



NATIONAL
QUALITY FORUM

Cancer Endorsement Maintenance Phase 2, 2011

DRAFT TECHNICAL REPORT FOR VOTING

August 17, 2012

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Cancer Endorsement Maintenance Phase 2

DRAFT TECHNICAL REPORT

Introduction

Cancer refers to a group of more than 100 diseases characterized by uncontrolled cellular growth, proliferation, and spread.ⁱ This group of diseases has an enormous impact on health in the US. As the second leading cause of death, cancer was responsible for an estimated 569,490 deaths among adults and children in 2010.ⁱⁱ The [National Cancer Institute](#) estimates that half of all men and one-third of all women in the US will develop cancer during their lifetimes. Diagnosis and treatment of cancer also has great economic impact as well. In 2010, the estimated total annual costs of cancer reached \$263.8 billion: \$102.8 billion in direct medical costs; \$20.9 billion in loss of productivity from illness; and \$140.1 billion in lost productivity from premature death.ⁱⁱⁱ Despite enormous focus on prevention and treatment of disease, inconsistencies in cancer care exist, with many patients not receiving care that follows clinical practice guidelines.^{iv} Studies demonstrate persistent socioeconomic disparities in treatment and survival for many different types of cancer, including gastric, breast, prostate, and lung cancers.^{v,vi,vii,viii}

Cancer care is complicated for many reasons: treatment regimens are complex, often involving multiple providers, settings of care, and levels of treatment; patients with cancer often require individualized therapies; an evolving evidence base for treatment exists; and care can be hampered by a sometimes limited supply of highly specialized personnel or technologies. There is a need for measures that address the quality of cancer care, taking into account the nuances mentioned.

The Cancer Endorsement Maintenance Project seeks to evaluate for endorsement measures for accountability and quality improvement that address breast, colorectal, lung, prostate, hematologic and skin cancers, as well as symptom management and end of life care. Cancer care consensus standards that have been endorsed by NQF before 2009 are evaluated under the maintenance process. Endorsement maintenance ensures the currency of NQF's portfolio of voluntary consensus standards, provides the opportunity to harmonize specifications, and ensures that endorsed measures represent the best in class. Measures that address specific aspects of the National Quality Strategy (NQS)—particularly those focused on person and family engagement, communication, coordination and safety are a priority.

Measure Evaluation

On May 23-24, 2012 the Cancer Steering Committee evaluated 6 new measures and 12 measures undergoing maintenance review against NQF's standard evaluation criteria. To facilitate the evaluation, the committee and candidate standards were divided into 3 workgroups for preliminary review of the measures against the sub-criteria prior to consideration by the entire steering committee. The committee's discussion and ratings of the criteria are summarized in the evaluation tables beginning on page 10.

CANCER ENDORSEMENT MAINTENANCE PHASE 2, 2011 SUMMARY

	MAINTENANCE	NEW	TOTAL
Measures under consideration	15	6	21
Withdrawn from consideration	3	0	3
Recommended	10	6	16
Consensus not yet reached	1	0	1
Not recommended	12	0	12
Reasons for Not Recommending	Importance - 12	N/A	

OVERARCHING ISSUES

During the Steering Committee’s discussion of the measures in Phase 2 of this project, several overarching issues emerged that were factored into their ratings and recommendations. These issues are discussed in detail in the following sections.

~~Gaps in Care Importance to Measure and Report~~

Steering Committee members expressed concern that several measures had high rates of performance, indicating a small gap in performance; however, the developer clarified that the performance gap data came from the American Society for Clinical Oncology’s Quality Oncology Practice Initiative (QOPI), which included self-selecting practices voluntarily reporting on measures. As such, the developer stated that it is likely that there is more variation in performance than was demonstrated through QOPI.

