received full endorsement.

[13] CMS announced the two-midnight rule in 2013. Under this rule, only patients that the physician expects will need to spend two nights in the hospital would be considered as hospital inpatients. http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=133

Appendix B: NQF Cancer Portfolio and Related Measures

Patient-Focused Episode of Care Model for Cancer Care



Measures in the Cancer Portfolio

**Denotes measures that were evaluated in the Cancer Care Project 2015-2016*

Bone Cancer

1822 External Beam Radiotherapy for Bone Metastases

Breast Cancer Measures

0219 Post breast conservation surgery irradiation*

0220 Adjuvant hormonal therapy*

0387 Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

0391 Breast Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade

0508 Diagnostic Imaging: Inappropriate Use of “Probably Benign” Assessment Category in Screening Mammograms*

0509 Diagnostic Imaging: Reminder System for Screening Mammograms*

0559 Combination chemotherapy is considered 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*

1855 Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

1857 Patients with breast cancer and negative or undocumented human epidermal growth factor receptor 2 (HER2) status who are spared treatment with trastuzumab*

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

1878 Human epidermal growth factor receptor 2 (HER2) testing in breast cancer*

Colon Cancer Measures

0223 Adjuvant hormonal therapy*

0225 At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer*

0385 Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

0392 Colorectal Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade

1859 KRAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy

1860 Patients with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies

Hematology Measures

0377 Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow*

0378 Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy*

0379 Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry

0380 Hematology: Multiple Myeloma: Treatment with Bisphosphonates

Lung and Thoracic Cancer Measures

0459 Risk-Adjusted Morbidity: Length of Stay >14 Days after Elective Lobectomy for Lung Cancer*

0460 Risk-Adjusted Morbidity and Mortality for Esophagectomy for Cancer*

1790 Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer

1854 Barrett's Esophagus

Prostate Cancer Measures

0389 Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients*

0390 Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients*

1853 Radical Prostatectomy Pathology Reporting

Other Oncology Measures

0381 Oncology: Treatment Summary Communication – Radiation Oncology

0382 Oncology: Radiation Dose Limits to Normal Tissues

0383 Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (paired with 0384)

0384 Oncology: Pain Intensity Quantified – Medical Oncology and Radiation Oncology (paired with 0383)

0386 Oncology: Cancer Stage Documented

Appendix C: Cancer Portfolio—Use in Federal Programs

NQF #	Title	Federal Programs: Finalized as of June, 2016
0220	Adjuvant hormonal therapy	Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting Program (PCHQR)
0223	Adjuvant chemotherapy is considered or administered within 4 months (120 days) of diagnosis to patients under the age of 80 with AJCC III (lymph node positive) colon cancer	Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting Program (PCHQR)
0377	Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow	Physician Quality Reporting System (PQRS)
0378	Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy	Physician Quality Reporting System (PQRS)
0379	Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry	Physician Quality Reporting System (PQRS)
0380	Hematology: Multiple Myeloma: Treatment with Bisphosphonates	Physician Quality Reporting System (PQRS)
0382	Oncology: Radiation Dose Limits to Normal Tissues	Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting Program (PCHQR)
0383	Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (paired with 0384)	Physician Quality Reporting System (PQRS)
0384	Oncology: Pain Intensity Quantified – Medical Oncology and Radiation Oncology (paired with 0383)	Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting Program (PCHQR)
0385	Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients	Physician Quality Reporting System (PQRS)
0389	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	Physician Quality Reporting System (PQRS)
0390	Prostate Cancer: Adjuvant Hormonal Therapy for High Risk Prostate Cancer Patients	Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting Program (PCHQR)
0391	Breast Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade	Physician Quality Reporting System (PQRS)

NQF #	Title	Federal Programs: Finalized as of June, 2016
0392	Colorectal Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade	Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting Program (PCHQR)
0508	Diagnostic Imaging: Inappropriate Use of “Probably Benign” Assessment Category in Screening Mammograms	Physician Quality Reporting System (PQRS)
0509	Diagnostic Imaging: Reminder System for Screening Mammograms	Physician Quality Reporting System (PQRS)
0559	C0559: Combination chemotherapy is considered 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.	Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting Program (PCHQR)
1822	External Beam Radiotherapy for Bone Metastases	Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting Program (PCHQR)
1853	Radical Prostatectomy Pathology Reporting	Physician Quality Reporting System (PQRS)
1854	Barrett's Esophagus	Physician Quality Reporting System (PQRS)
1855	Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines	Physician Quality Reporting System (PQRS)

Appendix D: Project Standing Committee and NQF Staff

STANDING COMMITTEE

David Cella, PhD (Co-Chair)
Professor and Chair, Northwestern University
Evanston, Illinois

Karen Fields, MD (Co-Chair)
Medical Director, Strategic Alliances, Moffitt Cancer Center
Tampa, Florida

Gregary Bocsi, DO, FCAP
Associate Director, University of Colorado Hospital Clinical Laboratory
Denver, Colorado

Brent Braveman, PhD, OTR/L, FAOTA
Director, Department of Rehabilitation Services, University of Texas M.D. Anderson Cancer Center
Houston Texas

Jennifer Carney, MD
Chief of Hematology and Oncology and Principle Investigator for Oncology Research Trials, Hawaii, Kaiser Permanente
Honolulu, Hawaii

Steven Chen, MD, MBA, FACS
Director of Surgical Oncology, OasisMD
San Diego, California

Crawford Clay
Patient Support Navigator & Advocacy Coordinator, Colon Cancer Alliance
Washington, DC

Matthew Facktor, MD, FACS
Director, Department of Thoracic Surgery, Geisinger Medical Center
Danville, Pennsylvania

Martin Fleisher, PhD, MS
Provider, American Association for Clinical Chemistry
Glen Cove, New York

Shelley Fuld Nasso, MPP
CEO, National Coalition for Cancer Survivorship
Washington, DC

Jennifer Harvey, MD, FACR
Professor of Radiology at the University of Virginia Health System, Chief of the Division of Breast Imaging, Co-Director of the UVA Breast Care Program, and Vice-Chair of Faculty Development
University of Virginia Health System
Charlottesville, Virginia

Bradford Hirsch, MD
Senior Medical Direction, Flatiron Health
New York, New York

Jette Hogenmiller, PhD, MN, APRN/ARNP, CDE, NTP, TNCC, CEE
Oncology Nurse Practitioner
Idaho Springs, Colorado

Joseph Laver, MD, MHA
Chief Medical Officer and Professor of Pediatrics, Stony Brook University Hospital
Stony Brook, New York

J. Leonard Lichtenfeld, MD, MACP
Deputy Chief Medical Officer, American Cancer Society
Atlanta, Georgia

Jennifer Malin, MD, PhD
Staff Vice President, Clinical Strategy, Anthem, Inc.
Thousand Oaks, California

Joanne Buzaglo, PhD
Senior Vice President of Research and Training, Cancer Support Community
Philadelphia, Pennsylvania

Jodi Maranchie, MD, FACS
Associate Professor, University of Pittsburgh, Department of Urology
Pittsburgh, Pennsylvania

Ali McBride, PharmD, MS, BCPS
Clinical Coordinator, Hematology/Oncology, Department of Pharmacy, The University of Arizona Cancer Center
Tucson, Arizona

Benjamin Movsas, MD
Chair, Radiation Oncology, Henry Ford Health System
Detroit, Michigan

Diane Otte, RN, MS, OCN
Director, Cancer Center, Mayo Clinic Health System - Franciscan Healthcare
La Crosse, Wisconsin

Beverly Reigle, PhD, RN
Associate Professor, University of Cincinnati College of Nursing
Cincinnati, Ohio

David J. Sher, MD, MPH
Associate Professor, UT Southwestern Medical Center
Dallas, Texas

Danielle Ziernicki, PharmD
Director of Healthcare Quality for Oncology, J&J Healthcare Systems
Horsham, Pennsylvania

NQF STAFF

Helen Burstin, MD, MPH
Chief Scientific Officer

Marcia Wilson, PhD, MBA
Senior Vice President

Elisa Munthali, MPH
Vice President

Melissa Mariñelarena, RN, MPA
Senior Director

Shaconna Gorham, MS, PMP
Senior Project Manager

Amber Sterling, MPH
Project Manager

Kaitlynn Ector-Robinson, MPH
Project Analyst

Appendix E: Measure Specifications

0219 Post breast conservation surgery irradiation

STEWARD

Commission on Cancer, American College of Surgeons

DESCRIPTION

Percentage of female patients, age 18-69, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage I, II, or III, receiving breast conserving surgery who receive radiation therapy within 1 year (365 days) of diagnosis.

TYPE

Process

DATA SOURCE

Paper Medical Records, Electronic Clinical Data : Registry Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base

No data collection instrument provided No data dictionary

LEVEL

Facility

SETTING

Hospital/Acute Care Facility

NUMERATOR STATEMENT

Radiation therapy to the breast is initiated within 1 year (365 days) of the date of diagnosis

NUMERATOR DETAILS

Regional Treatment Modality [NAACCR Item#1570]=20-98, and Date Radiation Started [NAACCR Item#1210] <= 365 days following the Date of Diagnosis [NAACCR Item#340]

DENOMINATOR STATEMENT

Include, if all of the following characteristics are identified:

Women

Age 18-69 at time of diagnosis

Known or assumed to be first or only cancer diagnosis

Primary tumors of the breast

Epithelial malignancy only,

AJCC Stage I, II, or III

Surgical treatmen

DENOMINATOR DETAILS

Sex [NAACCR Item#220]=2; Age at Diagnosis [NAACCR Item#230] < 70; AND Surgical Procedure of the Primary Site [NAACCR Item#1290] = 20–24

EXCLUSIONS

Exclude, if any of the following characteristics are identified:

Men

Under age 18 at time of diagnosis

Over age 69 at time of diagnosis

Second or subsequent cancer diagnosis

Tumor not originating in the breast

Non-epithelial malignancies

Phyllodes tumor histology

Stage 0, in-situ tumor

Stage IV, metastatic tumor

None of 1st course therapy performed at reporting facility

Died within 12 months (365 days) of diagnosis

Patient participating in clinical trial that directly impacts delivery of the standard of care

EXCLUSION DETAILS

See: https://www.facs.org/~/media/files/quality%20programs/cancer/quality%20breast.ashx

RISK ADJUSTMENT

No risk adjustment or risk stratification

STRATIFICATION

No stratification applied

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

This measure score is calculated by dividing the numerator cases by denominator eligible cases.

Denominator eligible cases are assessed in a step-wise fashion:

- Include breast cancer cases

- Exclude Patients enrolled in a clinical trial that directly impacts delivery of the standard of care

- Include female cases only

- Include first and only primary tumors

- Include epithelial tumors staged according to AJCC 7th edition

- Exclude 8940 - Mixed tumor, malignant, NOS; 8950 - Mullerian mixed tumor; 8980 – Carcinosarcoma; 8981 - Carcinosarcoma, embryonal

- Include invasive tumors only

- Exclude pathologic evidence of in situ or metastatic disease

- Exclude clinical evidence of in situ or metastatic disease

- Include cases with all or part of the first course of treatment was performed at the reporting facility

- Include cases with receipt of breast conserving surgery

- Include patient reported living within 365 days from the date of diagnosis

Numerator cases are then assessed from denominator eligible cases:

- Cases are included in the numerator if

Radiation therapy was administered within 365 days following diagnosis.

The measure score is calculated with the numerator divided by the denominator.

See: https://www.facs.org/~/media/files/quality%20programs/cancer/quality%20breast.ashx Available at measure-specific web page URL identified in S.1

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0220 Adjuvant hormonal therapy

STEWARD

Commission on Cancer, American College of Surgeons

DESCRIPTION

Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage T1cN0M0,IB to III, who's primary tumor is progesterone or estrogen receptor positive with tamoxifen or third generation aromatase inhibitor (recommended or administered) within 1 year (365 days) of diagnosis.

TYPE

Process

DATA SOURCE

Paper Medical Records, Electronic Clinical Data : Registry Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base

No data collection instrument provided No data dictionary

LEVEL

Facility

SETTING

Hospital/Acute Care Facility

NUMERATOR STATEMENT

Hormone therapy is administered within 1 year (365 days) of the date of diagnosis or it is recommended but not received

NUMERATOR DETAILS

Hormone Therapy recommended and not received [NAACCR Item#1400]=82-87 (82:not recommended/administered because it was contraindicated due to patient risk factors, 85:not administered because the patient died prior to planned or recommended therapy,86:It was recommended by the patient's physician, but was not administered as part of first-course therapy. No reason was stated in the patient record. 87: it was recommended by the patient's

physician, but this treatment was refused by the patient, the patient's family member, or the patient's guardian. The refusal was noted in the patient record)

OR; Hormone Therapy administered [NAACCR Item#1400]=1, AND Date Hormone Therapy Started (NAACCR Item#710] <=365 days following Date of Diagnosis [NAACCR Item# 340]

DENOMINATOR STATEMENT

Include if all of the following characteristics are identified:

Women

Age >=18 at time of diagnosis

Known or assumed to be first or only cancer diagnosis

Epithelial malignancy only

Primary tumors of the breast

AJCC T1cN0M0 or Stage IB - III

Primary tumor

DENOMINATOR DETAILS

Sex [NAACCR Item#220]=2; and

Age [NAACCR Item# 230] >=18; and

Stageable Epithelial tumors histology [NAACCR Item# 522] 8000-8576, 8941-8949 and

Invasive tumor behavior [NAACCR Item# 522] =3 and

AJCC T1c or Stage IB-III:Tumor Size [NAACCR Item#2800]= 11-989, 992-995 and AJCC pN [NAACCR Item#890]=0, I-, I+, 0M-, M=, 0M+ OR AJCC pN [NAACCR Item#890]=1,1M, 1M1, 1A, 1B, 1C,2, 2A, 2B, 3, 3A, 3B, or 3C; and

CS SSF1 (ERA) [NAACCR Item#2880]=010 or 030; AND CS SSF2 (PRA) [NAACCR Item#2890]=010 or 030;

AND Surgical Procedure of the Primary Site [NAACCR Item#1290] = 20–90

EXCLUSIONS

Exclude, if any of the following characteristics are identified:

Men

Under age 18 at time of diagnosis

Second or subsequent cancer diagnosis

Tumor not originating in the breast

Non-epithelial malignancies, exclude malignant phyllodes tumors, 8940 - Mixed tumor, malignant, NOS, 8950 - Mullerian mixed tumor , 8980 - Carcinosarcoma,8981 - Carcinosarcoma, embryona

Stage 0, in-situ tumor

AJCC T1mic, or T1a tumor

Stage IV, metastatic tumor

Primary tumor is estrogen receptor negative and progesterone receptor negative

None of 1st course therapy performed at reporting facility

Died within 1 year (365 days) of diagnosis,

Patient enrolled in a clinical trial that directly impacts delivery of the standard of care

EXCLUSION DETAILS

See: https://www.facs.org/~/media/files/quality%20programs/cancer/quality%20breast.ashx

RISK ADJUSTMENT

No risk adjustment or risk stratification

STRATIFICATION

No stratification applied

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

See: https://www.facs.org/~/media/files/quality%20programs/cancer/quality%20breast.ashx
Available at measure-specific web page URL identified in S.1

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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

STEWARD

Commission on Cancer, American College of Surgeons

DESCRIPTION

Percentage of patients under the age of 80 with AJCC III (lymph node positive) colon cancer for whom adjuvant chemotherapy is recommended and not received or administered within 4 months (120 days) of diagnosis.

TYPE

Process

DATA SOURCE

Paper Medical Records, Electronic Clinical Data : Registry Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base

No data collection instrument provided No data dictionary

LEVEL

Facility

SETTING

Hospital/Acute Care Facility

NUMERATOR STATEMENT

Chemotherapy is administered within 4 months (120 days) of diagnosis or it is recommended and not received

NUMERATOR DETAILS

Chemotherapy Recommended and not received [NAACCR Item#1390]=82-87 (82:not recommended/administered because it was contraindicated due to patient risk factors, 85:not administered because the patient died prior to planned or recommended therapy,86:It was recommended by the patient's physician, but was not administered as part of first-course therapy. No reason was stated in the patient record. 87: it was recommended by the patient's physician, but this treatment was refused by the patient, the patient's family member, or the patient's guardian. The refusal was noted in the patient record)

OR; Chemotherapy [NAACCR Item#1390]=3, and Date Chemotherapy Started (NAACCR Item#1220] <=120 days following Date of Diagnosis [NAACCR Item# 340]

DENOMINATOR STATEMENT

Include, if all of the following characteristics are identified:

Age 18-79 at time of diagnosis

Known or assumed to be first or only cancer diagnosis

Primary tumors of the colon

Epithelial malignancy only

At least one pathologically examined regional lym

DENOMINATOR DETAILS

Age at Diagnosis [NAACCR Item#230] 18-79 AND Male or female [NAACCR item #220] = 1,2; AND Surgical Procedure of the Primary Site [NAACCR Item#1290] = 30–90, AND Regional Lymph Nodes Positive [NAACCR Item#820] = 1-90, 95, 97

EXCLUSIONS

Exclude, if any of the following characteristics are identified:

Age <18 and >=80; not a first or only cancer diagnosis; non-epithelial and non-invasive tumors; no regional lymph nodes pathologically examined; metastatic disease (AJCC Stage IV); not treated surgically; died within 4 months (120 days) of diagnosis; Patient participating in clinical trial which directly impacts receipt of standard of care.

EXCLUSION DETAILS

See: https://www.facs.org/~/media/files/quality%20programs/cancer/ncdb/measure%20specs%20colon_03312015.ashx

RISK ADJUSTMENT

No risk adjustment or risk stratification

STRATIFICATION

No stratification applied

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

This measure score is calculated by dividing the numerator cases by denominator eligible cases.

Denominator eligible cases are assessed in a step-wise fashion:

- Include all colon cancer cases

- Adult patients 18 and over and under 80

- Males and female cases only

- Include first or only primaries

- Include epithelial tumors based on AJCC 7th Ed.

- Include invasive tumors only

- Exclude cases with clinical or pathologic evidence of in situ disease

- Exclude cases with clinical or pathologic evidence of metastatic disease

- Include only cases where all or part of first course treatment was performed at the reporting facility

- Include only surgically treated cases

- Include only patients which were alive for at least 120 days following diagnosis

- Include only lymph node positive disease

Numerator cases are then assessed from denominator eligible cases:

- Cases are included in the numerator if:

a) Chemotherapy is administered the number of days between diagnosis and start of chemotherapy within 120 days are included in the numerator or

b) Chemotherapy is recommended but not administered based on:

-Chemotherapy was not recommended/administered because it was contraindicated due to patient risk factors,

-Chemotherapy was not administered because the patient died prior to planned or recommended therapy,

-Chemotherapy was not administered. It was recommended by the patient's physician but was not administered as part of the first course of therapy.

-Chemotherapy was not administered, it was recommended by the patients' physician but refused by the patient, patient's family member or guardian. The refusal was noted in patient record.

The measure score is calculated with the numerator divided by the denominator.

Detailed steps are found here: https://www.facs.org/~/media/files/quality%20programs/cancer/ncdb/measure%20specs%20colon_03312015.ashx Available at measure-specific web page URL identified in S.1

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0225 At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer

STEWARD

Commission on Cancer, American College of Surgeons

DESCRIPTION

Percentage of patients >18yrs of age, who have primary colon tumors (epithelial malignancies only), at AJCC stage I, II or III who have at least 12 regional lymph nodes removed and pathologically examined for resected colon cancer.

TYPE

Process

DATA SOURCE

Paper Medical Records, Electronic Clinical Data : Registry Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base

No data collection instrument provided No data dictionary

LEVEL

Facility

SETTING

Hospital/Acute Care Facility

NUMERATOR STATEMENT

>=12 regional lymph nodes pathologically examined.

NUMERATOR DETAILS

Regional Lymph Nodes Examined [NAACCR Item#830] = 12-90

DENOMINATOR STATEMENT

Include, if all of the following characteristics are identified:

Age >=18 at time of diagnosis

Primary tumors of the colon

Epithelial malignancy only

AJCC Stage I, II, or III

Surgical resection performed at the reporting facility

DENOMINATOR DETAILS

Surgical Procedure of the Primary Site at This Facility [NAACCR Item#670] = 30-80

EXCLUSIONS

Exclude, if any of the following characteristics are identified:

Age <18; non-epithelial and non-invasive tumors; metastatic disease (AJCC Stage IV); not treated surgically at the reporting facility; perforation of the primary site; acute obstruction

EXCLUSION DETAILS

See: https://www.facs.org/~/media/files/quality%20programs/cancer/quality%20colon.ashx

RISK ADJUSTMENT

No risk adjustment or risk stratification

STRATIFICATION

No stratification applied

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

This measure score is calculated by dividing the numerator cases by denominator eligible cases.

Denominator eligible cases are assessed in a step-wise fashion:

First include diagnosis of colon cancer,

male or females,

adult patients,

malignant tumors

epithelial tumors based on AJCC 7th edition staging

Exclude clinical or pathologic evidence of in-situ disease

Exclude clinical or pathologic evidence of metastatic disease

All or part of first course of treatment at reporting facility

surgically treated at this facility

These cases are included in the denominator

Then numerator cases are assessed from denominator eligible cases

The number of regional lymph nodes examined are 12-90

The number of nodes examined is greater or equal to the number of positive lymph nodes.

The measure score is calculated by the numerator divided by the denominator. Available at measure-specific web page URL identified in S.1

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0377 Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow

STATUS

Steering Committee Review

STEWARD

American Society of Hematology

DESCRIPTION

Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow

TYPE

Process

DATA SOURCE

Electronic Clinical Data : Registry Not Applicable

Attachment NQF0377__I9toI10_conversion.xlsx

LEVEL

Clinician : Group/Practice, Clinician : Individual, Clinician : Team

SETTING

Ambulatory Care : Clinician Office/Clinic

NUMERATOR STATEMENT

Patients who had baseline cytogenetic testing performed on bone marrow

NUMERATOR DETAILS

Numerator Definition:

Baseline Cytogenetic Testing: Testing that is performed at time of diagnosis or prior to initiating treatment (transfusion, growth factors, or antineoplastic therapy) for that diagnosis

For Registry:

Report the CPT Category II code: 3155F – Cytogenetic testing performed on bone marrow at time of diagnosis or prior to initiating treatment

DENOMINATOR STATEMENT

All patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia

DENOMINATOR DETAILS

Denominator Note:

This measure is to be reported a minimum of once per reporting period for all myelodysplastic syndrome (MDS) and Acute Leukemia patients seen during the reporting period, regardless of when MDS or Acute Leukemia diagnosis was made; the quality action being measured is that baseline cytogenetic testing on bone marrow was performed for each patient with MDS and Acute Leukemia at the time of diagnosis or prior to initiating treatment.

For Registry:

Patients aged >= 18 years

AND

Diagnosis for MDS or acute leukemia - not in remission (ICD-9-CM) [reportable through 09/30/2015]: 204.00, 204.02, 205.00, 205.02, 206.00, 206.02, 207.00, 207.02, 207.20, 207.22, 208.00, 208.02, 238.72, 238.73, 238.74, 238.75

Diagnosis for MDS or acute leukemia - not in remission (ICD-10-CM) [reportable beginning 10/1/2015]: C91.00, C91.02, C92.00, C92.02, C92.40, C92.42, C92.50, C92.52, C92.60, C92.62, C92.A0, C92.A2, C93.00, C93.02, C94.00, C94.02, C94.20, C94.22, C95.00, C95.02, D46.0, D46.1, D46.20, D46.21, D46.22, D46.4, D46.9, D46.A, D46.B, D46.C, D46.Z

AND

CPT codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245

EXCLUSIONS

For Registry:

Documentation of medical reason(s) for not performing baseline cytogenetic testing (eg, no liquid bone marrow or fibrotic marrow)

Documentation of patient reason(s) for not performing baseline cytogenetic testing (eg, at time of diagnosis receiving palliative care or not receiving treatment as defined above)

Documentation of system reason(s) for not performing baseline cytogenetic testing (eg, patient previously treated by another physician at the time cytogenetic testing performed)

EXCLUSION DETAILS

Exceptions are used to remove a patient from the denominator of a performance measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons. The patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment, individual patient characteristics, or patient preferences. The PCPI exception methodology uses three categories of reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For the measure Myelodysplastic Syndrome (MDS) and Acute Leukemias – Baseline Cytogenetic Testing Performed on Bone Marrow, exceptions may include medical reasons (eg, no liquid bone marrow or fibrotic marrow), patient reasons (eg, at time of diagnosis receiving palliative care or not receiving treatment as defined above), or system reasons (eg, patient previously treated by another physician at the time cytogenetic testing performed). Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement.

Additional details by data source are as follows:

For Registry:

Documentation of medical reason(s) for not performing baseline cytogenetic testing on bone marrow (eg, no liquid bone marrow or fibrotic marrow) - Append modifier to CPT Category II code: 3155F-1P

Documentation of patient reason(s) for not performing baseline cytogenetic testing on bone marrow (eg, at time of diagnosis receiving palliative care or not receiving treatment as defined above) - Append modifier to CPT Category II code: 3155F-2P

Documentation of system reason(s) for not performing baseline cytogenetic testing on bone marrow (eg, patient previously treated by another physician at the time cytogenetic testing performed) - Append modifier to CPT Category II code: 3155F-3P

RISK ADJUSTMENT

No risk adjustment or risk stratification

No risk adjustment or risk stratification.

STRATIFICATION

Consistent with CMS' Measures Management System Blueprint and recent national recommendations put forth by the IOM and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer.

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

To calculate performance rates:

1. Find the patients who meet the initial population (ie, the general group of patients that a set of performance measures is designed to address).

2. From the patients within the initial population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial population and denominator are identical.

3. From the patients within the denominator, find the patients who meet the numerator criteria (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator

4. From the patients who did not meet the numerator criteria, determine if the provider has documented that the patient meets any criteria for exception when denominator exceptions have been specified [for this measure: include medical reasons (eg, no liquid bone marrow or fibrotic marrow), patient reasons (eg, at time of diagnosis receiving palliative care or not receiving treatment as defined above), or system reasons (eg, patient previously treated by another physician at the time cytogenetic testing performed). If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. --Although the exception cases are removed from the denominator population for the performance calculation, the exception rate (ie, percentage with valid exceptions) should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.

If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure. No diagram provided

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0378 Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy

STEWARD

American Society of Hematology

DESCRIPTION

Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) who are receiving erythropoietin therapy with documentation of iron stores within 60 days prior to initiating erythropoietin therapy

TYPE

Process

DATA SOURCE

Electronic Clinical Data : Registry Not Applicable

No data collection instrument provided Attachment NQF0378__I9toI10_conversion.xlsx

LEVEL

Clinician : Group/Practice, Clinician : Individual, Clinician : Team

SETTING

Ambulatory Care : Clinician Office/Clinic

NUMERATOR STATEMENT

Patients with documentation of iron stores within 60 days prior to initiating erythropoietin therapy

NUMERATOR DETAILS

Numerator Definition:

Documentation of Iron Stores – Includes either: 1) bone marrow examination including iron stain OR 2) serum iron measurement including ferritin, serum iron and total iron-binding capacity (TIBC)

For Registry:

Report the CPT Category II code: 3160F - Documentation of iron stores prior to initiating erythropoietin therapy

DENOMINATOR STATEMENT

All patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) who are receiving erythropoietin therapy

DENOMINATOR DETAILS

Denominator Note:

This measure is to be reported a minimum of once per reporting period for all myelodysplastic syndrome (MDS) patients seen during the reporting period, regardless of when erythropoietin therapy is initiated; the quality action being measured is that iron stores were documented for each MDS patient receiving erythropoietin therapy within 60 days of starting erythropoietin therapy, regardless of how far back the erythropoietin therapy initiated.

Denominator Definition:

Erythropoietin Therapy – Includes the following medications: epoetin and darbepoetin for the purpose of this measure

For Registry:

Patients aged >= 18 years

AND

Diagnosis for MDS (ICD-9-CM) [reportable through 9/30/2015]: 238.72, 238.73, 238.74, 238.75

Diagnosis for MDS (ICD-10-CM) [reportable beginning 10/01/2015]: D46.0, D46.1, D46.20, D46.21, D46.22, D46.4, D46.9, D46.A, D46.B, D46.C, D46.Z

AND

Patient encounter during the reporting period (CPT): 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99243, 99244, 99245

AND

CPT Category II 4090F: Patient receiving erythropoietin therapy

EXCLUSIONS

Documentation of system reason(s) for not documenting iron stores prior to initiating erythropoietin therapy

EXCLUSION DETAILS

Exceptions are used to remove a patient from the denominator of a performance measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons. The patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment, individual patient characteristics, or patient preferences. The PCPI exception methodology uses three categories

of reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. For the measure Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy, exceptions may include system reasons. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement.

Additional details by data source are as follows:

For Registry:

Documentation of system reason(s) for not documenting iron stores prior to initiating erythropoietin therapy - Append modifier to CPT Category II code: 3160F-3P

RISK ADJUSTMENT

No risk adjustment or risk stratification

No risk adjustment or risk stratification.

STRATIFICATION

Consistent with CMS' Measures Management System Blueprint and recent national recommendations put forth by the IOM and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer.

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

To calculate performance rates:

1. Find the patients who meet the initial population (ie, the general group of patients that a set of performance measures is designed to address).

2. From the patients within the initial population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial population and denominator are identical.

3. From the patients within the denominator, find the patients who meet the numerator criteria (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator

4. From the patients who did not meet the numerator criteria, determine if the provider has documented that the patient meets any criteria for exception when denominator exceptions have been specified for this measure: include system reasons. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. --Although the exception cases are removed from the denominator population for the performance calculation, the exception rate (ie, percentage with valid exceptions) should be

calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.

If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure. No diagram provided

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0389 Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

STEWARD

PCPI

DESCRIPTION

Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer

TYPE

Process

DATA SOURCE

Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry Not applicable.

No data collection instrument provided Attachment EP_eCQM_ValueSets_CMS129v6_NQF0389_02182016.xls

LEVEL

Clinician : Group/Practice, Clinician : Individual, Clinician : Team

SETTING

Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Other Radiation Oncology Clinic/Department

NUMERATOR STATEMENT

Patients who did not have a bone scan performed at any time since diagnosis of prostate cancer

NUMERATOR DETAILS

For Registry:

To submit the numerator option for patients who did not have a bone scan performed at any time since diagnosis of prostate cancer, report the following CPT Category II code:

3270F – Bone scan not performed prior to initiation of treatment nor at any time since diagnosis of prostate cancer

For EHR Specifications:

HQMF eMeasure developed and is included in this submission.

DENOMINATOR STATEMENT

All patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence, receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy

DENOMINATOR DETAILS

Definitions:

Risk Strata Definitions: 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.

Note: Only patients with prostate cancer with low risk of recurrence will be counted in the denominator of this measure

For Registry:

Any male patient, regardless of age

AND

Diagnosis for prostate cancer (ICD-9-CM): 185

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

AND

Patient encounter during the reporting period (CPT): 55810, 55812, 55815, 55840, 55842, 55845, 55866, 55873, 55875, 77427, 77435, 77772, 77778, 77799

AND

Report the following CPT Category II Code to identify the risk of recurrence:

3271F: Low risk of recurrence, prostate cancer

For EHR:

HQMF eMeasure developed and is included in this submission.

EXCLUSIONS

Documentation of medical reason(s) for having a bone scan performed (including documented pain, salvage therapy, other medical reasons)

Documentation of system reason(s) for having a bone scan performed (including bone scan ordered by someone other than reporting physician)

EXCLUSION DETAILS

Exceptions are used to remove a patient from the denominator of a performance measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons. The patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment, individual patient characteristics, or patient preferences. The PCPI exception methodology uses three categories of reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For measure Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients, exceptions may include medical reason(s) (eg, documented pain, salvage therapy, other medical reasons) or system reason(s) (eg, bone scan ordered by someone other than reporting physician). Where examples of exceptions are included in the measure language, value sets for these examples are developed and included in the eMeasure. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic

review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement.

Additional details by data source are as follows:

For Registry:

Append modifier to CPT Category II code:

3269F with 1P - Documentation of medical reason(s) for performing a bone scan (including documented pain, salvage therapy, other medical reasons)

Append modifier to CPT Category II code:

3269F with 3P - Documentation of system reason(s) for performing a bone scan (including bone scan ordered by someone other than reporting physician)

For EHR:

HQMF eMeasure developed and is included in this submission.

RISK ADJUSTMENT

No risk adjustment or risk stratification

No risk adjustment or risk stratification

STRATIFICATION

Consistent with CMS' Measures Management System Blueprint and recent national recommendations put forth by the IOM and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer and have included these variables as recommended data elements to be collected.

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

To calculate performance rates:

1. Find the patients who meet the initial population (ie, the general group of patients that a set of performance measures is designed to address).

2. From the patients within the initial population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial population and denominator are identical.

3. From the patients within the denominator, find the patients who meet the numerator criteria (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator

4. From the patients who did not meet the numerator criteria, determine if the provider has documented that the patient meets any criteria for exception when denominator exceptions have been specified [for this measure: medical reason(s) (eg, documented pain, salvage therapy, other medical reasons) or system reason(s) (eg, bone scan ordered by someone other than reporting physician)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. --Although the exception cases are removed from

the denominator population for the performance calculation, the exception rate (ie, percentage with valid exceptions) should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.

If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure. No diagram provided

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0390 Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

STEWARD

American Urological Association

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)

TYPE

Process

DATA SOURCE

Electronic Clinical Data, Electronic Clinical Data : Registry Not applicable. Not a PRO.

No data collection instrument provided Attachment NQF0390_I9toI10_conversion.xlsx

LEVEL

Clinician : Group/Practice, Clinician : Individual, Clinician : Team

SETTING

Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Other Radiation Oncology Clinic/Department

NUMERATOR STATEMENT

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

NUMERATOR DETAILS

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.

For Registry:

To submit the numerator option for patients who were prescribed adjuvant hormonal therapy (GnRH agonist or antagonist), report the following CPT Category II code:

4164F - 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

DENOMINATOR STATEMENT

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

DENOMINATOR DETAILS

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.

Note: Only male patients with prostate cancer with high or very high risk of recurrence will be counted in the performance denominator of this measure.

For Registry:

Any male patient, regardless of age

AND

Diagnosis for prostate cancer (ICD-9-CM): 185

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

AND NOT

Diagnosis for metastatic cancer (ICD-9-CM): 196.0, 196.1, 196.2, 196.3, 196.5, 196.6, 196.8, 196.9, 197.0, 197.1, 197.2, 197.3, 197.4, 197.5, 197.6, 197.7, 197.8, 198.0, 198.1, 198.2, 198.3, 198.4, 198.5, 198.6, 198.7, 198.81, 198.82, 198.89

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

AND

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

AND

Report the following quality-data code (G-code) to identify the risk of recurrence:

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

EXCLUSIONS

AUA methodology uses three categories of reasons for which a patient may be excluded from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For this measure, exceptions for not prescribing/administering adjuvant hormonal therapy may include medical reason(s) (eg, salvage therapy) or patient reason(s). Although this methodology does not require the external reporting of more detailed exception data, the AUA recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The AUA also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that physicians have identified as meeting the criteria for exception. Additional details by data source are as follows:

Documentation of medical reason(s) for not prescribing/administering adjuvant hormonal therapy (eg, salvage therapy)

Documentation of patient reason(s) for not prescribing/administering adjuvant hormonal therapy

EXCLUSION DETAILS

Exceptions are used to remove a patient from the denominator of a performance measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons. The patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment, individual patient characteristics, or patient preferences. The AUA exception methodology uses three categories of reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For measure Adjuvant Hormonal Therapy for High Risk or Very High Risk Prostate Cancer Patients, exceptions may include medical reason(s) (eg, salvage therapy) or patient reason(s) for not prescribing/administering adjuvant hormonal therapy. Although this methodology does not require the external reporting of more detailed exception data, the AUA recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The AUA also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement.

Additional details by data source are as follows:

For Registry:

Documentation of medical reason(s) for not prescribing/administering adjuvant hormonal therapy (eg, salvage therapy)

Append modifier to CPT Category II code: 4164F with 1P

Documentation of patient reason(s) for not prescribing/administering adjuvant hormonal therapy

Append modifier to CPT Category II code: 4164F with 2P

RISK ADJUSTMENT

No risk adjustment or risk stratification

No risk adjustment or risk stratification

STRATIFICATION

Consistent with CMS' Measures Management System Blueprint and recent national recommendations put forth by the IOM and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer.

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

To calculate performance rates:

1) Find the patients who meet the initial patient population (ie, the general group of patients that the performance measure is designed to address).

2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical.

3) From the patients within the denominator, find the patients who qualify for the Numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator

4) From the patients who did not meet the numerator criteria, determine if the physician has documented that the patient meets any criteria for denominator exception when exceptions have been specified [for this measure: medical reason(s) for not prescribing adjuvant hormonal therapy (eg, salvage therapy) or patient reason(s)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation.

–Although the exception cases are removed from the denominator population for the performance calculation, the number of patients with valid exceptions should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.

If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure. No diagram provided

0459 Risk-Adjusted Length of Stay >14 Days after Elective Lobectomy for Lung Cancer

STEWARD

The Society of Thoracic Surgeons

DESCRIPTION

Percentage of patients aged 18 years and order undergoing elective lobectomy for lung cancer who had a prolonged length of stay >14 days

TYPE

Outcome

DATA SOURCE

Electronic Clinical Data : Registry STS General Thoracic Surgery Database (GTSD) Version 2.2; STS GTSD Version 2.3 went live on January 1, 2015.

Available at measure-specific web page URL identified in S.1 Attachment S.15._Detailed_risk_model_specifications_-_0459_Lobectomy_LOS.docx

LEVEL

Facility, Clinician : Group/Practice

SETTING

Hospital/Acute Care Facility

NUMERATOR STATEMENT

Number of patients aged 18 years and older undergoing elective lobectomy for lung cancer who had a prolonged length of stay >14 days

NUMERATOR DETAILS

Prolonged Postoperative Length of Stay (PLOS) is defined as a Yes/No variable indicating postoperative hospital stay of greater than 14 days, using surgery date (SurgDt- STS General Thoracic Surgery Database (GTSD) v 2.2, sequence number 1340) and discharge date (DischDt- STS GTSD v 2.2, sequence number 2190) to calculate PLOS.

DENOMINATOR STATEMENT

Number of patients aged 18 years and older undergoing elective lobectomy for lung cancer

DENOMINATOR DETAILS

1. Lung cancer (LungCancer - STS GTS Database, v 2.2, sequence number 830) is marked "yes" and Category of Disease – Primary (CategoryPrim - STS GTS Database, v 2.2, sequence number 1300) is marked as one of the following:

(ICD-9, ICD-10)

Lung cancer, main bronchus, carina (162.2, C34.00)

Lung cancer, upper lobe (162.3, C34.10)

Lung cancer, middle lobe (162.4, C34.2)

Lung cancer, lower lobe (162.5, C34.30)

Lung cancer, location unspecified (162.9, C34.90)

2. Primary procedure is one of the following CPT codes:

Thoracoscopy, surgical; with lobectomy (32663)

Thoracoscopy with removal of two lobes (bilobectomy) (32670)

Removal of lung, single lobe (lobectomy) (32480)

Removal of lung, two lobes (bilobectomy) (32482)

Removal of lung, sleeve lobectomy (32486)

3. Status of Operation (Status - STS GTS Database, v 2.2, sequence number 1420) is marked as "Elective"

4. Gender (Gender -STS GTS Database, v 2.2, sequence number 190) is marked “Male” or “Female,” surgery date (SurgDt - sequence number 1340), and discharge date (DischDt – sequence number 2190) are provided

5. Only analyze first operation of hospitalization meeting criteria 1-4.

EXCLUSIONS

None

EXCLUSION DETAILS

N/A

RISK ADJUSTMENT

Statistical risk model

STRATIFICATION

N/A

TYPE SCORE

Rate/proportion better quality = lower score

ALGORITHM

Please refer to numerator and denominator sections for detailed information. No diagram provided

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N/A

0460 Risk-Adjusted Morbidity and Mortality for Esophagectomy for Cancer

STEWARD

The Society of Thoracic Surgeons

DESCRIPTION

Percentage of patients aged 18 years and older undergoing elective esophagectomy for esophageal cancer who developed any of the following postoperative conditions: bleeding requiring reoperation, anastomosis leak requiring medical or surgical treatment, reintubation, ventilation >48 hours, pneumonia, or discharge mortality

TYPE

Outcome

DATA SOURCE

Electronic Clinical Data : Registry STS General Thoracic Surgery Database (GTSD) Version 2.2; STS GTSD Version 2.3 went live on January 1, 2015.

Available at measure-specific web page URL identified in S.1 Attachment S.15._Detailed_risk_model_specifications_-_0460_MM_for_Esophagectomy_for_Cancer.docx

LEVEL

Facility, Clinician : Group/Practice

SETTING

Hospital/Acute Care Facility

NUMERATOR STATEMENT

Number of patients aged 18 years and older undergoing elective esophagectomy for esophageal cancer who developed any of the following postoperative conditions: bleeding requiring reoperation, anastomosis leak requiring medical or surgical treatment, reintubation, ventilation >48 hours, pneumonia, or discharge mortality.

NUMERATOR DETAILS

Number of patients undergoing elective esophagectomy for esophageal cancer for whom:

1. Unexpected return to the operating room (ReturnOR - STS General Thoracic Surgery Database (GTSD), Version 2.2, sequence number 1720) is marked "yes" and primary reason for return to OR (ReturnORRsn – STS GTSD, Version 2.2, sequence number 1730) is marked "bleeding" or "anastomatic leak following esophageal surgery"

or

2. Postoperative events (POEvents - STS GTSD v 2.2, sequence number 1710) is marked "Yes" and one of the following items is marked:

a. Anastomotis requiring medical treatment only (i.e., interventional radiation drainage, NPO, antibiotics) (AnastoMed- STS GTSD v 2.2, sequence number 1950)

b. Reintubate, Reintube (STS GTSD v 2.2, sequence number 1850)

c. Initial ventilator support > 48 hours (Vent- STS GTSD v 2.2, sequence number 1840)

d. Pneumonia (Pneumonia- STS GTSD v 2.2, sequence number 1780)

e. Discharge Status (MtDCStat - STS GTSD v 2.2, sequence number 2200) is marked as "Dead"

DENOMINATOR STATEMENT

Number of patients aged 18 years and older undergoing elective esophagectomy for esophageal cancer

DENOMINATOR DETAILS

1. Esophageal cancer (EsophCancer- STS GTSD v 2.2, sequence number 1140) is marked "yes" and Category of Disease – Primary (CategoryPrim- STS GTSD v 2.2, sequence number 1300) is marked as one of the following:

(ICD-9, ICD-10)

Esophageal cancer, lower third(150.5, C15.5)

Esophageal cancer, middle third (150.4, C15.4)

Esophageal cancer, upper third (150.3, C15.3)

Malignant other part esophagus (150.8, C15.8)

Esophageal cancer, esophagogastric junction (cardia) (151.0, C16.0)

2. Primary procedure (Primary- STS GTSD v 2.2, sequence number 1500) is marked as one of the following:

Transhiatal-Total esophagectomy, without thoracotomy, with cervical esophagogastrostomy (43107)

Three hole-Total esophagectomy with thoracotomy; with cervical esophagogastrostomy (43112)

Ivor Lewis-Partial esophagectomy, distal two-thirds, with thoracotomy and separate abdominal incision (43117)

Thoracoabdominal-Partial esophagectomy, thoracoabdominal approach (43122)

Minimally invasive three hole esophagectomy (43XXX)

Minimally invasive esophagectomy, Ivor Lewis approach (43XXX)

Minimally invasive esophagectomy, Abdominal and neck approach (43XXX)

Total esophagectomy without thoracotomy; with colon interposition or small intestine reconstruction (43108)

Total esophagectomy with thoracotomy; with colon interposition or small intestine reconstruction (43113)

Partial esophagectomy, cervical, with free intestinal graft, including microvascular anastomosis (43116)

Partial esophagectomy, with thoracotomy and separate abdominal incision with colon interposition or small intestine (43118)

Partial esophagectomy, distal two-thirds, with thoracotomy only (43121)

Partial esophagectomy, thoracoabdominal with colon interposition or small intestine (43123)

Total or partial esophagectomy, without reconstruction with cervical esophagostomy (43124)

3. Status of operation (Status - STS General Thoracic Surgery Database v 2.2, sequence number 1420) is marked as “Elective”

4. Gender and discharge mortality status information are provided; Gender (STS GTSD v 2.2, sequence number 190) is marked as “Male” or “Female, and discharge status (MtDCStat-STS GTSD v 2.2, sequence number 2200) is marked as “Alive” or “Dead”

5. Only analyze first operation of hospitalization meeting criteria 1-4.

EXCLUSIONS

None

EXCLUSION DETAILS

N/A

RISK ADJUSTMENT

Statistical risk model

The model was developed by multivariate logistic regression. The details of risk adjustment model development were published in 2009:

Wright CD, Kucharczuk JC, O'Brien SM, Grab JD, Allen MS. Society of Thoracic Surgeons General Thoracic Surgery Database

Available in attached Excel or csv file at S.2b

STRATIFICATION

N/A

TYPE SCORE

Rate/proportion better quality = lower score

ALGORITHM

Please refer to numerator and denominator sections for detailed information. No diagram provided

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N/A

0508 Diagnostic Imaging: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms

STEWARD

American College of Radiology (ACR)

DESCRIPTION

Percentage of final reports for screening mammograms that are classified as "probably benign"

TYPE

Process

DATA SOURCE

Administrative claims, Electronic Clinical Data : Registry Not applicable

Available at measure-specific web page URL identified in S.1 No data dictionary

LEVEL

Clinician : Individual

SETTING

Ambulatory Care : Clinician Office/Clinic, Imaging Facility

NUMERATOR STATEMENT

Final reports classified as "probably benign"

NUMERATOR DETAILS

Numerator Definition:

Probably Benign Classification – Mammography Quality Standards Act (MQSA) assessment category of "probably benign"; Breast Imaging-Reporting and Data System (BI-RADS®) category 3; or Food and Drug Administration (FDA)-approved equivalent assessment category

Numerator Instructions: For performance, a lower percentage, with a definitional target approaching 0%, indicates appropriate assessment of screening mammograms (eg, the proportion of screening mammograms that are classified as "probably benign").

FOR EHR SPECIFICATIONS:

No Current HQMF eCQM Available.

FOR ADMINISTRATIVE CLAIMS SPECIFICATIONS:

Report CPT Category II code: 3343F: Mammogram assessment category of “probably benign”, documented

DENOMINATOR STATEMENT

All final reports for screening mammograms

DENOMINATOR DETAILS

FOR EHR SPECIFICATIONS:

No Current HQMF eCQM Available.

FOR ADMINISTRATIVE CLAIMS SPECIFICATIONS:

Diagnosis for screening mammogram (ICD-9-CM) [for use 1/1/2015-9/30/2015]: V76.11, V76.12

Diagnosis for screening mammogram (ICD-10-CM) [for use 10/01/2015-12/31/2015]: Z12.31

AND

Patient encounter during the reporting period (CPT or HCPCS): 77057, G0202

EXCLUSIONS

No Denominator Exclusions or Denominator Exceptions

EXCLUSION DETAILS

None

RISK ADJUSTMENT

No risk adjustment or risk stratification

Not Applicable

STRATIFICATION

We encourage the results of this measure to be stratified by race, ethnicity, sex, and payer.

TYPE SCORE

Rate/proportion better quality = lower score

ALGORITHM

To calculate performance rates:

1) Find the patients who meet the initial patient population (ie, the general group of patients that the performance measure is designed to address).

2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical.

3) From the patients within the denominator, find the patients who qualify for the Numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator

If the patient does not meet the numerator, this case represents a quality failure. Available at measure-specific web page URL identified in S.1

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0509 Diagnostic Imaging: Reminder System for Screening Mammograms

STEWARD

American College of Radiology

DESCRIPTION

Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram

TYPE

Process

DATA SOURCE

Administrative claims, Electronic Clinical Data : Registry N/A

No data collection instrument provided No data dictionary

LEVEL

Clinician : Individual

SETTING

Hospital/Acute Care Facility, Imaging Facility

NUMERATOR STATEMENT

Patients whose information is entered into a reminder system with a target due date for the next mammogram

NUMERATOR DETAILS

Numerator Note: The reminder system should be linked to a process for notifying patients when their next mammogram is due and should include the following elements at a minimum: patient identifier, patient contact information, dates(s) of prior screening mammogram(s) (if known), and the target due date for the next mammogram

FOR ELECTRONIC SPECIFICATIONS:

Not Applicable

FOR ADMINISTRATIVE CLAIMS SPECIFICATIONS:

Report CPT II Code 7025F: Patient information entered into a reminder system with a target due date for the next mammogram

DENOMINATOR STATEMENT

All patients undergoing a screening mammogram

DENOMINATOR DETAILS

FOR ELECTRONIC SPECIFICATIONS:

Not Applicable

FOR ADMINISTRATIVE CLAIMS SPECIFICATIONS:

Diagnosis for mammogram screening (ICD-9-CM) [for use 1/1/2015-9/30/2015]: V76.11, V76.12

Diagnosis for mammogram screening (ICD-10-CM) [for use 10/01/2015-12/31/2015]: Z12.31

AND

Patient encounter during the reporting period (CPT or HCPCS): 77057, G0202

EXCLUSIONS

Documentation of medical reason(s) for not entering patient information into a reminder system [(eg, further screening mammograms are not indicated, such as patients with a limited life expectancy, other medical reason(s)]

EXCLUSION DETAILS

FOR ELECTRONIC SPECIFICATIONS:

Not Applicable

FOR ADMINISTRATIVE CLAIMS SPECIFICATIONS:

Report CPT II Code 7025F-1P: Documentation of medical reason(s) for not entering patient information into a reminder system [(eg, further screening mammograms are not indicated, such as patients with a limited life expectancy, other medical reason(s)]

RISK ADJUSTMENT

No risk adjustment or risk stratification

Not Applicable

STRATIFICATION

We encourage the results of this measure to be stratified by race, ethnicity, sex, and payer.

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

To calculate performance rates:

1) Find the patients who meet the initial patient population (ie, the general group of patients that the performance measure is designed to address).

2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical.

3) From the patients within the denominator, find the patients who qualify for the Numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator

If the patient does not meet the numerator, this case represents a quality failure. Available at measure-specific web page URL identified in S.1

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ACR encourages use of the Measures by other health care professionals, where appropriate.

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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.

STEWARD

Commission on Cancer, American College of Surgeons

DESCRIPTION

Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage T1cN0M0 (tumor greater than 1 cm), or Stage IB - III, whose primary tumor is progesterone and estrogen receptor negative recommended for multiagent chemotherapy (recommended or administered) within 4 months (120 days) of diagnosis.

TYPE

Process

DATA SOURCE

Paper Medical Records, Electronic Clinical Data : Registry Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base. Data is collected in accordance with the North American Association of Central Cancer Registries (NAACCR) coding http://www.naac

No data collection instrument provided No data dictionary

LEVEL

Facility

SETTING

Hospital/Acute Care Facility

NUMERATOR STATEMENT

Combination chemotherapy is administered within 4 months (120 days) of the date of diagnosis or it is recommended and not received.

NUMERATOR DETAILS

Chemotherapy [NAACCR Item#1390]=3, and Date Chemotherapy Started (NAACCR Item#1220] <=120 days following Date of Diagnosis [NAACCR Item# 340] OR

Chemotherapy recommeneded and not received [NAACCR Item#1390]=82-87 (82:not recommended/administered because it was contraindicated due to patient risk factors, 85:not administered because the patient died prior to planned or recommended therapy,86:It was recommended by the patient's physician, but was not administered as part of first-course therapy. No reason was stated in the patient record. 87: it was recommended by the patient's physician, but this treatment was refused by the patient, the patient's family member, or the patient's guardian. The refusal was noted in the patient record) OR;

OR

For patients ER/PR negative; Her2 Positive disease

Chemotherapy [NAACCR Item#1390]=2,3 and Date Chemotherapy Started (NAACCR Item#1220] <=120 days following Date of Diagnosis [NAACCR Item# 340]

AND

Immunotherapy/BRM recommended and not received [NAACCR Item#1410]=82-87 (82:not recommended/administered because it was contraindicated due to patient risk factors, 85:not administered because the patient died prior to planned or recommended therapy,86: recommended by the patient's physician, but was not administered as part of first-course therapy. No reason was stated in the patient record. 87: recommended by the patient's physician, but this treatment was refused by the patient, the patient's family member, or the patient's guardian. The refusal was noted in the patient record)

OR; Immunotherapy/BRM [NAACCR Item#1410]=1 and Date Immunotherapy Started (NAACCR Item#1240] <=120 days following Date of Diagnosis [NAACCR Item# 340]

DENOMINATOR STATEMENT

Women under the age of 70 with AJCC T1cN0M0, or Stage IB-III hormone receptor negative breast cancer:

- Women
- Age 18-69 at time of diagnosis
- Known or assumed first or only cancer diagnosis
- Primary tumors of the breast
- Epithelial invasive malignanc

DENOMINATOR DETAILS

Sex [NAACCR Item#220]=2; Age at Diagnosis [NAACCR Item#230] =18-69; Sequence number [NAACCR Item # 560] = 00-01;

Tumor Size [NAACCR Item#2800]= 011-898, 992-995 and AJCC pN [NAACCR Item#890]=0,0i-, 0I=, 0M-, 0M+; OR AJCC pN [NAACCR Item#890]=1,1a, 1b, 1c, 2,2a, 2b, or 3, 3a, 3b,3c; AND CS SSF1 (ERA) [NAACCR Item#2880]=020, 30; AND CS SSF2 (PRA) [NAACCR Item#2890]=020 or 030; AND Surgical Procedure of the Primary Site [NAACCR Item#1290] = 20–90

EXCLUSIONS

Exclude, if any of the following characteristics are identified:

Men;

Age <18 and >=70;

not a first or only cancer diagnosis;

non-epithelial and non-invasive tumors;

phyllodes tumor histology;

rare histology not supported by clinical trials: 8940 - Mixed tumor, malignant, NOS, 8950 - Mullerian mixed tumor, 8980 – Carcinosarcoma, 8981 - Carcinosarcoma, embryonal

Tumor size <=1cm and AJCC pN=0;

ERA positive;

PRA positive;

Evidence of in situ or metastatic disease;

Not treated surgically;

Died within 4 months (120 days) of diagnosis;

Participation in a clinical trial which directly impacts the delivery of the standard of care

EXCLUSION DETAILS

See: https://www.facs.org/~/media/files/quality%20programs/cancer/quality%20breast.ashx

RISK ADJUSTMENT

No risk adjustment or risk stratification

NA

STRATIFICATION

No stratification applied

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

This measure score is calculated by dividing the numerator cases by denominator eligible cases.

Denominator eligible cases are assessed in a step-wise fashion:

- Include breast cancer case

- Exclude patients enrolled in a clinical trial that directly impacts the delivery of the standard of care.

- Include female patients only

- inlcude patients 18-69

- Include epithelial tumors which can be staged according to the AJCC 7th Ed (8000-8199, 8201-5876, 8941-8949)

- Include invasive tumors only

- Exclude patients with pathologic evidence of in situ or metastatic disease

- Exclude patients with clinical evidence of in situ or metastatic disease

- Include cases where all or part of the first course of treatment was performed at the reporting facility

- Include only surgically treated cases

- Includes patients reported living withing 120 days from diagnosis

- Include AJCC T1cN0M0 or AJCC Stage IB -III tumor

- Hormone receptor negative cases

Numerator cases are then assessed from denominator eligible cases:

- Cases with HER2 negative disease: Combination chemotherapy administered within 120 following diagnosis or Chemotherapy recommended but not administered

- Cases with HER2 positive disease: Chemotherapy and Her2 targeted therapy (immunotherapy) both administered within 120 days following diagnosis or chemotherapy administered within 120 days and Her 2 targeted therapy (immunotherapy) recommended

The measure score is calculated with the numerator divided by the denominator.

See: https://www.facs.org/~/media/files/quality%20programs/cancer/quality%20breast.ashx Available at measure-specific web page URL identified in S.1

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1857 HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies

STEWARD

American Society of Clinical Oncology

DESCRIPTION

Proportion of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2)/neu negative who are not administered HER2-targeted therapies

TYPE

Process

DATA SOURCE

Electronic Clinical Data : Registry ASCO Quality Oncology Practice Initiative (QOPI®)

No data collection instrument provided No data dictionary

LEVEL

Clinician : Group/Practice

SETTING

Ambulatory Care : Clinician Office/Clinic

NUMERATOR STATEMENT

HER2-targeted therapies not administered during the initial course of treatment.

NUMERATOR DETAILS

HER2 targeted therapy administered during initial treatment course = HER2 targeted therapy NOT administered

OR

HER2 targeted therapy administered during initial treatment course = HER2 targeted therapy administered

AND

HER2 targeted therapy administered according to clinical trial protocol = Yes)

'HER2 targeted therapies' include trastuzumab, pertuzumab, T-DM1.

DENOMINATOR STATEMENT

Adult women with breast cancer that are HER2 negative or HER2 undocumented.

DENOMINATOR DETAILS

Female

And

2 or more encounters at the reporting site

And

Age at diagnosis greater than or equal to 18 years

And

Initial breast cancer diagnosis [C50.01-, C50.11-, C50.21-, C50.31-, C50.41-, C50.51-, C50.61-, C50.81-, C50.91-]

AND

(HER-2/neu status = HER2 negative

OR

HER-2/neu status = Test ordered, results not yet documented

OR

HER-2/neu status = Test NOT ordered/no documentation

OR

HER-2/neu status=Test ordered, insufficient sample for results

Or

HER-2/neu status= HER2 equivocal)

Definitions

Encounter: Patients must have been first seen in the office by a medical oncology or hematology oncology practitioner for the cancer diagnosis eligible for inclusion within the 1-year time frame of the reporting period. Enter the most recent visit that occurred during the 6-month visit window before the abstraction date. This can include visits to other office sites within the practice only if the practice uses a common medical record and shares management of care for the patient. This does not include visits during which a practitioner wasn't seen (e.g., laboratory testing), inpatient consults/visits, phone or email consults, or visits to a surgeon or radiation oncologist.

HER2 status:

Select ‘Test ordered, results not yet documented' only if there is documentation in the chart that a test that included HER2 analyses was ordered.

In the absence of any documentation regarding HER-2/neu status, select ‘Test not ordered/no documentation.’

Enter information from the most recent test report. If the most recent report indicates insufficient sample, select ‘Test ordered, insufficient sample for results.’

If a physician note and the HER-2/neu report differ in results, report the status in the physician note if the note explains the discrepancy. Otherwise, report the status from the HER-2/neu report.

Use the following definitions to determine HER-2/neu status:

Positive:

IHC 3+ based on circumferential membrane staining that is complete, intense

- ISH positive based on:

- Single-probe average HER2 copy number =6.0 signals/cell

- Dual-probe HER2/CEP17 ratio =2.0 with an average HER2 copy number =4.0 signals/cell

- Dual-probe HER2/CEP17 ratio =2.0 with an average HER2 copy number <4.0 signals/cell

- Dual-probe HER2/CEP17 ratio < 2.0 with an average HER2 copy number =6.0 signals/cell

Equivocal:

- IHC 2+ based on circumferential membrane staining that is incomplete and/or weak/moderate and within > 10% of the invasive tumor cells or complete and circumferential membrane staining that is intense and within = 10% of the invasive tumor cells

ISH equivocal based on:

- Single-probe ISH average HER2 copy number = 4.0 and < 6.0 signals/cell

- Dual-probe HER2/CEP17 ratio < 2.0 with an average HER2 copy number = 4.0 and < 6.0 signals/cell

Negative:

IHC 1+ as defined by incomplete membrane staining that is faint/barely perceptible and within > 10% of the invasive tumor cells or

IHC 0 as defined by no staining observed or membrane staining that is incomplete and is faint/barely perceptible and within = 10% of the invasive tumor cells

ISH negative based on:

- Single-probe average HER2 copy number < 4.0 signals/cell

- Dual-probe HER2/CEP17 ratio < 2.0 with an average HER2 copy number < 4.0 signals/cell

Indeterminate:

Indeterminate if technical issues prevent one or both tests (IHC and ISH) from being reported as positive, negative, or equivocal. Conditions may include:

- Inadequate specimen handling,

- Artifacts (crush or edge artifacts) that make interpretation difficult

- Analytic testing failure.

EXCLUSIONS

Patient transfer to practice during or after initial course.

EXCLUSION DETAILS

Transfer-in Status does not equal Reporting practice has/had primary responsibility for the initial course of the patient's medical oncology care

RISK ADJUSTMENT

No risk adjustment or risk stratification

Not applicable

STRATIFICATION

Not applicable

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

Performance is calculated as:

1. Identify those patients that meet the denominator criteria defined in the measure.

2. Subtract those patients with a denominator exclusion from the denominator if applicable.

3. From the patients who qualify for the denominator (after any exclusions are removed), identify those who meet the numerator criteria.

4. Calculation: Numerator/Denominator-Denominator Exclusions No diagram provided

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1878 HER2 testing for overexpression or gene amplification in patients with breast cancer

STEWARD

American Society of Clinical Oncology

DESCRIPTION

Proportion of female patients (aged 18 years and older) with breast cancer who receive human epidermal growth factor receptor 2 (HER2) testing for overexpression or gene amplification

TYPE

Process

DATA SOURCE

Electronic Clinical Data : Registry ASCO Quality Oncology Practice Initiative (QOPI®)

No data collection instrument provided No data dictionary

LEVEL

Clinician : Group/Practice

SETTING

Ambulatory Care : Clinician Office/Clinic

NUMERATOR STATEMENT

HER2 testing performed

NUMERATOR DETAILS

HER-2/neu status = HER2 positive

OR

HER-2/neu status = HER2 negative

OR

HER-2/neu status = Test ordered, results not yet documented

OR

HER-2/neu status = Test ordered, insufficient sample for results

OR

(HER-2 equivocal AND New test ordered within 10 days of report = Yes or N/A (patient died or transferred out of practice))

Practices are required to order tests within 31 days from first office visit (HER2 test date – first office visit date = 31 days) and if a new test is ordered, it must be within 10 days of original report

Numerator definitions:

Select ‘Test ordered, results not yet documented’ only if there is documentation in the chart that a test that reports HER-2/neu analyses was ordered.

In the absence of any documentation regarding HER-2/neu status, select ‘Test not ordered/no documentation.’

Enter information from the most recent test report.

Patients are classified as having HER-2 positive disease based on positive results with either test.

If the most recent report indicates insufficient sample, select ‘Test ordered, insufficient sample for results.’

If a physician note and the HER-2/neu report differ in results, report the status in the physician note if the note explains the discrepancy. Otherwise, report the status from the HER-2/neu report.

Use the following definitions to determine HER-2/neu status:

Positive:

- IHC 3+ cell surface protein expression (defined as uniform intense membrane staining of >30% of invasive tumor cells) or
- FISH ratio >2.2 or
- HER2 gene copy >6.0

Equivocal:

- Not positive according to any of the criteria above, AND
- (IHC with scores 2+ AND FISH ratio 1.8-2.2) or
- HER2 gene copy 4.0-6.0

Negative:

- Not positive according to any of the criteria above, AND
- IHC 0 or 1+ or
- FISH ratio 1.8 or
- HER2 gene copy <4.0
- If the results indicate ‘non-amplified’, choose HER-2/neu negative.
- If the results indicate ‘weakly positive’, choose HER-2/neu positive.

New test ordered within 10 days of report of equivocal result: Respond ‘Yes’ if a new test was ordered within 10 days of oncologist review of the report with inconclusive results. Choose ‘N/A’ if the patient died or transferred out of the practice within 10 days of review of the report with inconclusive results or fewer than 10 days have passed.

If the chart documents that the pathologist has ordered a new test, respond ‘Yes.’

DENOMINATOR STATEMENT

Adult women with breast cancer

DENOMINATOR DETAILS

Female

And

2 or more encounters at the reporting site

And

Age at diagnosis greater than or equal to 18 years

And

Breast cancer diagnosis [C50.01-, C50.11-, C50.21-, C50.31-, C50.41-, C50.51-, C50.61-, C50.81-, C50.91-]

Definitions

Encounter: Patients must have been first seen in the office by a medical oncology or hematology oncology practitioner for the cancer diagnosis eligible for inclusion within the 1-year time frame of the reporting period. Enter the most recent visit that occurred during the 6-month visit window before the abstraction date. This can include visits to other office sites within the practice only if the practice uses a common medical record and shares management of care for the patient. This does not include visits during which a practitioner wasn't seen (e.g., laboratory testing), inpatient consults/visits, phone or email consults, or visits to a surgeon or radiation oncologist.

EXCLUSIONS

None

EXCLUSION DETAILS

None

RISK ADJUSTMENT

No risk adjustment or risk stratification

Not applicable

STRATIFICATION

Not applicable

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

Performance is calculated as:

1. Identify those patients that meet the denominator criteria defined in the measure.

2. Subtract those patients with a denominator exclusion from the denominator. Note: this measure does not have exclusions.

3. From the patients who qualify for the denominator (after any exclusions are removed), identify those who meet the numerator criteria.

4. Calculation: Numerator/Denominator-Denominator Exclusions No diagram provided

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The AMA's and PCPI's significant past efforts and contributions to the development and updating of the Measures is acknowledged. ASCO is solely responsible for the review and enhancement ("Maintenance") of the Measures as of 2016.

ASCO encourages use of the Measures by other health care professionals, where appropriate.

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2930 Febrile Neutropenia Risk Assessment Prior to Chemotherapy

STEWARD

RAND Corporation

DESCRIPTION

Percentage of patients with a solid malignant tumor or lymphoma who had a febrile neutropenia (FN) risk assessment completed and documented in the medical record prior to the first cycle of intravenous chemotherapy

TYPE

Process

DATA SOURCE

Electronic Clinical Data : Electronic Health Record, Paper Medical Records The data source for the measure is medical records in electronic or paper form. The instrument used to abstract the information from the medical record was developed for this measure and is attached as a file called "Measure Data Collection Tool" to the A

No data collection instrument provided Attachment NQF_2930_Code_Sets_3-11-16_To_NQF.xls

LEVEL

Clinician : Group/Practice

SETTING

Ambulatory Care : Clinician Office/Clinic, Other Outpatient chemotherapy clinic

NUMERATOR STATEMENT

Number of patients who had an FN risk assessment documented in the medical record prior to the first cycle of intravenous chemotherapy.

NUMERATOR DETAILS

The numerator is defined as patients with an FN risk assessment documented in the medical record within 30 days before the first cycle of intravenous chemotherapy. An FN risk assessment is defined as at least one of the following:

- Template in the record or evidence that an online tool was used to assess FN risk (e.g., a Febrile Neutropenia Risk Assessment Tool similar to that described in the study by O'Brien et al. [2014])
- FN risk of the planned regimen was noted as a percentage (e.g., >20%) OR noted qualitatively (e.g., "high FN risk")
- Patient factor(s) was noted as a contributor to elevated FN risk (e.g., "high FN risk due to advanced age and comorbidity")
- Justification for USE of CSF was documented (e.g., "high risk regimen, CSF support will be used;" "due to the presence of expanders and risk of infection, CSF will be used")
- Justification for NOT using CSF was documented (e.g., "due to patient's youth and excellent health, CSF support will not be used")

Citation

O'Brien, C., Dempsey, O., & Kennedy, M. J. (2014). Febrile neutropenia risk assessment tool: improving clinical outcomes for oncology patients. Eur J Oncol Nurs, 18(2), 167-174.

DENOMINATOR STATEMENT

Number of patients 18 years of age or older with a solid malignant tumor or lymphoma receiving the first cycle of intravenous chemotherapy.

DENOMINATOR DETAILS

IDENTIFICATION OF PATIENTS WITH SOLID MALIGNANT TUMOR OR LYMPHOMA IN MEDICAL RECORDS

The time period is defined as any time during the measurement period (12 consecutive months). The denominator includes patients treated for a solid malignant tumor or lymphoma with first cycle of intravenous chemotherapy who meet the following conditions:

1. Patient was 18 years of age or older when first-cycle intravenous chemotherapy of the current regimen was initiated.
2. Patient's first-cycle intravenous chemotherapy was initiated any time during months 2 through 12 of the 12-month measurement period.
3. The treatment ordered was intravenous chemotherapy (see sheet labeled "IV Chemotherapy" in the attached Excel file for a list of CPT procedure codes for chemotherapy).
4. Patient was being treated for a solid malignant tumor or lymphoma (see sheets labeled "Denom Diagnoses ICD9," "Denom Diagnoses ICD10," and "Denom Diagnoses ICD9-ICD10" in the attached Excel file for a list of ICD-9-CM diagnosis codes, ICD-10 CM diagnosis codes, and a conversion table between ICD-9-CM and ICD-10-CM diagnosis codes, respectively).
5. Patient did not receive chemotherapy in the 12 months prior to the first cycle of chemotherapy.

6. Patients receiving experimental therapy or participating in clinical trials are not eligible because the trial protocol dictates CSF prophylaxis decisions.

7. Patients on weekly chemotherapy regimens are not eligible because the intervals between treatments are not long enough for CSF prophylaxis to have an effect.

8. Patients receiving concurrent radiation therapy (see sheet labeled "Radiation Therapy" in the attached Excel file for CPT codes) are not eligible because CSF prophylaxis is contraindicated for those patients due to the risk of irreversible stem cell damage. Patients who receive palliative local radiation for pain control are eligible.

9. Record of care was complete (e.g., provider notes prior to cycle #1 of chemotherapy are available).

EXCLUSIONS

There are no denominator exclusions.

EXCLUSION DETAILS

Not applicable.

RISK ADJUSTMENT

No risk adjustment or risk stratification

STRATIFICATION

Measure results may be stratified by:

- Age – Divided into five categories: 18-44, 45-64, 65-74, 75-84, and 85+ years
- Race/Ethnicity
- Gender
- Curative/adjuvant and palliative chemotherapy
- Periodicity of chemotherapy (2-, 3- and 4-week cycles)

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

Denominator: Number of patients 18 years of age or older with a solid malignant tumor or lymphoma receiving the first cycle of intravenous chemotherapy.

Create Denominator:

1. Identify patients who received intravenous chemotherapy in an outpatient setting during the measurement year (see sheet labeled "IV Chemotherapy" in the attached Excel file for CPT procedure codes for chemotherapy).

2. Of patients identified in Step 1, keep only patients who were being treated for a solid malignant tumor or lymphoma (see sheets labeled "Denom Diagnoses ICD9," "Denom Diagnoses ICD10," and "Denom Diagnoses ICD9-ICD10" in the attached Excel file for a list of ICD-9-CM diagnosis codes, ICD-10 CM diagnosis codes, and a conversion table between ICD-9-CM and ICD-10-CM diagnosis codes, respectively).

3. Of patients identified in Step 2, keep patients who initiated the first cycle of intravenous chemotherapy between February 1 and December 31 of the measurement year.

4. Of patients identified in Step 3, keep those who were 18 years of age or older when first-cycle intravenous chemotherapy was initiated.

5. Of patients identified in Step 4, keep patients who did not receive chemotherapy in the 12 months prior to the initiation of the first cycle of chemotherapy. This is the denominator of the measure.

Numerator: Number of patients who had an FN risk assessment documented in the medical record prior to the first cycle of intravenous chemotherapy.

Create Numerator:

For patients in the denominator, identify those with an FN risk assessment documented in the medical record prior to the first cycle of intravenous chemotherapy. This is the numerator of the measure. Any of the following can be counted as evidence that a risk assessment for FN was performed:

- Template in the record or online tool was used to assess FN risk (e.g., a Febrile Neutropenia Risk Assessment Tool similar to that described in the study by O'Brien et al. [2014])
- FN risk of the planned regimen was noted as a percentage (e.g., >20%) OR noted qualitatively (e.g., "high FN risk")
- Patient factor(s) was noted as a contributor to elevated FN risk (e.g., "high FN risk due to advanced age and comorbidity")
- Justification for USE of CSF was documented (e.g., "high risk regimen, CSF support will be used;" "due to the presence of expanders and risk of infection, CSF will be used")
- Justification for NOT using CSF was documented (e.g., "due to patient's youth and excellent health, CSF support will not be used")

The measure is calculated as the numerator divided by the denominator.

Citation

O'Brien, C., Dempsey, O., & Kennedy, M. J. (2014). Febrile neutropenia risk assessment tool: improving clinical outcomes for oncology patients. Eur J Oncol Nurs, 18(2), 167-174. No diagram provided

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2963 Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

STEWARD

PCPI

DESCRIPTION

Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer

TYPE

Process

DATA SOURCE

Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry Not applicable.

No data collection instrument provided Attachment EP_eCQM_ValueSets_CMS129v6_NQF0389_02182016-635948416089607351.xls

LEVEL

Clinician : Group/Practice, Clinician : Individual, Clinician : Team

SETTING

Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Other Radiation Oncology Clinic/Department

NUMERATOR STATEMENT

Patients who did not have a bone scan performed at any time since diagnosis of prostate cancer

NUMERATOR DETAILS

For Registry:

To submit the numerator option for patients who did not have a bone scan performed at any time since diagnosis of prostate cancer, report the following CPT Category II code:

3270F – Bone scan not performed prior to initiation of treatment nor at any time since diagnosis of prostate cancer

For EHR Specifications:

HQMF eMeasure developed and is included in this submission.

DENOMINATOR STATEMENT

All patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence, receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy

DENOMINATOR DETAILS

Definitions:

Risk Strata Definitions: 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.

Note: Only patients with prostate cancer with low risk of recurrence will be counted in the denominator of this measure

For Registry:

Any male patient, regardless of age

AND

Diagnosis for prostate cancer (ICD-9-CM): 185

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

AND

Patient encounter during the reporting period (CPT): 55810, 55812, 55815, 55840, 55842, 55845, 55866, 55873, 55875, 77427, 77435, 77772, 77778, 77799

AND

Report the following CPT Category II Code to identify the risk of recurrence:

3271F: Low risk of recurrence, prostate cancer

For EHR:

HQMF eMeasure developed and is included in this submission.

EXCLUSIONS

Documentation of medical reason(s) for having a bone scan performed (including documented pain, salvage therapy, other medical reasons)

Documentation of system reason(s) for having a bone scan performed (including bone scan ordered by someone other than reporting physician)

EXCLUSION DETAILS

Exceptions are used to remove a patient from the denominator of a performance measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons. The patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment, individual patient characteristics, or patient preferences. The PCPI exception methodology uses three categories of reasons for which a patient may be removed from the denominator of an individual measure.

These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For measure Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients, exceptions may include medical reason(s) (eg, documented pain, salvage therapy, other medical reasons) or system reason(s) (eg, bone scan ordered by someone other than reporting physician). Where examples of exceptions are included in the measure language, value sets for these examples are developed and included in the eMeasure. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement.

Additional details by data source are as follows:

For Registry:

Append modifier to CPT Category II code:

3269F with 1P - Documentation of medical reason(s) for performing a bone scan (including documented pain, salvage therapy, other medical reasons)

Append modifier to CPT Category II code:

3269F with 3P - Documentation of system reason(s) for performing a bone scan (including bone scan ordered by someone other than reporting physician)

For EHR:

HQMF eMeasure developed and is included in this submission.

RISK ADJUSTMENT

No risk adjustment or risk stratification

STRATIFICATION

Consistent with CMS' Measures Management System Blueprint and recent national recommendations put forth by the IOM and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer and have included these variables as recommended data elements to be collected.

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

To calculate performance rates:

1. Find the patients who meet the initial population (ie, the general group of patients that a set of performance measures is designed to address).

2. From the patients within the initial population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial population and denominator are identical.

3. From the patients within the denominator, find the patients who meet the numerator criteria (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator

4. From the patients who did not meet the numerator criteria, determine if the provider has documented that the patient meets any criteria for exception when denominator exceptions have been specified [for this measure: medical reason(s) (eg, documented pain, salvage therapy, other medical reasons) or system reason(s) (eg, bone scan ordered by someone other than reporting physician)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. --Although the exception cases are removed from the denominator population for the performance calculation, the exception rate (ie, percentage with valid exceptions) should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.

If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure. No diagram provided

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2936 Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy

STATUS

Public and Member Commenting

STEWARD

Centers for Medicare & Medicaid Services (CMS)

DESCRIPTION

Measure estimates hospital-level, risk-adjusted rates of inpatient admissions or ED visits for cancer patients >18 years of age for at least one of the following diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of hospital outpatient chemotherapy treatment. The two rates are calculated and reported separately.

TYPE

Outcome

DATA SOURCE

Claims (Only) Medicare administrative claims and enrollment data.

No data collection instrument provided Attachment ChemoMeasure_NQF_Attachment_Data_Dictionary.xlsx

LEVEL

Facility

SETTING

Hospital

NUMERATOR STATEMENT

This measure involves calculating two mutually exclusive outcomes: one or more inpatient admissions or one or more ED visits for any of the following diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of chemotherapy treatment among cancer patients receiving treatment in a hospital outpatient setting. These 10 conditions are potentially preventable through appropriately managed outpatient care. The qualifying diagnosis on the admission or ED visit claim must be (1) the principal diagnosis or (2) a secondary diagnosis accompanied by a principal diagnosis of cancer.

NUMERATOR DETAILS

Outcome Definition:

This measure has two reported outcomes. The outcomes for this measure are one or more inpatient admissions or one or more ED visits for one of the following diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of receiving hospital outpatient chemotherapy treatment for cancer. The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes that identify these diagnoses are in the attached Data Dictionary on sheets “S.6 Numerator-Anemia,” “S.6

Numerator-Dehydration," "S.6 Numerator-Diarrhea," "S.6 Numerator-Emesis," "S.6 Numerator-Fever," "S.6 Numerator-Nausea," "S.6 Numerator-Neutropenia," "S.6 Numerator-Pain," "S.6 Numerator-Pneumonia," and "S.6 Numerator-Sepsis." The ICD-9-CM codes were used during development and testing; the Data Dictionary also includes the mapping from these ICD-9-CM codes to ICD-10-CM codes.

Identification of Outcomes:

Outcomes are identified using Medicare Part A Inpatient and Part B Outpatient hospital claims. The qualifying diagnosis on the admission or ED visit claim must be listed as (1) the principal diagnosis or (2) a secondary diagnosis accompanied by a principal diagnosis of cancer. These ten conditions are considered potentially preventable through appropriately managed outpatient care.

Outcomes are identified separately for the inpatient and ED categories. A patient can only qualify for an outcome once. Patients who experience both an inpatient admission and an ED visit during the performance period are counted towards the inpatient admission outcome. Among those with no qualifying inpatient admissions, qualifying ED visits will be counted. As a result, the rates can be viewed as additive to provide a comprehensive performance estimate of quality of care following hospital-based outpatient chemotherapy treatment. The rates are calculated separately because the severity and cost of an inpatient admission is different from that of an ED visit, but both adverse events are important signals of quality and represent patient-important outcomes of care.

Outcome attribution:

The measure attributes the outcome to the hospital where the patient received chemotherapy treatment during the 30 days before the outcome. If a patient received outpatient chemotherapy treatment from more than one hospital in the 30 days before the outcome, the measure will attribute the outcome to all the hospitals that provided treatment in those 30 days. For example, if a patient received an outpatient chemotherapy treatment at Hospital A on January 1, a second treatment at Hospital B on January 10, and then experienced a qualifying admission on January 15, the measure would count this outcome for both Hospital A and Hospital B because both hospitals provided outpatient chemotherapy treatment to the patient within the 30-day window. However, if a patient received an outpatient chemotherapy treatment from Hospital A on January 1, and a second treatment from Hospital B on March 1, and then experienced a qualifying outcome on March 3, the measure would attribute this outcome only to Hospital B. Note that in the testing of this measure, using Medicare Fee-For-Service (FFS) claims data from July 1, 2012, to June 30, 2013, only 5 percent of patients in the cohort received outpatient chemotherapy treatment from more than one facility during the year.

Outcome Time Frame:

The measure limits the outcome time frame to the 30 days following the date of each chemotherapy treatment (including the day of treatment) in an outpatient setting for four reasons. First, existing literature suggests the vast majority of adverse events occur within 30 days after treatment [1, 2, 3], indicating that a 30-day period is a reasonable timeframe to observe the side effects of treatment. Second, we observed in our own data that the highest rates of hospital visits occur within 30 days after chemotherapy treatment. Third, restricting the time period ensures that patients' experiences are attributed to the hospitals that provided their recent treatment while accounting for variations in duration between outpatient treatments. Fourth, relating the time frame to a specific chemotherapy administration supports

the idea that the admission stems from the management of side effects of treatment and ongoing care, rather than progression of the disease or other unrelated events.

Citations:

1. Aprile, G., F.E. Pisa, A. Follador, L. Foltran, F. De Pauli, M. Mazzer, S. Lutrino, C.S. Sacco, M. Mansutti, and G. Fasola. “Unplanned Presentations of Cancer Outpatients: A Retrospective Cohort Study.” Supportive Care in Cancer, vol. 21, no. 2, 2013, pp. 397–404.

2. Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, S.E. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. “Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study.” Supportive Care in Cancer, vol. 22, no. 9, 2014, pp. 2527–2533.

3. McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. “Chemotherapy Outpatients’ Unplanned Presentations to Hospital: A Retrospective Study.” Supportive Care in Cancer, vol. 19, no. 7, 2011, pp. 963–969.

DENOMINATOR STATEMENT

The measure cohort includes Medicare FFS patients aged 18 years and older as of the start of the performance period with a diagnosis of any cancer who received at least one hospital outpatient chemotherapy treatment at the reporting hospital during the performance period.

DENOMINATOR DETAILS

Target Population:

The target population is patients aged 18 years and older who are enrolled in Medicare FFS with a diagnosis of cancer (except leukemia; see Denominator Exclusion, Section S.10 for exclusion details) during the performance period and at least one chemotherapy treatment performed in a hospital outpatient department (OPD). The ICD-9 codes that identify cancer diagnoses are in the attached Data Dictionary, sheets “S.9 Denominator-Cancer.” The ICD-9-CM codes were used during development and testing; the Data Dictionary also includes the mapping from these ICD-9-CM codes to ICD-10-CM codes.

Target Age Group:

This measure includes all adult Medicare FFS patients because all adult patients with a treatment plan allowing for chemotherapy treatment in a hospital outpatient setting should have their care properly managed to reduce the need for acute care for the specific conditions on which this measure focuses. Additionally, by including all adult patients, rather than restricting to those 65 years of age or older, the measure assesses a broader population and more comprehensively evaluates the quality of care provided by the hospital OPD.

Because persons under 65 enrolled in Medicare and with a cancer diagnosis are likely to differ substantially from the older population with cancer due to either their co-existing medical conditions and/or the cancer stage, we explored the appropriateness of including Medicare patients aged 18 to 64 years in the cohort by (1) reviewing patient characteristics separately for these two subsets, (2) reviewing the observed performance rates for the two subsets, and (3) fitting the risk adjustment model separately for these subsets. We found that patients aged 18 to 64 years represent 13 percent of the final measure cohort, and although the younger population has higher observed outcome rates, the inpatient admission and ED visit risk-adjustment models behave similarly on both subsets of patients (patients 18-64 and patients 65+). The risk-adjustment models fit both subsets of patients similarly because the models capture and adjust for key differences, such as age, cancer type, and comorbidities, which are

likely to vary between the two groups (see results in the attached Data Dictionary, sheet “S.15 Risk Model Specs” for risk factors). Based on these findings, we determined there was not a strong statistical or clinical reason to exclude the younger patients. We therefore include all adult patients 18 years and older in the measure cohort.

Focus on Chemotherapy Provided in Outpatient Setting:

This measure focuses on the management of symptoms for patients receiving care in the hospital outpatient setting and is not intended to be a comprehensive assessment of the level of symptom management for all cancer patients treated at the hospital (inpatient and outpatient). Rather, this measure assesses an aspect of care with documented unmet patient needs resulting in reduction of patient's quality of life and increase in healthcare utilization and costs. Several studies illustrate a gap in care for outpatients as they are "invisible" from the system when they return home following treatment [1, 3, 4]. In addition, this measure focuses on treatments in the hospital outpatient setting rather than in the inpatient setting because of the increase in hospital-based chemotherapy, which presents an opportunity to coordinate care. Among Medicare patients who are receiving chemotherapy, from 2008 to 2012 the proportion of those patients receiving chemotherapy in a hospital-based outpatient setting (as opposed to a physician office) increased from 18 to 29 percent, and this trend is likely to continue [5]. By focusing the measure on this population, we think the performance rate provides meaningful and actionable feedback to hospitals.

Identifying Chemotherapy Patients in the Hospital Outpatient Setting:

During development we considered the most appropriate target population—all chemotherapy patients or limit to only patients on palliative treatment regimens, where keeping patients out of the hospital is a desirable outcome and focus of care improvement. We worked with a range of stakeholders, including oncologists and cancer center and hospital representatives, throughout the measure development process to reach consensus on the measure intent and specifications. Through these efforts and review of published literature, we have determined that all patients receiving outpatient chemotherapy, regardless of the reason for chemotherapy (palliative vs curative) may experience a gap in care that leads to acute, potentially preventable hospitalizations, and that improving patients' quality of life by keeping patients out of the hospital is a main goal of cancer care. As a result, this measure currently includes all patients receiving chemotherapy in the hospital OPD and focuses on preventable reasons for admission. Regardless of the reason for chemotherapy, providers should assess patient risks and take preventative action where possible; communication lines should be open so the patient clearly understands expectations and how to handle. Additionally, the reason for treatment cannot be determined from claims data.

The measure identifies chemotherapy treatment using ICD-9-CM procedure and encounter codes and Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) procedure and medication procedure codes. The ICD-9-CM, CPT, and HCPCS codes that identify chemotherapy treatment are in the attached Data Dictionary, sheets “S.9 Denominator-Chemo Procedure,” “S.9 Denominator-Chemo Encounter,” and “S.9 Denominator-Chemo Medicine.” The measure excludes procedure codes for oral chemotherapy because it is challenging to identify oral chemotherapy without using pharmacy claims data and, according to our TEP, most oral chemotherapies have fewer adverse reactions that result in admissions.

We have developed a ‘coding crosswalk’ between ICD-9-CM codes and ICD-10-CM codes. For detailed information on the cohort definition including the ICD-9-CM, ICD-10-CM, CPT, and HCPCS codes that identify chemotherapy treatment, see the Data Dictionary appendix.

Inclusion of Chemotherapy Treatments Affected by the Medicare 3-Day Payment Window Policy:

The measure depends on identifying chemotherapy treatments performed in hospital OPDs. The Medicare 3-day payment window affects our ability to identify some outpatient chemotherapy treatments performed in hospital OPDs that resulted in an admission. The policy states that outpatient services (including some non-diagnostic services such as chemotherapy) provided by a hospital or any Part B entity wholly owned or wholly operated by a hospital (such as a hospital OPD) in the three calendar days preceding the date of a beneficiary's inpatient admission are deemed to be related to the admission [2]. For outpatient chemotherapy treatments subject to the 3-day payment policy, the outpatient chemotherapy service should be bundled and billed with the inpatient claim.

To ensure the inclusion of all hospital OPD chemotherapies, the measure first identifies all chemotherapy treatments during the performance period within the hospital outpatient claims file and then supplements this cohort by identifying chemotherapy treatments included on inpatient claims with a date of service prior to or equal to the date of admission on the claim. The measure includes outpatient-based chemotherapy procedures on inpatient claims with the same date of service as the admission date because, clinically, patients would receive an outpatient chemotherapy treatment and then have a qualifying inpatient admission. That is, we do not expect cancer patients with a qualifying admission for the 10 potentially preventable conditions to receive chemotherapy on that same day, as generally they would not receive chemotherapy if they required acute care for these diagnoses. Moreover, the expectation is that chemotherapy administration and the surrounding care is what accounted for the qualifying diagnosis that was the principal reason for the admission or ED visit. We will continue to assess this approach to identifying chemotherapy treatments subject to CMS 3-day payment window billing during annual measure maintenance and prior to implementation.

Citations:

1. Aprile, G., F.E. Pisa, A. Follador, L. Foltran, F. De Pauli, M. Mazzer, S. Lutrino, C.S. Sacco, M. Mansutti, and G. Fasola. "Unplanned Presentations of Cancer Outpatients: A Retrospective Cohort Study." Supportive Care in Cancer, vol. 21, no. 2, 2013, pp. 397–404.

2. Centers for Medicare & Medicaid Services (CMS). Three Day Payment Window. 2013; http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Three_Day_Payment_Window.html

3. Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, S.E. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. "Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study." Supportive Care in Cancer, vol. 22, no. 9, 2014, pp. 2527–2533.

4. McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. "Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study." Supportive Care in Cancer, vol. 19, no. 7, 2011, pp. 963–969.

5. Vandervelde, Aaron, Henry Miller, and JoAnna Younts. "Impact on Medicare Payments of Shift in Site of Care for Chemotherapy Administration." Washington, DC: Berkeley Research Group, June 2014. Available at http://www.communityoncology.org/UserFiles/BRG_340B_SiteofCare_ReportF_6-9-14.pdf. Accessed September 16, 2015.

EXCLUSIONS

We established the following exclusion criteria after reviewing the literature, examining existing measures, reviewing feedback from a public comment period, and discussing alternatives with the Cancer Working Group and TEP members (see Section Ad.1. for description of group and membership). The goal was to be as inclusive as possible; we excluded only those patient groups for which hospital visits were not typically a quality signal or for which risk adjustment would not be adequate. The exclusions, based on clinical rationales, prevent unfair distortion of performance results.

1) Patients with a diagnosis of leukemia at any time during the performance period.

Rationale: Patients with leukemia are excluded due to the high toxicity of treatment and recurrence of disease so that admissions do not reflect poorly managed outpatient care for this population. Patients with leukemia have an expected admission rate due to relapse, so including leukemia patients in the cohort could be conceptualized as a planned admission, which does not align with the intent of the measure.

2) Patients who were not enrolled in Medicare FFS Parts A and B in the year prior to the first outpatient chemotherapy treatment during the performance period.

Rationale: We exclude these patients to ensure complete patient diagnosis data for the risk-adjustment model, which uses the year prior to the first chemotherapy treatment during the period to identify comorbidities.

3) Patients who do not have at least one outpatient chemotherapy treatment followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the procedure.

Rationale: We exclude these patients to ensure full data availability for outcome assessment.

EXCLUSION DETAILS

1) Patients with a diagnosis of leukemia at any time during the performance period.

Details: The ICD-9-CM codes that define leukemia are in the attached Data Dictionary, sheet "S.11 Denom Exclusion-Leukemia." We check hospital inpatient, hospital outpatient, and Carrier (Part B) claims for a diagnosis of leukemia. The ICD-9-CM codes were used during development and testing; the Data Dictionary also includes the mapping from these ICD-9-CM codes to ICD-10-CM codes.

2) Patients who were not enrolled in Medicare FFS Parts A and B in the year prior to the first outpatient chemotherapy treatment during the performance period.

Details: Lack of continuous enrollment in Medicare FFS for the 12 months prior to the first procedure during the performance period is determined by patient enrollment status in FFS Parts A and B using the Medicare enrollment files. The enrollment indicators must be appropriately marked for all 12 months which fall within 1 year prior to the procedure date.

3) Patients who do not have at least one outpatient chemotherapy treatment followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the procedure.

Details: Lack of continuous enrollment in Medicare FFS for 1 month after the procedure is determined by patient enrollment status in FFS Parts A and B using the Medicare enrollment files. The enrollment indicators must be appropriately marked for the month(s) which falls within 30 days of the procedure date.

RISK ADJUSTMENT

Statistical risk model

Our approach to risk adjustment is tailored to, and appropriate for, a publicly reported outcome measure as articulated in published scientific guidelines [1,2].

Since the measure has two mutually exclusive outcomes—qualifying inpatient admissions and qualifying ED visits—we developed two risk-adjustment models, one for each dependent variable (inpatient admissions and ED visits). We use a two-level hierarchical logistic regression model to estimate risk-standardized outcome rates. This approach accounts for differences in patient mix, the clustering of patients within hospitals, and variation in sample size.

The measure adjusts for variables that are clinically relevant and associated with the outcome. It seeks to adjust for differences in patient demographics, clinical comorbidities, and treatment exposure (that is, the number of chemotherapy treatments undergone by the patient in the hospital outpatient setting during the performance period), which vary across patient populations and influence the outcome but do not relate to quality. Specifically, the risk-standardization model for inpatient admissions has 20 patient-level variables (age, sex, exposure, nine comorbidity variables, and eight cancer categories). The risk-standardization model for ED visits has 15 patient-level variables (age, sex, exposure, six comorbidity variables, and six cancer categories). We define the exposure variable as the count of hospital outpatient chemotherapy treatments the patient received during the performance period; it is important to adjust for exposure because the more treatments a patient receives, the higher the chance that one of them will be followed by a qualifying outcome.

We define comorbidity variables using condition categories (CCs), which are clinically meaningful groupings of more than 15,000 ICD-9 diagnosis codes. A map showing the assignment of ICD-9-CM codes to CCs can be found in the attached Data Dictionary, sheet “S.14 ICD-9 to CC mapping.” We worked with a subset of our TEP to narrow the CCs to those most appropriate for this measure. In reviewing the CCs to identify those conditions appropriate for inclusion in our model, we considered the number of patients potentially affected, whether the condition affects admission for one of the ten outcome qualifying diagnoses, and whether inclusion of the condition in the model would incentivize appropriate treatment.

The end result was 9 bundled CCs for potential inclusion in the models: (1) diabetes, (2) metabolic disorders, (3) gastrointestinal (GI) disorders, (4) psychiatric disorders, (5) neurological conditions, (6) cardiovascular disease, (7) respiratory disorders, (8) renal disease, and (9) other injuries. We define the cancer type in nine categories developed based on clinical similarities and distribution of patients. The nine categories for potential inclusion in the model included: (1) breast cancer, (2) digestive cancer, (3) genitourinary cancer, (4) respiratory cancer, (5) lymphoma, (6) prostate cancer, (7) secondary cancer of the lymph nodes, (8) secondary cancer of solid tumors, and (9) other cancers. The Condition Categories (CCs) that define each of these comorbidities and the ICD-9-CM codes that define the cancer categories are included in the Data Dictionary, on the following sheets “S.15 Risk Model Specs.”

Inpatient Admission Model Variables

The patient-level risk-adjustment variables are:

1. Age (continuous)
2. Sex (male)
3. Exposure
4. Respiratory Disorder (CC 107-110)
5. Renal Disease (CC 128-131)
6. Diabetes (CC 15-20)

7. Other Injuries (CC 162)
8. Metabolic Disorder (CC 21-24)
9. Gastrointestinal Disorder (CC 25-36)
10. Psychiatric Disorder (CC 48-66)
11. Neurological Conditions (CC 67-76)
12. Cardiovascular Disease (CC 77-106)
13. Breast Cancer
14. Digestive Cancer
15. Respiratory Cancer
16. Lymphoma
17. Prostate Cancer
18. Secondary Cancer of Lymph Nodes
19. Secondary Cancer of Solid Tumors
20. Other Cancer

ED Visits Model Variables

The patient-level risk-adjustment variables are:

1. Age (continuous)
2. Sex (male)
3. Exposure
4. Respiratory Disorder (CC 107-110)
5. Other Injuries (CC 162)
6. Gastrointestinal Disorder (CC 25-36)
7. Psychiatric Disorder (CC 48-66)
8. Neurological Conditions (CC 67-76)
9. Cardiovascular Disease (CC 77-106)
10. Breast Cancer
11. Digestive Cancer
12. Respiratory Cancer
13. Secondary Cancer of Lymph Nodes
14. Secondary Cancer of Solid Tumors
15. Other Cancer

Citations

1. Krumholz HM, Brindis RG, Brush JE, et al. Standards for Statistical Models Used for Public Reporting of Health Outcomes: An American Heart Association Scientific Statement From the Quality of Care and Outcomes Research Interdisciplinary Writing Group: Cosponsored by the Council on Epidemiology and Prevention and the Stroke Council Endorsed by the American College of Cardiology Foundation. Circulation. 2006; 113 (3): 456-462.

2. Normand S-LT, Shahian DM. Statistical and Clinical Aspects of Hospital Outcomes Profiling. Stat Sci. 2007; 22 (2): 206-226.

Available in attached Excel or csv file at S.2b

STRATIFICATION

Not applicable. This measure is not stratified.

TYPE SCORE

Rate/proportion better quality = lower score

ALGORITHM

The measure estimates hospital-specific risk-adjusted rates of potentially avoidable inpatient admissions or ED visits for cancer patients aged 18 years or older receiving chemotherapy treatment in a hospital OPD using a hierarchical logistic regression model. The cohort includes Medicare FFS patients aged 18 years or older at the start of the performance period with a diagnosis of cancer (other than leukemia) during the performance period who: had at least one hospital outpatient chemotherapy treatment during the performance period; were enrolled in Part A and Part B Medicare for the 12 months prior to the first chemotherapy treatment during the performance period; and were enrolled in Part A and B for the 30 days following at least one outpatient chemotherapy treatment. A single patient may be attributed to more than one hospital if the patient received chemotherapy treatment in a hospital OPD from more than one hospital during the performance period.

For each patient in the cohort, two outcomes are assessed. The first outcome is defined as any inpatient admissions within 30 days of any chemotherapy treatment in a hospital OPD during the performance period with either (a) a principal diagnosis of anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis or (b) a principal diagnosis of cancer and one of those ten diagnoses listed as secondary on the same claim. These ten conditions are seen as potentially preventable through appropriately managed outpatient care. The second outcome is defined as ED visits over that same time period with the same qualifying diagnoses. The second outcome is assessed only for patients who do not qualify for the first outcome. In addition, a patient can only qualify for an outcome once. As a result, the rates can be viewed as additive to get a full picture of patients in the cohort that had at least one potentially preventable outcome. The rates are calculated separately because severity and cost of inpatient admission is different from an ED visit, but both are adverse events and important pieces of information for quality improvement efforts.

These rates are risk-adjusted using hierarchical regression models; separate models are utilized for each outcome. The measure calculates the hospital-specific risk-adjusted rate as the ratio of a hospital's "predicted" number of outcomes to "expected" number of outcomes multiplied by the national observed outcome rate. It estimates the expected number of outcomes for each hospital using the hospital's patient mix and the average hospital-specific intercept (that is, the average intercept among all hospitals in the sample). The measure estimates the predicted number of outcomes for each hospital using the same patient mix, but an estimated hospital-specific intercept. Operationally, the measure obtains the expected number of outcomes for each hospital by summing the expected probabilities of outcomes for all patients treated at the hospital. It calculates the expected probability of outcomes for each patient via the hierarchical model, which applies the estimated regression coefficients to the observed patient characteristics and adds the average of the hospital-specific intercept. It calculates the predicted number of outcomes for each hospital by summing the predicted probabilities for all patients in the hospital. The measure calculates the predicted probability for each patient through the hierarchical model, which applies the estimated regression coefficients to the observed patient characteristics and adds the hospital-specific intercept.

If a hospital's ratio of predicted to expected outcomes is less than 1, it indicates that the hospital is performing better than expected given its case mix. If a hospital's ratio of predicted to expected outcomes is greater than 1, it indicates that the hospital is performing worse than expected given its case mix. For ease of interpretation, we transform this ratio to a rate by multiplying by the national observed rate for that outcome. If the "predicted" number of outcomes is higher (or lower) than the "expected" number of outcomes for a given hospital, the risk-adjusted rate will be higher (or lower) than the national observed admission rate. No diagram provided

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Not applicable

Appendix F1: Related and Competing Measures (tabular format)

Comparison of NQF 0220 and NQF 0387

	0220: Adjuvant hormonal therapy	0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
Steward	Commission on Cancer, American College of Surgeons	AMA-convened Physician Consortium for Performance Improvement
Description	Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage T1cN0M0,IB to III, who's primary tumor is progesterone or estrogen receptor positive with tamoxifen or third generation aromatase inhibitor (recommended or administered) within 1 year (365 days) of diagnosis.	Percentage of female patients aged 18 years and older with Stage IC through IIIC, estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12 month reporting period
Type	Process	Process
Data Source	Paper Medical Records, Electronic Clinical Data : Registry Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base No data collection instrument provided No data dictionary	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records, Electronic Clinical Data : Registry Not applicable. Zip file for data dictionary/code table to be sent separately (cannot be attached to 2a1.30). No data dictionary
Level	Facility	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Hospital/Acute Care Facility	Ambulatory Care : Clinician Office/Clinic, Other Oncology/Outpatient Clinic
Numerator Statement	Hormone therapy is administered within 1 year (365 days) of the date of diagnosis or it is recommended but not received	Patients who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12 month reporting period
Numerator Details	Hormone Therapy recommended and not received [NAACCR Item#1400]=82-87 (82:not recommended/administered because it was contraindicated due to patient risk factors, 85:not administered because the patient died prior to planned or recommended therapy,86:It was recommended by the patient's physician, but was not administered as part of first-course therapy. No reason was stated in the patient record. 87: it was recommended by the patient's physician, but this treatment was refused by the patient, the patient's family member, or the patient's guardian. The refusal was noted in the patient record) OR; Hormone Therapy administered [NAACCR Item#1400]=1, AND Date Hormone Therapy Started (NAACCR Item#710] <=365 days	Definition: Prescribed may include prescription given to the patient for tamoxifen or aromatase inhibitor (AI) at one or more visits in the 12-month period OR patient already taking tamoxifen or aromatase inhibitor (AI) as documented in the current medication list. FOR EHR SPECIFICATIONS: For HQMF eCQM, see reference attachment in field S2a. For value sets, please reference the VSAC. Administrative claims: Report the CPT Category II code: 4179F - Tamoxifen or aromatase inhibitor (AI) prescribed

	0220: Adjuvant hormonal therapy	0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
	following Date of Diagnosis [NAACCR Item# 340]	
Denominator Statement	Include if all of the following characteristics are identified: Women Age >=18 at time of diagnosis Known or assumed to be first or only cancer diagnosis Epithelial malignancy only Primary tumors of the breast AJCC T1cN0M0 or Stage IB - III Primary tumor	All female patients aged 18 years and older with Stage IC through IIIC, estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer
Denominator Details	Sex [NAACCR Item#220]=2; and Age [NAACCR Item# 230] >=18; and Stageable Epithelial tumors histology [NAACCR Item# 522] 8000-8576, 8941-8949 and Invasive tumor behavior [NAACCR Item# 522] =3 and AJCC T1c or Stage IB-III:Tumor Size [NAACCR Item#2800]= 11-989, 992-995 and AJCC pN [NAACCR Item#890]=0, I-, I+, 0M-, M=, 0M+ OR AJCC pN [NAACCR Item#890]=1,1M, 1M1, 1A, 1B, 1C,2, 2A, 2B, 3, 3A, 3B, or 3C; and CS SSF1 (ERA) [NAACCR Item#2880]=010 or 030; AND CS SSF2 (PRA) [NAACCR Item#2890]=010 or 030; AND Surgical Procedure of the Primary Site [NAACCR Item#1290] = 20–90	FOR EHR SPECIFICATIONS: For HQMF eCQM, see reference attachment in field S2a. For value sets, please reference the VSAC. Administrative claims: AGE:>= 18 years and older Gender:>Female Diagnosis: Breast Cancer with Stage IC through IIIC, estrogen receptor (ER) or progesterone receptor (PR) AND ICD-9-CM diagnosis codes: 174.0, 174.1, 174.2, 174.3, 174.4, 174.5, 174.6, 174.8, 174.9 (malignant neoplasm of female breast ICD-10-CM diagnosis codes: C50.011, C50.012, C50.019, C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.311, C50.312, C50.319, C50.411, C50.412, C50.419, C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, C50.812, C50.819, C50.911, C50.912, C50.919 AND CPT® Codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, AND CPT II 3374F: AJCC Breast Cancer Stage I: TIC (tumor size > 1 cm to 2 cm), documented OR CPT II 3376F: AJCC Breast Cancer Stage II, documented OR CPT II 3378F: AJCC Breast Cancer Stage III, documented

	0220: Adjuvant hormonal therapy	0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
		AND CPT II 3315F: Estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer
Exclusions	Exclude, if any of the following characteristics are identified: Men Under age 18 at time of diagnosis Second or subsequent cancer diagnosis Tumor not originating in the breast Non-epithelial malignancies, exclude malignant phyllodes tumors, 8940 - Mixed tumor, malignant, NOS, 8950 - Mullerian mixed tumor , 8980 - Carcinosarcoma,8981 - Carcinosarcoma, embryona Stage 0, in-situ tumor AJCC T1mic, or T1a tumor Stage IV, metastatic tumor Primary tumor is estrogen receptor negative and progesterone receptor negative None of 1st course therapy performed at reporting facility Died within 1 year (365 days) of diagnosis, Patient enrolled in a clinical trial that directly impacts delivery of the standard of care	Documentation of medical reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient's disease has progressed to metastatic, patient is receiving a gonadotropin-releasing hormone analogue, patient has received oophorectomy, patient is currently receiving radiation or chemotherapy, patient's diagnosis date was >= 5 years from reporting date, patient's diagnosis date is within 120 days of the end of the 12 month reporting period) Documentation of patient reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient refusal) Documentation of system reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient is currently enrolled in a clinical trial)
Exclusion Details	See: https://www.facs.org/~/media/files/quality%20programs/cancer/quality%20breast.ashx	The PCPI methodology uses three categories of reasons for which a patient may be excluded from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For this measure, exceptions may include medical reason(s) (eg, patient's disease has progressed to metastatic, patient is receiving a gonadotropin-releasing hormone analogue, patient has received oophorectomy, patient is currently receiving radiation or chemotherapy, patient's diagnosis date was = 5 years from reporting date, patient's diagnosis date is within 120 days of the end of the 12 month reporting period), patient reason(s) (eg, patient refusal) or system reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient is currently enrolled in a clinical trial). Where examples of exceptions are included in the

	0220: Adjuvant hormonal therapy	0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
		measure language, these examples are coded and included in the eSpecifications. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that physicians have identified as meeting the criteria for exception. Additional details by data source are as follows: FOR EHR SPECIFICATIONS: For HQMF eCQM, see reference attachment in field S2a. For value sets, please reference the VSAC. Administrative claims: Append modifier to CPT Category II code: 4179F-1P Append modifier to CPT Category II code: 4179F-2P Append modifier to CPT Category II code: 4179F-3P
Risk Adjustment	No risk adjustment or risk stratification	No risk adjustment or risk stratification None
Stratification	No stratification applied	We encourage the results of this measure to be stratified by race, ethnicity, payer and administrative sex, and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = higher score	Rate/proportion better quality = higher score
Algorithm	See: https://www.facs.org/~/media/files/quality%20programs/cancer/quality%20breast.ashx Available at measure-specific web page URL identified in S.1	To calculate performance rates: 1) Find the patients who meet the initial patient population (ie, the general group of patients that the performance measure is designed to address). 2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical.

	0220: Adjuvant hormonal therapy	0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
		3) From the patients within the denominator, find the patients who qualify for the Numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator 4) From the patients who did not meet the numerator criteria, determine if the physician has documented that the patient meets any criteria for denominator exception when exceptions have been specified [for this measure: medical reason(s) ((eg, patient's disease has progressed to metastatic, patient is receiving a gonadotropin-releasing hormone analogue, patient has received oophorectomy, patient is currently receiving radiation or chemotherapy, patient's diagnosis date was = 5 years from reporting date, patient's diagnosis date is within 120 days of the end of the 12 month reporting period), patient reason(s) (eg, patient refusal), or system reason(s) (eg, patient is currently enrolled in a clinical trial)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. --Although the exception cases are removed from the denominator population for the performance calculation, the number of patients with valid exceptions should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI. If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure. See calculation algorithm in attachment 2a1.21.
Submission items	5.1 Identified measures: 0387 : Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer 5a.1 Are specs completely harmonized? No 5a.2 If not completely harmonized, identify difference, rationale, impact: These measures are related but assess different levels of analysis and different data systems are used to determine eligibility and compliance. 5b.1 If competing, why superior or rationale for additive value: 0387 assesses hormone therapy for patients with stage Ic through III hormone receptor positive cancer. 0387 assesses if hormone therapy was prescribed within a 12 month period while our measure	5.1 Identified measures: 5a.1 Are specs completely harmonized? No 5a.2 If not completely harmonized, identify difference, rationale, impact: No related measures; See competing measures section below regarding the harmonization of measure specifications. 5b.1 If competing, why superior or rationale for additive value: Measure 0220 is similarly limited to stage I through III breast cancer patients whose primary tumor is progesterone or estrogen receptor positive. Measure 0220 requires that the agents be considered or administered within 1 year of diagnosis while our measure looks at the

	0220: Adjuvant hormonal therapy	0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
	(0220) assesses if hormone therapy was administered within on	receipt of adjuvant endocrine therapy over time, specifically whether the agents were prescribed once within a 12 month reporting period. Since the recommended treatment duration of adjuvant endocrine therapy is 5 years, our measure includes medical reason exceptions to allow physicians to exclude patients who have already received the agents for the recommended duration and for other medical reasons. Our measure assess performance at the individual physician level while measure 0220 was designed to assess performance at the facility level.

Comparison of NQF 0223 and NQF 0385

	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	0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients
Steward	Commission on Cancer, American College of Surgeons	AMA-convened Physician Consortium for Performance Improvement
Description	Percentage of patients under the age of 80 with AJCC III (lymph node positive) colon cancer for whom adjuvant chemotherapy is recommended and not received or administered within 4 months (120 days) of diagnosis.	Percentage of patients aged 18 years through 80 years with AJCC stage III colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy or have previously received adjuvant chemotherapy within the 12 month reporting period
Type	Process	Process
Data Source	Paper Medical Records, Electronic Clinical Data : Registry Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base No data collection instrument provided No data dictionary	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records, Electronic Clinical Data : Registry Not applicable. Zip file for data dictionary/code table to be sent separately (cannot be attached to 2a1.30). No data dictionary
Level	Facility	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Hospital/Acute Care Facility	Ambulatory Care : Clinician Office/Clinic, Other Oncology/Outpatient Clinic; Radiation Oncology Dept/Clinic
Numerator Statement	Chemotherapy is administered within 4 months (120 days) of diagnosis or it is recommended and not received	Patients who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or who have previously received adjuvant chemotherapy within the 12 month reporting period
Numerator Details	Chemotherapy Recommended and not received [NAACCR Item#1390]=82-87 (82:not recommended/administered because it was contraindicated due to patient risk factors, 85:not administered because the patient died prior to planned or recommended therapy,86:It was recommended by the patient's physician, but was not administered as part of first-course therapy. No reason was stated in the patient record. 87: it was recommended by the patient's physician, but this treatment was refused by the patient, the patient's family member, or the patient's guardian. The refusal was noted in the patient record) OR; Chemotherapy [NAACCR Item#1390]=3, and Date Chemotherapy Started (NAACCR	Definition: Adjuvant Chemotherapy: According to current NCCN guidelines, the following therapies are recommended: 5-FU/LV /oxaliplatin (mFOLFOX6) as the standard of care (Category 1); bolus 5-FU/LV/oxaliplatin (FLOX, Category 1), capecitabine/oxaliplatin (CapeOx, Category 1); or single agent capecitabine (Category 2A) or 5-FU/LV (Category 2A) in patients felt to be inappropriate for oxaliplatin therapy. Due to the leucovorin shortage in the United States, levo-leucovorin used in its place may also satisfy the measure. Prescribed – may include prescription ordered for the patient for adjuvant chemotherapy at one or more visits in the 12-month period OR patient already receiving adjuvant chemotherapy as documented in the current medication list

	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	0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients
	Item#1220] <=120 days following Date of Diagnosis [NAACCR Item# 340]	FOR EHR SPECIFICATIONS: For HQMF eCQM, see reference attachment in field S2a. For value sets, please reference the VSAC. For Administrative claims: Report the CPT Category II code: 4180F - Adjuvant chemotherapy referred, prescribed, or previously received for Stage III colon cancer
Denominator Statement	Include, if all of the following characteristics are identified: Age 18-79 at time of diagnosis Known or assumed to be first or only cancer diagnosis Primary tumors of the colon Epithelial malignancy only At least one pathologically examined regional lym	All patients aged 18 through 80 years with AJCC stage III colon cancer
Denominator Details	Age at Diagnosis [NAACCR Item#230] 18-79 AND Male or female [NAACCR item #220] = 1,2; AND Surgical Procedure of the Primary Site [NAACCR Item#1290] = 30–90, AND Regional Lymph Nodes Positive [NAACCR Item#820] = 1-90, 95, 97	FOR EHR SPECIFICATIONS: For HQMF eCQM, see reference attachment in field S2a. For value sets, please reference the VSAC. Administrative claims data: AGE: >= 18 years and <= 80 years AND Diagnosis: Colon Cancer ICD-9-CM diagnosis codes: 153.0, 153.1, 153.2, 153.3, 153.4, 153.6, 153.7, 153.8, 153.9 (malignant neoplasm of colon). ICD-10-CM diagnosis codes: C18.0, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C18.9 AND CPT® Codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215
Exclusions	Exclude, if any of the following characteristics are identified: Age <18 and >=80; not a first or only cancer diagnosis; non-epithelial and non-invasive tumors; no regional lymph nodes pathologically examined; metastatic disease (AJCC Stage IV); not treated surgically; died within 4 months (120 days) of diagnosis; Patient participating in clinical trial which directly impacts receipt of standard of care.	Documentation of medical reason(s) for not referring for or prescribing adjuvant chemotherapy (eg, medical comorbidities, diagnosis date more than 5 years prior to the current visit date, diagnosis date is within 120 days of the end of the 12 month reporting period, patient's cancer has metastasized, medical contraindication/allergy, poor performance status)

	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	0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients
		Documentation of patient reason(s) for not referring for or prescribing adjuvant chemotherapy (eg, patient refusal) Documentation of system reason(s) for not referring for or prescribing adjuvant chemotherapy (eg, patient is currently enrolled in a clinical trial that precludes prescription of chemotherapy)
Exclusion Details	See: https://www.facs.org/~/media/files/quality%20programs/cancer/ncdb/measure%20specs%20colon_03312015.ashx	The PCPI methodology uses three categories of reasons for which a patient may be excluded from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For this measure, exceptions may include medical reason(s) (eg, medical comorbidities, patient over the age of 80, diagnosis date more than 5 years prior to the current visit date, diagnosis date is within 120 days of the end of the 12 month reporting period, patient's cancer has metastasized, medical contraindication/allergy, poor performance status), patient reason(s) (eg, patient refusal) or system reason(s) for not referring for or prescribing adjuvant chemotherapy (eg, patient is currently enrolled in a clinical trial that precludes prescription of chemotherapy). Where examples of exceptions are included in the measure language, these examples are coded and included in the eSpecifications. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that physicians have identified as

	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	0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients
		meeting the criteria for exception. Additional details by data source are as follows: For EHR: eMeasure (See attached) Administrative claims: Denominator Exceptions: Append modifier to CPT Category II code: 4180F-1P Append modifier to CPT Category II code: 4180F-2P Append modifier to CPT Category II code: 4180F-3P
Risk Adjustment	No risk adjustment or risk stratification	No risk adjustment or risk stratification None
Stratification	No stratification applied	We encourage the results of this measure to be stratified by race, ethnicity, payer and administrative sex, and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = higher score	Rate/proportion better quality = higher score
Algorithm	This measure score is calculated by dividing the numerator cases by denominator eligible cases. Denominator eligible cases are assessed in a step-wise fashion: - Include all colon cancer cases - Adult patients 18 and over and under 80 - Males and female cases only - Include first or only primaries - Include epithelial tumors based on AJCC 7th Ed. - Include invasive tumors only - Exclude cases with clinical or pathologic evidence of in situ disease - Exclude cases with clinical or pathologic evidence of metastatic disease - Include only cases where all or part of first course treatment was performed at the reporting facility - Include only surgically treated cases - Include only patients which were alive for at least 120 days following diagnosis - Include only lymph node positive disease	To calculate performance rates: 1) Find the patients who meet the initial patient population (ie, the general group of patients that the performance measure is designed to address). 2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical. 3) From the patients within the denominator, find the patients who qualify for the numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator. 4) From the patients who did not meet the numerator criteria, determine if the physician has documented that the patient meets any criteria for denominator exception when exceptions have been specified. If the patient meets any exception criteria, they should be removed from the denominator for

	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	0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients
	Numerator cases are then assessed from denominator eligible cases: - Cases are included in the numerator if: a) Chemotherapy is administered the number of days between diagnosis and start of chemotherapy within 120 days are included in the numerator or b) Chemotherapy is recommended but not administered based on: -Chemotherapy was not recommended/administered because it was contraindicated due to patient risk factors, -Chemotherapy was not administered because the patient died prior to planned or recommended therapy, -Chemotherapy was not administered. It was recommended by the patient's physician but was not administered as part of the first course of therapy. -Chemotherapy was not administered, it was recommended by the patients' physician but refused by the patient, patient's family member or guardian. The refusal was noted in patient record. The measure score is calculated with the numerator divided by the denominator. Detailed steps are found here: https://www.facs.org/~/media/files/quality%20programs/cancer/ncdb/measure%20specs%20colon_03312015.ashx Available at measure-specific web page URL identified in S.1	performance calculation. –Although exception cases are removed from the denominator population for the performance calculation, the number of patients with valid exceptions should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI. If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure.
Submission items	5.1 Identified measures: 0385 : Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients 5a.1 Are specs completely harmonized? No 5a.2 If not completely harmonized, identify difference, rationale, impact: The measures assess different levels of data analysis, 0385 assesses clinical group practice while 0223 assesses facility level performance. The data sources are also different for the two measures increasing the burden of collection for harmonization. 5b.1 If competing, why superior or rationale for additive value: The target populations of these measures and the level of analysis are	5.1 Identified measures: 5a.1 Are specs completely harmonized? No 5a.2 If not completely harmonized, identify difference, rationale, impact: No related measures; See competing measures section below regarding the harmonization of measure specifications. 5b.1 If competing, why superior or rationale for additive value: Measure 0223 is limited to Stage III colon cancer patients under the age of 80 following surgical treatment. Although our measure focuses on stage III colon cancer patients, it does not focus only on patients following surgical treatment. However, the

	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	0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients
	sufficiently different to warrant both measures. Measure 0223 assesses adjuvant chemotherapy on surgically treated patients to be reported at the facility level for CoC-accredited can	numerator of the measure allows for current OR PREVIOUS receipt of adjuvant chemotherapy as well as a referral for adjuvant chemotherapy. This approach offers a great likelihood of achieving a sufficient sample size to measure performance at the individual physician level. Additionally, patients over the age of 80 can be excluded from the patient population through the use of a medical reason exception. Our measure assesses performance at the individual physician level while measure 0223 was designed to assess performance at the facility level.

Comparison of NQF 0389, NQF 0390, and NQF 1853

	0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients	1853: Radical Prostatectomy Pathology Reporting
Steward	PCPI	American Urological Association	College of American Pathologists
Description	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer	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)	Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.
Type	Process	Process	Process
Data Source	Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry Not applicable. No data collection instrument provided Attachment EP_eCQM_ValueSets_CMS129v6_NQF0389_02182016.xls	Electronic Clinical Data, Electronic Clinical Data : Registry Not applicable. Not a PRO. No data collection instrument provided Attachment NQF0390_I9toI10_conversion.xlsx	Administrative claims, Other, Paper Records Medical records/Pathology Report and Claims forms are used as the specific data sources.
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team	Clinician : Group/Practice, Clinician : Individual, Clinician : Team	Clinician : Group/Practice, Clinician : Individual
Setting	Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Other Radiation Oncology Clinic/Department	Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Other Radiation Oncology Clinic/Department	Laboratory
Numerator Statement	Patients who did not have a bone scan performed at any time since diagnosis of prostate cancer	Patients who were prescribed adjuvant hormonal therapy (GnRH [gonadotropin-releasing hormone] agonist or antagonist)	Numerator: Radical prostatectomy pathology reports that include the pT category, the pN category, Gleason score and a statement about margin status ? Report the following CPT Category II code to confirm the inclusion of the designated elements in a radical prostatectomy

	0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients	1853: Radical Prostatectomy Pathology Reporting
			pathology report: 3267F – pathology report
Numerator Details	For Registry: To submit the numerator option for patients who did not have a bone scan performed at any time since diagnosis of prostate cancer, report the following CPT Category II code: 3270F – Bone scan not performed prior to initiation of treatment nor at any time since diagnosis of prostate cancer For EHR Specifications: HQMF eMeasure developed and is included in this submission.	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. For Registry: To submit the numerator option for patients who were prescribed adjuvant hormonal therapy (GnRH agonist or antagonist), report the following CPT Category II code: 4164F - 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	Report the following CPT Category II code to confirm the inclusion of the designated elements in a radical prostatectomy pathology report: 3267F –pathology report
Denominator Statement	All patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence, receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy	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	All radical prostatectomy pathology reports
Denominator Details	Definitions: Risk Strata Definitions: 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;	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;	Denominator (Eligible Population): All radical prostatectomy pathology reports CPT code: 88309 - Level VI - Surgical pathology, gross and microscopic examination AND

	0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients	1853: Radical Prostatectomy Pathology Reporting
	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. Note: Only patients with prostate cancer with low risk of recurrence will be counted in the denominator of this measure For Registry: Any male patient, regardless of age AND Diagnosis for prostate cancer (ICD-9-CM): 185 Diagnosis for prostate cancer (ICD-10-CM): C61 AND	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. Note: Only male patients with prostate cancer with high or very high risk of recurrence will be counted in the performance denominator of this measure. For Registry: Any male patient, regardless of age AND Diagnosis for prostate cancer (ICD-9-CM): 185	ICD-9 code: 185 – malignant neoplasm of prostate

	0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients	1853: Radical Prostatectomy Pathology Reporting
	Patient encounter during the reporting period (CPT): 55810, 55812, 55815, 55840, 55842, 55845, 55866, 55873, 55875, 77427, 77435, 77772, 77778, 77799 AND Report the following CPT Category II Code to identify the risk of recurrence: 3271F: Low risk of recurrence, prostate cancer For EHR: HQMF eMeasure developed and is included in this submission.	Diagnosis for prostate cancer (ICD-10-CM): C61 AND NOT Diagnosis for metastatic cancer (ICD-9-CM): 196.0, 196.1, 196.2, 196.3, 196.5, 196.6, 196.8, 196.9, 197.0, 197.1, 197.2, 197.3, 197.4, 197.5, 197.6, 197.7, 197.8, 198.0, 198.1, 198.2, 198.3, 198.4, 198.5, 198.6, 198.7, 198.81, 198.82, 198.89 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 AND Patient encounter during the reporting period (CPT): 77427, 77435 AND Report the following quality-data code (G-code) to identify the risk of recurrence: G8465: High or very high risk of recurrence of prostate cancer	
Exclusions	Documentation of medical reason(s) for having a bone scan performed (including documented pain, salvage therapy, other medical reasons) Documentation of system reason(s) for having a bone scan performed (including bone scan ordered by	AUA methodology uses three categories of reasons for which a patient may be excluded from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale	Documentation of medical reason for exclusion (e.g., specimen originated from other malignant neoplasms, secondary site prostatic carcinomas, and transurethral resections of the prostate (TURP)

	0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients	1853: Radical Prostatectomy Pathology Reporting
	someone other than reporting physician)	to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For this measure, exceptions for not prescribing/administering adjuvant hormonal therapy may include medical reason(s) (eg, salvage therapy) or patient reason(s). Although this methodology does not require the external reporting of more detailed exception data, the AUA recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The AUA also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that physicians have identified as meeting the criteria for exception. Additional details by data source are as follows: Documentation of medical reason(s) for not prescribing/administering adjuvant hormonal therapy (eg, salvage therapy) Documentation of patient reason(s) for not prescribing/administering adjuvant hormonal therapy	
Exclusion Details	Exceptions are used to remove a patient from the denominator of a performance	Exceptions are used to remove a patient from the denominator of a performance	Documentation of medical reason for exclusion (e.g., specimen originated from

	0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients	1853: Radical Prostatectomy Pathology Reporting
	measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons. The patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment, individual patient characteristics, or patient preferences. The PCPI exception methodology uses three categories of reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For measure Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients, exceptions may include medical reason(s) (eg, documented pain, salvage therapy, other medical reasons) or system reason(s) (eg, bone scan ordered by someone other than reporting physician). Where examples of exceptions are included in the measure language, value sets for these examples are developed and included in the eMeasure. Although this methodology does not require	measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons. The patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment, individual patient characteristics, or patient preferences. The AUA exception methodology uses three categories of reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For measure Adjuvant Hormonal Therapy for High Risk or Very High Risk Prostate Cancer Patients, exceptions may include medical reason(s) (eg, salvage therapy) or patient reason(s) for not prescribing/administering adjuvant hormonal therapy. Although this methodology does not require the external reporting of more detailed exception data, the AUA recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient	other malignant neoplasms, secondary site prostatic carcinomas, or transurethral resections of the prostate (TURP) [For patient with appropriate exclusion criteria, report 3267F with modifier 1P.]

	0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients	1853: Radical Prostatectomy Pathology Reporting
	the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. Additional details by data source are as follows: For Registry: Append modifier to CPT Category II code: 3269F with 1P - Documentation of medical reason(s) for performing a bone scan (including documented pain, salvage therapy, other medical reasons) Append modifier to CPT Category II code: 3269F with 3P - Documentation of system reason(s) for performing a bone scan (including bone scan ordered by someone other than reporting physician) For EHR: HQMF eMeasure developed and is included in this submission.	management and audit-readiness. The AUA also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. Additional details by data source are as follows: For Registry: Documentation of medical reason(s) for not prescribing/administering adjuvant hormonal therapy (eg, salvage therapy) Append modifier to CPT Category II code: 4164F with 1P Documentation of patient reason(s) for not prescribing/administering adjuvant hormonal therapy Append modifier to CPT Category II code: 4164F with 2P	
Risk Adjustment	No risk adjustment or risk stratification No risk adjustment or risk stratification	No risk adjustment or risk stratification No risk adjustment or risk stratification	No risk adjustment or risk stratification Not applicable
Stratification	Consistent with CMS' Measures Management System Blueprint and recent	Consistent with CMS' Measures Management System Blueprint and recent	Not applicable

	0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients	1853: Radical Prostatectomy Pathology Reporting
	national recommendations put forth by the IOM and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer and have included these variables as recommended data elements to be collected.	national recommendations put forth by the IOM and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer.	
Type Score	Rate/proportion better quality = higher score	Rate/proportion better quality = higher score	Rate/proportion better quality = higher score
Algorithm	To calculate performance rates: 1. Find the patients who meet the initial population (ie, the general group of patients that a set of performance measures is designed to address). 2. From the patients within the initial population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial population and denominator are identical. 3. From the patients within the denominator, find the patients who meet the numerator criteria (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator 4. From the patients who did not meet the numerator criteria, determine if the provider has documented that	To calculate performance rates: 1) Find the patients who meet the initial patient population (ie, the general group of patients that the performance measure is designed to address). 2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical. 3) From the patients within the denominator, find the patients who qualify for the Numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator 4) From the patients who did not meet the numerator criteria, determine if the physician has documented	Performance Measure: 3267F/Claims using CPT code 88309 and ICD-9 code 185

	0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients	1853: Radical Prostatectomy Pathology Reporting
	the patient meets any criteria for exception when denominator exceptions have been specified [for this measure: medical reason(s) (eg, documented pain, salvage therapy, other medical reasons) or system reason(s) (eg, bone scan ordered by someone other than reporting physician)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. -- Although the exception cases are removed from the denominator population for the performance calculation, the exception rate (ie, percentage with valid exceptions) should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI. If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure. No diagram provided	that the patient meets any criteria for denominator exception when exceptions have been specified [for this measure: medical reason(s) for not prescribing adjuvant hormonal therapy (eg, salvage therapy) or patient reason(s)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. –Although the exception cases are removed from the denominator population for the performance calculation, the number of patients with valid exceptions should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI. If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure. No diagram provided	
Submission items	5.1 Identified measures: 0390 : Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients 1853 : Radical Prostatectomy Pathology Reporting 5a.1 Are specs completely harmonized? No 5a.2 If not completely harmonized, identify difference, rationale, impact: The related measure 1853, Radical Prostatectomy Pathology Reporting, addresses the percentage of	5.1 Identified measures: 0220 : Adjuvant hormonal therapy 0389 : Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients 1853 : Radical Prostatectomy Pathology Reporting 5a.1 Are specs completely harmonized? No 5a.2 If not completely harmonized, identify difference, rationale, impact: For measure 0220, Adjuvant Hormonal Therapy, the related measure focuses on adjuvant	5.1 Identified measures: 5a.1 Are specs completely harmonized? 5a.2 If not completely harmonized, identify difference, rationale, impact: 5b.1 If competing, why superior or rationale for additive value:

	0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients	1853: Radical Prostatectomy Pathology Reporting
	radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status, which is a different action than measure 0389. The two measures do not share similar target populations and address different aspects of prostate cancer care. The related measure 0390, Prostate Cancer: Adjuvant Hormonal Therapy for High Risk or Very High Risk Prostate Cancer Patients addresses the use of adjuvant hormonal therapy and external beam radiation therapy in high-risk prostate cancer patients which is a different quality action from measure 0389. The two measures do not share similar target populations and address different aspects of prostate cancer care. 5b.1 If competing, why superior or rationale for additive value:	hormonal therapy for breast cancer patients, which is not consistent with the target population addressed in measure 0390. While this is the same action, it is a different drug and target population addressed in each measure. The related measure 0389, Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients addresses the use of bone scan in low-risk prostate cancer patients which is a different quality action from measure 0390. The two measures do not share similar target populations and address different aspects of prostate cancer care. The related measure 1853, Radical Prostatectomy Pathology Reporting, addresses the percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status, which is a different action than measure 0390. The two measures do not share similar target populations and address different aspects of prostate cancer care. 5b.1 If competing, why superior or rationale for additive value:	

Comparison of NQF 1855 and NQF 1878

	1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines	1878: HER2 testing for overexpression or gene amplification in patients with breast cancer
Steward	College of American Pathologists	American Society of Clinical Oncology
Description	Percentage of patients with quantitative breast tumor HER2 IHC evaluation using the ASCO/CAP recommended manual system or a computer-assisted system consistent with the optimal algorithm for HER2 testing as described in the current ASCO/CAP guidelines.	Proportion of female patients (aged 18 years and older) with breast cancer who receive human epidermal growth factor receptor 2 (HER2) testing for overexpression or gene amplification
Type	Process	Process
Data Source	Administrative claims, Other, Paper Medical Records Data can be collectected from Pathology Report/Medical Records, Laboratory procedures and claims forms.	Electronic Clinical Data : Registry ASCO Quality Oncology Practice Initiative (QOPI®) No data collection instrument provided No data dictionary
Level	Clinician : Group/Practice, Clinician : Individual	Clinician : Group/Practice
Setting	Laboratory	Ambulatory Care : Clinician Office/Clinic
Numerator Statement	Breast cancer patients receiving quantitative breast tumor HER2 IHC evaluation using the ASCO/CAP recommended manual system or a computer-assisted system consistent with the optimal algorithm for HER2 testing as described in the ASCO/CAP guideline *	HER2 testing performed
Numerator Details	Breast cancer patients receiving quantitative breast tumor HER2 IHC evaluation using the ASCO/CAP recommended manual system or a computer-assisted system consistent with the optimal algorithm for HER2 testing as described in the current ASCO/CAP guideline Report one of the following CPT Category II codes to confirm the use of the recommended scoring system: • 3394F –Quantitative HER2 IHC evaluation consistent with scoring system defined in the ASCO/CAP guidelines • 3395F– Quantitative non-HER2 IHC evaluation (eg, testing for estrogen or progesterone receptors, [ER/PR]) performed	HER-2/neu status = HER2 positive OR HER-2/neu status = HER2 negative OR HER-2/neu status = Test ordered, results not yet documented OR HER-2/neu status = Test ordered, insufficient sample for results OR (HER-2 equivocal AND New test ordered within 10 days of report = Yes or N/A (patient died or transferred out of practice)) Practices are required to order tests within 31 days from first office visit (HER2 test date – first office visit date = 31 days) and if a new test is ordered, it must be within 10 days of original report Numerator definitions: Select 'Test ordered, results not yet documented' only if there is documentation in the chart that a test that reports HER-2/neu analyses was ordered.

	1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines	1878: HER2 testing for overexpression or gene amplification in patients with breast cancer
		In the absence of any documentation regarding HER-2/neu status, select 'Test not ordered/no documentation.' Enter information from the most recent test report. Patients are classified as having HER-2 positive disease based on positive results with either test. If the most recent report indicates insufficient sample, select 'Test ordered, insufficient sample for results.' If a physician note and the HER-2/neu report differ in results, report the status in the physician note if the note explains the discrepancy. Otherwise, report the status from the HER-2/neu report. Use the following definitions to determine HER-2/neu status: Positive: • IHC 3+ cell surface protein expression (defined as uniform intense membrane staining of >30% of invasive tumor cells) or • FISH ratio >2.2 or • HER2 gene copy >6.0 Equivocal: • Not positive according to any of the criteria above, AND • (IHC with scores 2+ AND FISH ratio 1.8-2.2) or • HER2 gene copy 4.0-6.0 Negative: • Not positive according to any of the criteria above, AND • IHC 0 or 1+ or • FISH ratio 1.8 or • HER2 gene copy <4.0 • If the results indicate 'non-amplified', choose HER-2/neu negative. • If the results indicate 'weakly positive', choose HER-2/neu positive. New test ordered within 10 days of report of equivocal result: Respond 'Yes' if a new test was ordered within 10 days of oncologist review of the report with inconclusive results. Choose 'N/A' if the patient died or transferred out of the practice within 10 days of review of the report with

	1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines	1878: HER2 testing for overexpression or gene amplification in patients with breast cancer
		inconclusive results or fewer than 10 days have passed. If the chart documents that the pathologist has ordered a new test, respond 'Yes.'
Denominator Statement	All breast cancer patients with quantitative breast tumor evaluation by HER2 IHC ICD-10 diagnosis codes for breast cancer: C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929 AND CPT codes: Quantitative IHC Evaluation – 88360 or 88361 (The CPT descriptor for 88360 and 88361 is, "Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semi-quantitative, each antibody.")	Adult women with breast cancer
Denominator Details	ICD-10 diagnosis codes for breast cancer: C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929 AND CPT codes: Quantitative IHC Evaluation – 88360 or 88361 (The CPT descriptor for 88360 and 88361 is, "Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semi-quantitative, each antibody.") Wolff, A.C., et al. American Society of Clinical Oncology/College of American Pathologists	Female And 2 or more encounters at the reporting site And Age at diagnosis greater than or equal to 18 years And Breast cancer diagnosis [C50.01-, C50.11-, C50.21-, C50.31-, C50.41-, C50.51-, C50.61-, C50.81-, C50.91-] Definitions Encounter: Patients must have been first seen in the office by a medical oncology or hematology oncology practitioner for the cancer diagnosis eligible for inclusion within the 1-year time frame of the reporting period. Enter the most recent visit that occurred during the 6-month visit window before the abstraction date. This can include visits to other office sites within the practice only if the practice uses a common medical record and shares management of care for the patient. This does not include visits during which a practitioner wasn't seen (e.g., laboratory testing), inpatient

	1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines	1878: HER2 testing for overexpression or gene amplification in patients with breast cancer
	Clinical Practice Guideline Update Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer. Arch Pathol Lab Med. 31:3997 -4014, 2013) • Positive HER2 test. (p.3998) Must report a HER2 test result as positive if: (a) IHC 3+ positive or (b) ISH positive using either a single-probe ISH or dual-probe ISH (Table 1; Figs 1 to 3). This assumes that there is no apparent histopathologic discordance observed by the pathologist (Table 2). • Equivocal HER2 test. (p. 3998) Must report a HER2 test result as equivocal and order reflex test on the same specimen (unless the pathologist has concerns about the specimen) using the alternative test if: (a) IHC 2+ equivocal or (b) ISH equivocal using single-probe ISH or dual-probe ISH (Table 1; Figs 1 to 3). This assumes that there is no apparent histopathologic discordance observed by the pathologist (Table 2). Note that there are some rare breast cancers (eg, gland-forming tumors, micropapillary carcinomas) that show IHC 1+ staining that is intense but incomplete (basolateral or U shaped) and that are found to be HER2 amplified. The pathologist should consider also reporting these specimens equivocal and request reflex testing using the alternative test. • Negative HER2 test. (p. 3998) Must report a HER2 test result as negative if a single test (or all tests) performed on a tumor specimen show: (a) IHC 1+ negative or IHC 0 negative or (b) ISH negative using single-probe ISH or dual-probe ISH (Table 1; Figs 1 to 3). This assumes that there is no apparent histopathologic discordance observed by the pathologist (Table 2). • Indeterminate HER2 test (p.3999) _ Must report a HER2 test result as indeterminate if technical issues prevent one or both tests (IHC and ISH) performed on a tumor specimen from being reported as positive, negative, or equivocal. This may occur if specimen handling was inadequate, if artifacts (crush or edge artifacts) make interpretation difficult, or if the analytic testing failed. Another specimen should be requested for	consults/visits, phone or email consults, or visits to a surgeon or radiation oncologist.

	1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines	1878: HER2 testing for overexpression or gene amplification in patients with breast cancer
	testing, if possible, and a comment should be included in the pathology report documenting intended action.	
Exclusions	None	None
Exclusion Details	Not applicable	None
Risk Adjustment	No risk adjustment or risk stratification Not applicable	No risk adjustment or risk stratification Not applicable
Stratification	Not applicable	Not applicable
Type Score	Rate/proportion better quality = higher score	Rate/proportion better quality = higher score
Algorithm	Performance Measure: 3394F + 3395F/ Claims identified by CPT code 88360 or 88361 and breast cancer ICD- 9 codes	Performance is calculated as: 1. Identify those patients that meet the denominator criteria defined in the measure. 2. Subtract those patients with a denominator exclusion from the denominator. Note: this measure does not have exclusions. 3. From the patients who qualify for the denominator (after any exclusions are removed), identify those who meet the numerator criteria. 4. Calculation: Numerator/Denominator-Denominator Exclusions No diagram provided
Submission items	5.1 Identified measures: 5a.1 Are specs completely harmonized? No 5a.2 If not completely harmonized, identify difference, rationale, impact: The CPT codes used to identify the denominator of the measure are different; the measures apply to differnet tests on the same target population. 5b.1 If competing, why superior or rationale for additive value: No competing measures.	5.1 Identified measures: 1855 : Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines 5a.1 Are specs completely harmonized? Yes 5a.2 If not completely harmonized, identify difference, rationale, impact: 5b.1 If competing, why superior or rationale for additive value: Measure #1878 assesses whether HER2 testing was completed within 31 days of a breast cancer diagnosis. Meanwhile, NQF endorsed measure #1855 focuses on whether HER2 testing was completed according to current ASCO/CAP standards in the laboratory setting. A

Appendix F2: Related and Competing Measures (narrative format)

Comparison of NQF 0220 and NQF 0387

0220: Adjuvant hormonal therapy
0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

Steward

0220: Adjuvant hormonal therapy

Commission on Cancer, American College of Surgeons

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

AMA-convened Physician Consortium for Performance Improvement

Description

0220: Adjuvant hormonal therapy

Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage T1cN0M0,IB to III, who's primary tumor is progesterone or estrogen receptor positive with tamoxifen or third generation aromatase inhibitor (recommended or administered) within 1 year (365 days) of diagnosis.

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

Percentage of female patients aged 18 years and older with Stage IC through IIIC, estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12 month reporting period

Type

0220: Adjuvant hormonal therapy

Process

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

Process

Data Source

0220: Adjuvant hormonal therapy

Paper Medical Records, Electronic Clinical Data : Registry Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base

No data collection instrument provided No data dictionary

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records, Electronic Clinical Data : Registry Not applicable. Zip file for data dictionary/code table to be sent separately (cannot be attached to 2a1.30).

No data dictionary

Level

0220: Adjuvant hormonal therapy

Facility

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Setting

0220: Adjuvant hormonal therapy

Hospital/Acute Care Facility

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

Ambulatory Care : Clinician Office/Clinic, Other Oncology/Outpatient Clinic

Numerator Statement

0220: Adjuvant hormonal therapy

Hormone therapy is administered within 1 year (365 days) of the date of diagnosis or it is recommended but not received

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

Patients who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12 month reporting period

Numerator Details

0220: Adjuvant hormonal therapy

Hormone Therapy recommended and not received [NAACCR Item#1400]=82-87 (82:not recommended/administered because it was contraindicated due to patient risk factors, 85:not administered because the patient died prior to planned or recommended therapy,86:It was recommended by the patient's physician, but was not administered as part of first-course therapy. No reason was stated in the patient record. 87: it was recommended by the patient's physician, but this treatment was refused by the patient, the patient's family member, or the patient's guardian. The refusal was noted in the patient record)

OR; Hormone Therapy administered [NAACCR Item#1400]=1, AND Date Hormone Therapy Started (NAACCR Item#710] <=365 days following Date of Diagnosis [NAACCR Item# 340]

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

Definition: Prescribed may include prescription given to the patient for tamoxifen or aromatase inhibitor (AI) at one or more visits in the 12-month period OR patient already taking tamoxifen or aromatase inhibitor (AI) as documented in the current medication list.

FOR EHR SPECIFICATIONS:

For HQMF eCQM, see reference attachment in field S2a.

For value sets, please reference the VSAC.

Administrative claims:

Report the CPT Category II code: 4179F - Tamoxifen or aromatase inhibitor (AI) prescribed

Denominator Statement

0220: Adjuvant hormonal therapy

Include if all of the following characteristics are identified:

Women

Age >=18 at time of diagnosis

Known or assumed to be first or only cancer diagnosis

Epithelial malignancy only

Primary tumors of the breast

AJCC T1cN0M0 or Stage IB - III

Primary tumor

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

All female patients aged 18 years and older with Stage IC through IIIC, estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer

Denominator Details

0220: Adjuvant hormonal therapy

Sex [NAACCR Item#220]=2; and

Age [NAACCR Item# 230] >=18; and

Stageable Epithelial tumors histology [NAACCR Item# 522] 8000-8576, 8941-8949 and

Invasive tumor behavior [NAACCR Item# 522] =3 and

AJCC T1c or Stage IB-III:Tumor Size [NAACCR Item#2800]= 11-989, 992-995 and AJCC pN [NAACCR Item#890]=0, I-, I+, 0M-, M=, 0M+ OR AJCC pN [NAACCR Item#890]=1,1M, 1M1, 1A, 1B, 1C,2, 2A, 2B, 3, 3A, 3B, or 3C; and

CS SSF1 (ERA) [NAACCR Item#2880]=010 or 030; AND CS SSF2 (PRA) [NAACCR Item#2890]=010 or 030;

AND Surgical Procedure of the Primary Site [NAACCR Item#1290] = 20–90

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

FOR EHR SPECIFICATIONS:

For HQMF eCQM, see reference attachment in field S2a.

For value sets, please reference the VSAC.

Administrative claims:

AGE:>= 18 years and older

Gender:>Female

Diagnosis: Breast Cancer with Stage IC through IIIC, estrogen receptor (ER) or progesterone receptor (PR)

AND

ICD-9-CM diagnosis codes: 174.0, 174.1, 174.2, 174.3, 174.4, 174.5, 174.6, 174.8, 174.9 (malignant neoplasm of female breast

ICD-10-CM diagnosis codes: C50.011, C50.012, C50.019, C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.311, C50.312, C50.319, C50.411, C50.412, C50.419,

C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, C50.812, C50.819, C50.911, C50.912, C50.919

AND

CPT® Codes:

99201, 99202, 99203, 99204, 99205,

99212, 99213, 99214, 99215,

AND

CPT II 3374F: AJCC Breast Cancer Stage I: TIC (tumor size > 1 cm to 2 cm), documented

OR

CPT II 3376F: AJCC Breast Cancer Stage II, documented

OR

CPT II 3378F: AJCC Breast Cancer Stage III, documented

AND

CPT II 3315F: Estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer

Exclusions

0220: Adjuvant hormonal therapy

Exclude, if any of the following characteristics are identified:

Men

Under age 18 at time of diagnosis

Second or subsequent cancer diagnosis

Tumor not originating in the breast

Non-epithelial malignancies, exclude malignant phyllodes tumors, 8940 - Mixed tumor, malignant, NOS, 8950 - Mullerian mixed tumor , 8980 - Carcinosarcoma,8981 - Carcinosarcoma, embryona

Stage 0, in-situ tumor

AJCC T1mic, or T1a tumor

Stage IV, metastatic tumor

Primary tumor is estrogen receptor negative and progesterone receptor negative

None of 1st course therapy performed at reporting facility

Died within 1 year (365 days) of diagnosis,

Patient enrolled in a clinical trial that directly impacts delivery of the standard of care

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

Documentation of medical reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient's disease has progressed to metastatic, patient is receiving a gonadotropin-releasing hormone analogue, patient has received oophorectomy, patient is currently receiving radiation or chemotherapy, patient's diagnosis date was >= 5 years from reporting date, patient's diagnosis date is within 120 days of the end of the 12 month reporting period)

Documentation of patient reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient refusal)

Documentation of system reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient is currently enrolled in a clinical trial)

Exclusion Details

0220: Adjuvant hormonal therapy

See:
https://www.facs.org/~/media/files/quality%20programs/cancer/quality%20breast.ashx

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

The PCPI methodology uses three categories of reasons for which a patient may be excluded from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For this measure, exceptions may include medical reason(s) (eg, patient's disease has progressed to metastatic, patient is receiving a gonadotropin-releasing hormone analogue, patient has received oophorectomy, patient is currently receiving radiation or chemotherapy, patient's diagnosis date was = 5 years from reporting date, patient's diagnosis date is within 120 days of the end of the 12 month reporting period), patient reason(s) (eg, patient refusal) or system reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient is currently enrolled in a clinical trial). Where examples of exceptions are included in the measure language, these examples are coded and included in the eSpecifications. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that physicians have identified as meeting the criteria for exception. Additional details by data source are as follows:

FOR EHR SPECIFICATIONS:

For HQMF eCQM, see reference attachment in field S2a.

For value sets, please reference the VSAC.

Administrative claims:

Append modifier to CPT Category II code: 4179F-1P

Append modifier to CPT Category II code: 4179F-2P

Append modifier to CPT Category II code: 4179F-3P

Risk Adjustment

0220: Adjuvant hormonal therapy

No risk adjustment or risk stratification

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

No risk adjustment or risk stratification

None

Stratification

0220: Adjuvant hormonal therapy

No stratification applied

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

We encourage the results of this measure to be stratified by race, ethnicity, payer and administrative sex, and have included these variables as recommended data elements to be collected.

Type Score

0220: Adjuvant hormonal therapy

Rate/proportion better quality = higher score

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

Rate/proportion better quality = higher score

Algorithm

0220: Adjuvant hormonal therapy

See:
https://www.facs.org/~/media/files/quality%20programs/cancer/quality%20breast.ashx
Available at measure-specific web page URL identified in S.1

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

To calculate performance rates:

1) Find the patients who meet the initial patient population (ie, the general group of patients that the performance measure is designed to address).

2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical.

3) From the patients within the denominator, find the patients who qualify for the Numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator

4) From the patients who did not meet the numerator criteria, determine if the physician has documented that the patient meets any criteria for denominator exception when exceptions have been specified [for this measure: medical reason(s) ((eg, patient's disease has progressed to metastatic, patient is receiving a gonadotropin-releasing hormone analogue, patient has received oophorectomy, patient is currently receiving radiation or chemotherapy, patient's diagnosis date was = 5 years from reporting date, patient's diagnosis date is within 120 days of the end of the 12 month reporting period), patient reason(s) (eg, patient refusal), or system reason(s) (eg, patient is currently enrolled in a clinical trial)]. If the patient meets any exception criteria, they should be removed from the

denominator for performance calculation. --Although the exception cases are removed from the denominator population for the performance calculation, the number of patients with valid exceptions should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.

If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure.

See calculation algorithm in attachment 2a1.21.

Submission items

0220: Adjuvant hormonal therapy

5.1 Identified measures: 0387 : Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: These measures are related but assess different levels of analysis and different data systems are used to determine eligibility and compliance.

5b.1 If competing, why superior or rationale for additive value: 0387 assesses hormone therapy for patients with stage Ic through III hormone receptor positive cancer. 0387 assesses if hormone therapy was prescribed within a 12 month period while our measure (0220) assesses if hormone therapy was administered within on

0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

5.1 Identified measures:

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: No related measures; See competing measures section below regarding the harmonization of measure specifications.

5b.1 If competing, why superior or rationale for additive value: Measure 0220 is similarly limited to stage I through III breast cancer patients whose primary tumor is progesterone or estrogen receptor positive. Measure 0220 requires that the agents be considered or administered within 1 year of diagnosis while our measure looks at the receipt of adjuvant endocrine therapy over time, specifically whether the agents were prescribed once within a 12 month reporting period. Since the recommended treatment duration of adjuvant endocrine therapy is 5 years, our measure includes medical reason exceptions to allow physicians to exclude patients who have already received the agents for the recommended duration and for other medical reasons.

Our measure assess performance at the individual physician level while measure 0220 was designed to assess performance at the facility level.

Comparison of NQF 0223 and NQF 0385

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
0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

Steward

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

Commission on Cancer, American College of Surgeons

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

AMA-convened Physician Consortium for Performance Improvement

Description

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

Percentage of patients under the age of 80 with AJCC III (lymph node positive) colon cancer for whom adjuvant chemotherapy is recommended and not received or administered within 4 months (120 days) of diagnosis.

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

Percentage of patients aged 18 years through 80 years with AJCC stage III colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy or have previously received adjuvant chemotherapy within the 12 month reporting period

Type

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

Process

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

Process

Data Source

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

Paper Medical Records, Electronic Clinical Data : Registry Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base

No data collection instrument provided No data dictionary

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records, Electronic Clinical Data : Registry Not applicable. Zip file for data dictionary/code table to be sent separately (cannot be attached to 2a1.30).

No data dictionary

Level

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

Facility

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Setting

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/Acute Care Facility

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

Ambulatory Care : Clinician Office/Clinic, Other Oncology/Outpatient Clinic; Radiation Oncology Dept/Clinic

Numerator Statement

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

Chemotherapy is administered within 4 months (120 days) of diagnosis or it is recommended and not received

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

Patients who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or who have previously received adjuvant chemotherapy within the 12 month reporting period

Numerator Details

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

Chemotherapy Recommended and not received [NAACCR Item#1390]=82-87 (82:not recommended/administered because it was contraindicated due to patient risk factors, 85:not administered because the patient died prior to planned or recommended therapy,86:It was recommended by the patient's physician, but was not administered as part of first-course therapy. No reason was stated in the patient record. 87: it was recommended by the patient's physician, but this treatment was refused by the patient, the patient's family member, or the patient's guardian. The refusal was noted in the patient record)

OR; Chemotherapy [NAACCR Item#1390]=3, and Date Chemotherapy Started (NAACCR Item#1220] <=120 days following Date of Diagnosis [NAACCR Item# 340]

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

Definition: Adjuvant Chemotherapy: According to current NCCN guidelines, the following therapies are recommended: 5-FU/LV

/oxaliplatin (mFOLFOX6) as the standard of care (Category 1); bolus 5-FU/LV/oxaliplatin (FLOX, Category 1), capecitabine/oxaliplatin (CapeOx, Category 1); or single agent

capecitabine (Category 2A) or 5-FU/LV (Category 2A) in patients felt to be inappropriate for oxaliplatin therapy. Due to the leucovorin shortage in the United States, levo-leucovorin used in its

place may also satisfy the measure.

Prescribed – may include prescription ordered for the patient for adjuvant chemotherapy at one or more visits in the 12-month period OR patient already receiving adjuvant chemotherapy as documented in the current medication list

FOR EHR SPECIFICATIONS:

For HQMF eCQM, see reference attachment in field S2a.

For value sets, please reference the VSAC.

For Administrative claims:

Report the CPT Category II code: 4180F - Adjuvant chemotherapy referred, prescribed, or previously received for Stage III colon cancer

Denominator Statement

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

Include, if all of the following characteristics are identified:

Age 18-79 at time of diagnosis

Known or assumed to be first or only cancer diagnosis

Primary tumors of the colon

Epithelial malignancy only

At least one pathologically examined regional lym

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

All patients aged 18 through 80 years with AJCC stage III colon cancer

Denominator Details

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

Age at Diagnosis [NAACCR Item#230] 18-79 AND Male or female [NAACCR item #220] = 1,2; AND Surgical Procedure of the Primary Site [NAACCR Item#1290] = 30–90, AND Regional Lymph Nodes Positive [NAACCR Item#820] = 1-90, 95, 97

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

FOR EHR SPECIFICATIONS:

For HQMF eCQM, see reference attachment in field S2a.

For value sets, please reference the VSAC.

Administrative claims data:

AGE: >= 18 years and <= 80 years

AND

Diagnosis: Colon Cancer

ICD-9-CM diagnosis codes: 153.0, 153.1, 153.2, 153.3, 153.4, 153.6, 153.7, 153.8, 153.9 (malignant neoplasm of colon).

ICD-10-CM diagnosis codes: C18.0, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C18.9

AND

CPT® Codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215

Exclusions

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

Exclude, if any of the following characteristics are identified:

Age <18 and >=80; not a first or only cancer diagnosis; non-epithelial and non-invasive tumors; no regional lymph nodes pathologically examined; metastatic disease (AJCC Stage IV); not treated surgically; died within 4 months (120 days) of diagnosis; Patient participating in clinical trial which directly impacts receipt of standard of care.

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

Documentation of medical reason(s) for not referring for or prescribing adjuvant chemotherapy (eg, medical comorbidities, diagnosis date more than 5 years prior to the current visit date, diagnosis date is within 120 days of the end of the 12 month reporting period, patient's cancer has metastasized, medical contraindication/allergy, poor performance status)

Documentation of patient reason(s) for not referring for or prescribing adjuvant chemotherapy (eg, patient refusal)

Documentation of system reason(s) for not referring for or prescribing adjuvant chemotherapy (eg, patient is currently enrolled in a clinical trial that precludes prescription of chemotherapy)

Exclusion Details

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

See:
https://www.facs.org/~/media/files/quality%20programs/cancer/ncdb/measure%20specs%20colon_03312015.ashx

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

The PCPI methodology uses three categories of reasons for which a patient may be excluded from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For this measure, exceptions may include medical reason(s) (eg, medical comorbidities, patient over the age of 80, diagnosis date more than 5 years prior to the current visit date, diagnosis date is within 120 days of the end of the 12 month reporting period, patient's cancer has metastasized, medical contraindication/allergy, poor performance status), patient reason(s) (eg, patient refusal) or system reason(s) for not referring for or prescribing adjuvant chemotherapy (eg, patient is currently enrolled in a clinical trial that precludes prescription of chemotherapy). Where examples of exceptions are included in the measure language, these examples are coded and included in the eSpecifications. Although this methodology does not require the

external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that physicians have identified as meeting the criteria for exception. Additional details by data source are as follows:

For EHR: eMeasure (See attached)

Administrative claims:

Denominator Exceptions:

Append modifier to CPT Category II code: 4180F-1P

Append modifier to CPT Category II code: 4180F-2P

Append modifier to CPT Category II code: 4180F-3P

Risk Adjustment

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

No risk adjustment or risk stratification

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

No risk adjustment or risk stratification

None

Stratification

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

No stratification applied

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

We encourage the results of this measure to be stratified by race, ethnicity, payer and administrative sex, and have included these variables as recommended data elements to be collected.

Type Score

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

Rate/proportion better quality = higher score

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

Rate/proportion better quality = higher score

Algorithm

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

This measure score is calculated by dividing the numerator cases by denominator eligible cases.

Denominator eligible cases are assessed in a step-wise fashion:

- Include all colon cancer cases

- Adult patients 18 and over and under 80

- Males and female cases only

- Include first or only primaries

- Include epithelial tumors based on AJCC 7th Ed.

- Include invasive tumors only

- Exclude cases with clinical or pathologic evidence of in situ disease

- Exclude cases with clinical or pathologic evidence of metastatic disease

- Include only cases where all or part of first course treatment was performed at the reporting facility

- Include only surgically treated cases

- Include only patients which were alive for at least 120 days following diagnosis

- Include only lymph node positive disease

Numerator cases are then assessed from denominator eligible cases:

- Cases are included in the numerator if:

a) Chemotherapy is administered the number of days between diagnosis and start of chemotherapy within 120 days are included in the numerator or

b) Chemotherapy is recommended but not administered based on:

-Chemotherapy was not recommended/administered because it was contraindicated due to patient risk factors,

-Chemotherapy was not administered because the patient died prior to planned or recommended therapy,

-Chemotherapy was not administered. It was recommended by the patient's physician but was not administered as part of the first course of therapy.

-Chemotherapy was not administered, it was recommended by the patients' physician but refused by the patient, patient's family member or guardian. The refusal was noted in patient record.

The measure score is calculated with the numerator divided by the denominator.

Detailed steps are found here:
https://www.facs.org/~/media/files/quality%20programs/cancer/ncdb/measure%20specs%20colon_03312015.ashx Available at measure-specific web page URL identified in S.1

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

To calculate performance rates:

1) Find the patients who meet the initial patient population (ie, the general group of patients that the performance measure is designed to address).

2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical.

3) From the patients within the denominator, find the patients who qualify for the numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator.

4) From the patients who did not meet the numerator criteria, determine if the physician has documented that the patient meets any criteria for denominator exception when exceptions have been specified. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. –Although exception cases are removed from the denominator population for the performance calculation, the number of patients with valid exceptions should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.

If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure.

Submission items

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

5.1 Identified measures: 0385 : Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: The measures assess different levels of data analysis, 0385 assesses clinical group practice while 0223 assesses facility level performance. The data sources are also different for the two measures increasing the burden of collection for harmonization.

5b.1 If competing, why superior or rationale for additive value: The target populations of these measures and the level of analysis are sufficiently different to warrant both measures. Measure 0223 assesses adjuvant chemotherapy on surgically treated patients to be reported at the facility level for CoC-accredited can

0385: Oncology: Chemotherapy for AJCC Stage III Colon Cancer Patients

5.1 Identified measures:

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: No related measures; See competing measures section below regarding the harmonization of measure specifications.

5b.1 If competing, why superior or rationale for additive value: Measure 0223 is limited to Stage III colon cancer patients under the age of 80 following surgical treatment. Although our measure focuses on stage III colon cancer patients, it does not focus only on patients following surgical treatment. However, the numerator of the measure allows for current OR PREVIOUS receipt of adjuvant chemotherapy as well as a referral for adjuvant chemotherapy. This approach offers a great likelihood of achieving a sufficient sample size to measure performance at the individual physician level. Additionally, patients over the age of 80 can be excluded from the patient population through the use of a medical reason exception.

Our measure assesses performance at the individual physician level while measure 0223 was designed to assess performance at the facility level.

Comparison of NQF 0389, NQF 0390, and NQF 1853

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients
0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients
1853: Radical Prostatectomy Pathology Reporting

Steward

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

PCPI

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

American Urological Association

1853: Radical Prostatectomy Pathology Reporting

College of American Pathologists

Description

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

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)

1853: Radical Prostatectomy Pathology Reporting

Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.

Type

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Process

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

Process

1853: Radical Prostatectomy Pathology Reporting

Process

Data Source

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry Not applicable.

No data collection instrument provided Attachment EP_eCQM_ValueSets_CMS129v6_NQF0389_02182016.xls

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

Electronic Clinical Data, Electronic Clinical Data : Registry Not applicable. Not a PRO.

No data collection instrument provided Attachment NQF0390_I9toI10_conversion.xlsx

1853: Radical Prostatectomy Pathology Reporting

Administrative claims, Other, Paper Records Medical records/Pathology Report and Claims forms are used as the specific data sources.

Level

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Clinician : Group/Practice, Clinician : Individual, Clinician : Team

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

Clinician : Group/Practice, Clinician : Individual, Clinician : Team

1853: Radical Prostatectomy Pathology Reporting

Clinician : Group/Practice, Clinician : Individual

Setting

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Other Radiation Oncology Clinic/Department

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

Ambulatory Care : Ambulatory Surgery Center (ASC), Ambulatory Care : Clinician Office/Clinic, Other Radiation Oncology Clinic/Department

1853: Radical Prostatectomy Pathology Reporting

Laboratory

Numerator Statement

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Patients who did not have a bone scan performed at any time since diagnosis of prostate cancer

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

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

1853: Radical Prostatectomy Pathology Reporting

Numerator: Radical prostatectomy pathology reports that include the pT category, the pN category, Gleason score and a statement about margin status

? Report the following CPT Category II code to confirm the inclusion of the designated elements in a radical prostatectomy pathology report: 3267F –pathology report

Numerator Details

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

For Registry:

To submit the numerator option for patients who did not have a bone scan performed at any time since diagnosis of prostate cancer, report the following CPT Category II code:

3270F – Bone scan not performed prior to initiation of treatment nor at any time since diagnosis of prostate cancer

For EHR Specifications:

HQMF eMeasure developed and is included in this submission.

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

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.

For Registry:

To submit the numerator option for patients who were prescribed adjuvant hormonal therapy (GnRH agonist or antagonist), report the following CPT Category II code:

4164F - 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

1853: Radical Prostatectomy Pathology Reporting

Report the following CPT Category II code to confirm the inclusion of the designated elements in a radical prostatectomy pathology report: 3267F –pathology report

Denominator Statement

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

All patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence, receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

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

1853: Radical Prostatectomy Pathology Reporting

All radical prostatectomy pathology reports

Denominator Details

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Definitions:

Risk Strata Definitions: 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.

Note: Only patients with prostate cancer with low risk of recurrence will be counted in the denominator of this measure

For Registry:

Any male patient, regardless of age

AND

Diagnosis for prostate cancer (ICD-9-CM): 185

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

AND

Patient encounter during the reporting period (CPT): 55810, 55812, 55815, 55840, 55842, 55845, 55866, 55873, 55875, 77427, 77435, 77772, 77778, 77799

AND

Report the following CPT Category II Code to identify the risk of recurrence:

3271F: Low risk of recurrence, prostate cancer

For EHR:

HQMF eMeasure developed and is included in this submission.

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

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.

Note: Only male patients with prostate cancer with high or very high risk of recurrence will be counted in the performance denominator of this measure.

For Registry:

Any male patient, regardless of age

AND

Diagnosis for prostate cancer (ICD-9-CM): 185

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

AND NOT

Diagnosis for metastatic cancer (ICD-9-CM): 196.0, 196.1, 196.2, 196.3, 196.5, 196.6, 196.8, 196.9, 197.0, 197.1, 197.2, 197.3, 197.4, 197.5, 197.6, 197.7, 197.8, 198.0, 198.1, 198.2, 198.3, 198.4, 198.5, 198.6, 198.7, 198.81, 198.82, 198.89

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

AND

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

AND

Report the following quality-data code (G-code) to identify the risk of recurrence:

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

1853: Radical Prostatectomy Pathology Reporting

Denominator (Eligible Population): All radical prostatectomy pathology reports

CPT code: 88309 - Level VI - Surgical pathology, gross and microscopic examination

AND

ICD-9 code: 185 – malignant neoplasm of prostate

Exclusions

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Documentation of medical reason(s) for having a bone scan performed (including documented pain, salvage therapy, other medical reasons)

Documentation of system reason(s) for having a bone scan performed (including bone scan ordered by someone other than reporting physician)

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

AUA methodology uses three categories of reasons for which a patient may be excluded from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For this measure, exceptions for not prescribing/administering adjuvant hormonal therapy may include medical reason(s) (eg, salvage therapy) or patient reason(s). Although this methodology does not require the external reporting of more detailed exception data, the AUA recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The AUA also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that physicians have identified as meeting the criteria for exception. Additional details by data source are as follows:

Documentation of medical reason(s) for not prescribing/administering adjuvant hormonal therapy (eg, salvage therapy)

Documentation of patient reason(s) for not prescribing/administering adjuvant hormonal therapy

1853: Radical Prostatectomy Pathology Reporting

Documentation of medical reason for exclusion (e.g., specimen originated from other malignant neoplasms, secondary site prostatic carcinomas, and transurethral resections of the prostate (TURP)

Exclusion Details

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Exceptions are used to remove a patient from the denominator of a performance measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons. The patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment, individual patient characteristics, or patient preferences. The PCPI exception methodology uses three categories of reasons for which a patient may be removed from the

denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For measure Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients, exceptions may include medical reason(s) (eg, documented pain, salvage therapy, other medical reasons) or system reason(s) (eg, bone scan ordered by someone other than reporting physician). Where examples of exceptions are included in the measure language, value sets for these examples are developed and included in the eMeasure. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement.

Additional details by data source are as follows:

For Registry:

Append modifier to CPT Category II code:

3269F with 1P - Documentation of medical reason(s) for performing a bone scan (including documented pain, salvage therapy, other medical reasons)

Append modifier to CPT Category II code:

3269F with 3P - Documentation of system reason(s) for performing a bone scan (including bone scan ordered by someone other than reporting physician)

For EHR:

HQMF eMeasure developed and is included in this submission.

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

Exceptions are used to remove a patient from the denominator of a performance measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons. The patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment, individual patient characteristics, or patient preferences. The AUA exception methodology uses three categories of reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For measure Adjuvant Hormonal Therapy for High Risk or Very High Risk Prostate Cancer Patients, exceptions may include medical reason(s) (eg, salvage therapy) or patient reason(s) for not prescribing/administering adjuvant hormonal therapy. Although this methodology does not require the external reporting of more detailed exception data, the AUA recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The AUA also advocates the systematic

review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement.

Additional details by data source are as follows:

For Registry:

Documentation of medical reason(s) for not prescribing/administering adjuvant hormonal therapy (eg, salvage therapy)

Append modifier to CPT Category II code: 4164F with 1P

Documentation of patient reason(s) for not prescribing/administering adjuvant hormonal therapy

Append modifier to CPT Category II code: 4164F with 2P

1853: Radical Prostatectomy Pathology Reporting

Documentation of medical reason for exclusion (e.g., specimen originated from other malignant neoplasms, secondary site prostatic carcinomas, or transurethral resections of the prostate (TURP) [For patient with appropriate exclusion criteria, report 3267F with modifier 1P.]

Risk Adjustment

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

No risk adjustment or risk stratification

No risk adjustment or risk stratification

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

No risk adjustment or risk stratification

No risk adjustment or risk stratification

1853: Radical Prostatectomy Pathology Reporting

No risk adjustment or risk stratification

Not applicable

Stratification

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Consistent with CMS' Measures Management System Blueprint and recent national recommendations put forth by the IOM and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer and have included these variables as recommended data elements to be collected.

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

Consistent with CMS' Measures Management System Blueprint and recent national recommendations put forth by the IOM and NQF to standardize the collection of race and

ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer.

1853: Radical Prostatectomy Pathology Reporting

Not applicable

Type Score

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Rate/proportion better quality = higher score

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

Rate/proportion better quality = higher score

1853: Radical Prostatectomy Pathology Reporting

Rate/proportion better quality = higher score

Algorithm

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

To calculate performance rates:

1. Find the patients who meet the initial population (ie, the general group of patients that a set of performance measures is designed to address).

2. From the patients within the initial population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial population and denominator are identical.

3. From the patients within the denominator, find the patients who meet the numerator criteria (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator

4. From the patients who did not meet the numerator criteria, determine if the provider has documented that the patient meets any criteria for exception when denominator exceptions have been specified [for this measure: medical reason(s) (eg, documented pain, salvage therapy, other medical reasons) or system reason(s) (eg, bone scan ordered by someone other than reporting physician)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. --Although the exception cases are removed from the denominator population for the performance calculation, the exception rate (ie, percentage with valid exceptions) should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.

If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure. No diagram provided

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

To calculate performance rates:

1) Find the patients who meet the initial patient population (ie, the general group of patients that the performance measure is designed to address).

2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical.

3) From the patients within the denominator, find the patients who qualify for the Numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator

4) From the patients who did not meet the numerator criteria, determine if the physician has documented that the patient meets any criteria for denominator exception when exceptions have been specified [for this measure: medical reason(s) for not prescribing adjuvant hormonal therapy (eg, salvage therapy) or patient reason(s)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation.

–Although the exception cases are removed from the denominator population for the performance calculation, the number of patients with valid exceptions should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.

If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure. No diagram provided

1853: Radical Prostatectomy Pathology Reporting

Performance Measure:

3267F/Claims using CPT code 88309 and ICD-9 code 185

Submission items

0389: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

5.1 Identified measures: 0390 : Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

1853 : Radical Prostatectomy Pathology Reporting

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: The related measure 1853, Radical Prostatectomy Pathology Reporting, addresses the percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status, which is a different action than measure 0389. The two measures do not share similar target populations and address different aspects of prostate cancer care. The related measure 0390, Prostate Cancer: Adjuvant Hormonal Therapy for High Risk or Very High Risk Prostate Cancer Patients addresses the use of adjuvant hormonal therapy and external beam radiation therapy in

high-risk prostate cancer patients which is a different quality action from measure 0389. The two measures do not share similar target populations and address different aspects of prostate cancer care.

5b.1 If competing, why superior or rationale for additive value:

0390: Prostate Cancer: Adjuvant Hormonal Therapy for High or Very High Risk Prostate Cancer Patients

5.1 Identified measures: 0220 : Adjuvant hormonal therapy

0389 : Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

1853 : Radical Prostatectomy Pathology Reporting

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: For measure 0220, Adjuvant Hormonal Therapy, the related measure focuses on adjuvant hormonal therapy for breast cancer patients, which is not consistent with the target population addressed in measure 0390. While this is the same action, it is a different drug and target population addressed in each measure. The related measure 0389, Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients addresses the use of bone scan in low-risk prostate cancer patients which is a different quality action from measure 0390. The two measures do not share similar target populations and address different aspects of prostate cancer care. The related measure 1853, Radical Prostatectomy Pathology Reporting, addresses the percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status, which is a different action than measure 0390. The two measures do not share similar target populations and address different aspects of prostate cancer care.

5b.1 If competing, why superior or rationale for additive value:

1853: Radical Prostatectomy Pathology Reporting

5.1 Identified measures:

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value:

Comparison of NQF 1855 and NQF 1878

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines
1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

Steward

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

College of American Pathologists

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

American Society of Clinical Oncology

Description

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

Percentage of patients with quantitative breast tumor HER2 IHC evaluation using the ASCO/CAP recommended manual system or a computer-assisted system consistent with the optimal algorithm for HER2 testing as described in the current ASCO/CAP guidelines.

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

Proportion of female patients (aged 18 years and older) with breast cancer who receive human epidermal growth factor receptor 2 (HER2) testing for overexpression or gene amplification

Type

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

Process

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

Process

Data Source

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

Administrative claims, Other, Paper Medical Records Data can be collectected from Pathology Report/Medical Records, Laboratory procedures and claims forms.

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

Electronic Clinical Data : Registry ASCO Quality Oncology Practice Initiative (QOPI®)

No data collection instrument provided No data dictionary

Level

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

Clinician : Group/Practice, Clinician : Individual

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

Clinician : Group/Practice

Setting

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

Laboratory

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

Ambulatory Care : Clinician Office/Clinic

Numerator Statement

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

Breast cancer patients receiving quantitative breast tumor HER2 IHC evaluation using the ASCO/CAP recommended manual system or a computer-assisted system consistent with the optimal algorithm for HER2 testing as described in the ASCO/CAP guideline *

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

HER2 testing performed

Numerator Details

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

Breast cancer patients receiving quantitative breast tumor HER2 IHC evaluation using the ASCO/CAP recommended manual system or a computer-assisted system consistent with the optimal algorithm for HER2 testing as described in the current ASCO/CAP guideline

Report one of the following CPT Category II codes to confirm the use of the recommended scoring system:

- 3394F –Quantitative HER2 IHC evaluation consistent with scoring system defined in the ASCO/CAP guidelines
- 3395F– Quantitative non-HER2 IHC evaluation (eg, testing for estrogen or progesterone receptors, [ER/PR]) performed

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

HER-2/neu status = HER2 positive

OR

HER-2/neu status = HER2 negative

OR

HER-2/neu status = Test ordered, results not yet documented

OR

HER-2/neu status = Test ordered, insufficient sample for results

OR

(HER-2 equivocal AND New test ordered within 10 days of report = Yes or N/A (patient died or transferred out of practice))

Practices are required to order tests within 31 days from first office visit (HER2 test date – first office visit date = 31 days) and if a new test is ordered, it must be within 10 days of original report

Numerator definitions:

Select 'Test ordered, results not yet documented' only if there is documentation in the chart that a test that reports HER-2/neu analyses was ordered.

In the absence of any documentation regarding HER-2/neu status, select 'Test not ordered/no documentation.'

Enter information from the most recent test report.

Patients are classified as having HER-2 positive disease based on positive results with either test.

If the most recent report indicates insufficient sample, select 'Test ordered, insufficient sample for results.'

If a physician note and the HER-2/neu report differ in results, report the status in the physician note if the note explains the discrepancy. Otherwise, report the status from the HER-2/neu report.

Use the following definitions to determine HER-2/neu status:

Positive:

- IHC 3+ cell surface protein expression (defined as uniform intense membrane staining of >30% of invasive tumor cells) or
- FISH ratio >2.2 or
- HER2 gene copy >6.0

Equivocal:

- Not positive according to any of the criteria above, AND
- (IHC with scores 2+ AND FISH ratio 1.8-2.2) or
- HER2 gene copy 4.0-6.0

Negative:

- Not positive according to any of the criteria above, AND
- IHC 0 or 1+ or
- FISH ratio 1.8 or
- HER2 gene copy <4.0
- If the results indicate 'non-amplified', choose HER-2/neu negative.
- If the results indicate 'weakly positive', choose HER-2/neu positive.

New test ordered within 10 days of report of equivocal result: Respond 'Yes' if a new test was ordered within 10 days of oncologist review of the report with inconclusive results. Choose 'N/A' if the patient died or transferred out of the practice within 10 days of review of the report with inconclusive results or fewer than 10 days have passed.

If the chart documents that the pathologist has ordered a new test, respond 'Yes.'

Denominator Statement

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

All breast cancer patients with quantitative breast tumor evaluation by HER2 IHC

ICD-10 diagnosis codes for breast cancer: C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929

AND

CPT codes: Quantitative IHC Evaluation – 88360 or 88361 (The CPT descriptor for 88360 and 88361 is, "Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semi-quantitative, each antibody.")

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

Adult women with breast cancer

Denominator Details

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

ICD-10 diagnosis codes for breast cancer: C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929

AND

CPT codes: Quantitative IHC Evaluation – 88360 or 88361 (The CPT descriptor for 88360 and 88361 is, "Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semi-quantitative, each antibody.")

Wolff, A.C., et al. American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Update Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer. Arch Pathol Lab Med. 31:3997 -4014, 2013)

- Positive HER2 test. (p.3998)

Must report a HER2 test result as positive if: (a) IHC 3+ positive or (b) ISH positive using either a single-probe ISH or dual-probe ISH (Table 1; Figs 1 to 3). This assumes that there is no apparent histopathologic discordance observed by the pathologist (Table 2).

- Equivocal HER2 test. (p. 3998)

Must report a HER2 test result as equivocal and order reflex test on the same specimen (unless the pathologist has concerns about the specimen) using the alternative test if: (a)

IHC 2+ equivocal or (b) ISH equivocal using single-probe ISH or dual-probe ISH (Table 1; Figs 1 to 3). This assumes that there is no apparent histopathologic discordance observed by the pathologist (Table 2). Note that there are some rare breast cancers (eg, gland-forming tumors, micropapillary carcinomas) that show IHC 1+ staining that is intense but incomplete (basolateral or U shaped) and that are found to be HER2 amplified. The pathologist should consider also reporting these specimens equivocal and request reflex testing using the alternative test.

- Negative HER2 test. (p. 3998)

Must report a HER2 test result as negative if a single test (or all tests) performed on a tumor specimen show: (a) IHC 1+ negative or IHC 0 negative or (b) ISH negative using single-probe ISH or dual-probe ISH (Table 1; Figs 1 to 3). This assumes that there is no apparent histopathologic discordance observed by the pathologist (Table 2).

- Indeterminate HER2 test (p.3999)

_ Must report a HER2 test result as indeterminate if technical issues prevent one or both tests (IHC and ISH) performed on a tumor specimen from being reported as positive, negative, or equivocal. This may occur if specimen handling was inadequate, if artifacts (crush or edge artifacts) make interpretation difficult, or if the analytic testing failed. Another specimen should be requested for testing, if possible, and a comment should be included in the pathology report documenting intended action.

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

Female

And

2 or more encounters at the reporting site

And

Age at diagnosis greater than or equal to 18 years

And

Breast cancer diagnosis [C50.01-, C50.11-, C50.21-, C50.31-, C50.41-, C50.51-, C50.61-, C50.81-, C50.91-]

Definitions

Encounter: Patients must have been first seen in the office by a medical oncology or hematology oncology practitioner for the cancer diagnosis eligible for inclusion within the 1-year time frame of the reporting period. Enter the most recent visit that occurred during the 6-month visit window before the abstraction date. This can include visits to other office sites within the practice only if the practice uses a common medical record and shares management of care for the patient. This does not include visits during which a practitioner wasn't seen (e.g., laboratory testing), inpatient consults/visits, phone or email consults, or visits to a surgeon or radiation oncologist.

Exclusions

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

None

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

None

Exclusion Details

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

Not applicable

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

None

Risk Adjustment

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

No risk adjustment or risk stratification

Not applicable

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

No risk adjustment or risk stratification

Not applicable

Stratification

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

Not applicable

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

Not applicable

Type Score

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

Rate/proportion better quality = higher score

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

Rate/proportion better quality = higher score

Algorithm

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

Performance Measure:

3394F + 3395F/

Claims identified by CPT code 88360 or 88361 and breast cancer ICD- 9 codes

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

Performance is calculated as:

1. Identify those patients that meet the denominator criteria defined in the measure.

2. Subtract those patients with a denominator exclusion from the denominator. Note: this measure does not have exclusions.

3. From the patients who qualify for the denominator (after any exclusions are removed), identify those who meet the numerator criteria.

4. Calculation: Numerator/Denominator-Denominator Exclusions No diagram provided

Submission items

1855: Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

5.1 Identified measures:

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: The CPT codes used to identify the denominator of the measure are different; the measures apply to differnet tests on the same target population.

5b.1 If competing, why superior or rationale for additive value: No competing measures.

1878: HER2 testing for overexpression or gene amplification in patients with breast cancer

5.1 Identified measures: 1855 : Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value: Measure #1878 assesses whether HER2 testing was completed within 31 days of a breast cancer diagnosis. Meanwhile, NQF endorsed measure #1855 focuses on whether HER2 testing was completed according to current ASCO/CAP standards in the laboratory setting. A

Appendix G: Previous Gaps Identified in Cancer Care

The Current State of Cancer Quality Measurement White Paper (2008)

- **Few measures focus on the following**:
  - Lung cancer
  - Prostate cancer
  - Pancreatic cancer
  - Ovarian cancer
  - Lymphoma
  - Follow-up care
  - Evaluation & treatment of later stage cancer
  - End-of-life care
  - Non-physician providers/clinics
  - Survivorship
  - Psychosocial needs of cancer patients
  - Care coordination
  - Patient-reported outcomes/quality of life
- **Current measures tend to focus on**:
  - Initial diagnosis & treatment of early stage cancer
  - Structural aspects & processes that are weakly linked to high-impact outcomes (e.g., amount of active treatment received prior to death)

National Voluntary Consensus Standards for Quality of Cancer Care 2009

- **Recommended measure development for breast and colorectal cancer**:
  - **Safe Care**:
    - Assessment of complications
  - **Follow-up:**
    - Appropriate/inappropriate testing
  - **Outcome measures**:
    - 5-year survival
    - 30-day mortality
    - Percentage of early stage & stage of diagnosis
    - Rates of local recurrence
  - **Functional status**
  - **Timely Care**
  - **Patient-Centered Care:**
    - Coordination & professional communication
    - Decision support
    - Information/education
    - Emotional support
    - Respect for preferences & values
  - **Efficient Care**
  - **Equitable Care**

Cancer Endorsement Maintenance 2011

- **Disease specific gaps**:
  - Measures addressing:
    - hematological malignancies, particularly first line therapies
    - targeted therapies for kidney and lung cancer, as well as other solid tumor cancers
    - management of complications such as febrile neutropenia (FN)
  - Measures capturing deviations in care for the CMS priority areas of prostate, lung, breast, and colon cancers
  - PSA screenings for patients diagnosed with prostate cancer
  - Measures for pediatric patients, including measures in cross cutting areas such as pain assessment and palliative care
- **Pathology and Treatment Reports**:
  - Measures ensuring that:
    - reporting details in pathology reports are standardized across all tumor types
    - treatment summaries are standardized across medical and radiation oncologists
- **Appropriateness of Care:**
  - Measures capturing:
    - enrollment of patients in clinical trials at appropriate times
    - access of patients to high quality hospice care facilities
  - Measures addressing:
    - whether appropriate patients are offered enrollment in clinical trials
    - readmissions and value-based care
  - Measures of care coordination
- **Patient Outcomes**:
  - Measures capturing:
    - Patient Reported Outcomes
    - Cancer survival rate curve measures that can be reported by stage, identified as both overall survival (OS) and disease free survival (DFS).
  - Measures applicable to patients with:
    - lung, pancreas, liver, esophagus and colon cancer: 5-year survival rates
    - breast cancer: 10-year survival rates
    - thyroid cancer: 20-25-year survival rates
- **Surgical Care:**
  - Measures capturing operating room procedures or processes that need to take place in the surgical theater
- **Next Generation Measures:**
  - Measures capturing:
    - patient adherence to prescribed medications or therapies, including oral chemotherapies
    - treatment of negative side effects from prescribed medications or therapies
    - gene mutations and appropriate therapies
    - use of biological therapies

    - Outcome measures rather than process measures
- **Quality of Care:**
    - Measures capturing:
        - surgical outcomes
        - surgical processes linked to outcomes
        - smoking cessation for patients with lung cancers
    - Measures assessing the quality of:
        - laboratory methodologies
        - laboratory reports
    - Measures related to predictive laboratory testing
    - Measures addressing maintenance of nutritional status throughout the course of treatment
    - Evidence-based measures related to surveillance of cancer survivors in order to minimize the probability of recurrence
    - Measures related to cancer survival in specific areas, e.g., smoking cessation for lung cancer patients; maintaining nutritional status
    - Measures related to the quality, value and effectiveness of surgical, radiation and medical therapies in cancer care over the course of treatment
- **Unique Patient Populations**:
    - Measures addressing:
        - pediatric patients with cancer
        - hematological cancers separately from other cancers
        - disparities stratified by race/ethnicity, gender, and language
- **Other Measures**:
    - Measures submitted by patient advocacy groups or other multidisciplinary stakeholders
    - Prevention measures
    - Screening measures
    - Combined measures to be used in "toolkits" to ensure a process is associated with an improved outcome

Performance Measure Coordination Strategy for PPS-Exempt Cancer Hospitals (2012)

- **Patient Outcomes:**
    - Cancer-and stage-specific survival
    - Patient-reported measures
- **Cost and efficiency of care:**
    - Total cost, underuse, and overuse
- **Appropriateness of care:**
    - Expected clinical benefit vs. expected clinical risk
- **Health and well-being:**
    - Quality of life
    - Social and emotional health
- **Safety:**
    - Febrile neutropenia

    - Surgical site infection
- **Person- and family-centered care:**
    - Shared decision making
    - Patient experience
- **Care Coordination:**
    - Transition communication between providers
    - Medication reconciliation
- **Prevention:**
    - Public outreach & education
- **Disparities:**
    - Risk-stratified process/outcome measures
    - Access measures
- **Pediatrics:**
    - Hematologic cancers
    - Transitions to adult care
- **Treatment of lung, prostate, and gynecological cancers**

National Quality Forum
1030 15th St NW, Suite 800
Washington, DC 20005
http://www.qualityforum.org

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