- [#1857 Trastuzumab not administered to breast cancer patients when human epidermal growth factor receptor 2 \(HER2\) is negative or undocumented,](#)
- [#1858 Trastuzumab administered to patients with AJCC stage I \(T1c\) – III, human epidermal growth factor receptor 2 \(HER2\) positive breast cancer,](#) and
- [#1878 Human epidermal growth factor receptor 2 \(HER2\) testing in breast cancer.](#)

Steering Committee discussion for all three measures focused on whether the criterion for opportunity for improvement was met. The Steering Committee agreed with the developer that it is likely that there is greater variation in use of trastuzumab and in HER2 testing, than indicated by the self-selected practices participating with QOPI. Taken in conjunction with several published and unpublished studies

suggesting overuse of trastuzumab, the Steering Committee recommended the measures for endorsement.

Harmonization of Related Measures

Related measures identified within Phase 2 of this project include those measuring hormonal therapy for patients with breast cancer, and those measuring chemotherapy for patients with colon cancer.

Please see the related measure comparison tables in Appendix C. ~~Comments are requested.~~

The Steering Committee evaluated two measures related to hormonal therapy for patients with breast cancer:

- [#0220 Adjuvant hormonal therapy \(ACS\)](#), and
- [#0387 Oncology: Hormonal Therapy for Stage IC through IIIC, ER/PR Positive Breast Cancer \(AMA-PCPI\)](#).

The Committee noted the two measures were related, but did not have recommendations for further harmonization. The measures addressed similar patient populations but at different levels of analysis; consequently, the specifications of the measures were slightly different to account for the data sources used in calculating the measures at the different levels of analysis.

	#0220 Adjuvant hormonal therapy (ACS)	#0387 Oncology: Hormonal Therapy for Stage IC through IIIC, ER/PR Positive Breast Cancer (AMA-PCPI)
Level of Analysis	Specified at the facility level.	Specified at the clinician level for group practices, individuals or teams.
Patient Population	Women 18 years or older at the time of diagnosis of breast cancer, <ul style="list-style-type: none"> • known or assumed to be first or only cancer diagnosis • epithelial malignancy only • primary tumors of the breast • AJCC T1c or Stage II or III • primary tumor is ER or PR positive • all or part of the first course of treatment performed at the reporting facility, and • known to be alive within 365 days of data of diagnosis. 	Women 18 years and older with Stage IC through IIIC ER or PR positive breast cancer.
Exclusions	Men, women under the age of 18 at time of diagnosis, second or subsequent cancer diagnosis, tumor not in originating in the breast, Stage 0, in-situ tumor, primary tumor is estrogen receptor negative and progesterone receptor negative, none of the first	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

	#0220 Adjuvant hormonal therapy (ACS)	#0387 Oncology: Hormonal Therapy for Stage IC through IIIC, ER/PR Positive Breast Cancer (AMA-PCPI)
	course therapy is performed at the reporting facility, or died within 365 days of diagnosis.	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)
Data Source	Registry and paper records.	Administrative claims, EHR, registry, paper records

The Steering committee evaluated two measures related to chemotherapy for patients with colon cancer:

- [#0223 Adjuvant chemotherapy is considered or administered within 4 months \(120\) days of surgery to patients under the age of 80 with AJCC III \(lymph node positive\) colon cancer \(ACS\)](#), and
- [#0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients \(AMA-PCPI\)](#).

The Committee requested that the developers harmonize the age cut-off for the measures at 80 years of age, as the National Comprehensive Cancer Network (NCCN) guidelines do not recommend the intervention for patients older than that due to diminishing benefits to the patient associated with increasing age. The AMA-PCPI will consider modifying its measure [in the future](#) as requested.

	#0223 Adjuvant chemotherapy is considered or administered within 4 months (120) days of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer (ACS),	#0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients (AMA-PCPI).
Level of Analysis	Specified at the facility level,	Specified at the clinician level for group practices, individuals or teams.
Patient Population	Patients age 18-79 at time of diagnosis <ul style="list-style-type: none"> • Known or assumed to be first or only cancer diagnosis • Primary tumors of the colon • Epithelial malignancy only • At least one pathologically examined 	Patients aged 18 years and older with Stage IIIA through IIIC colon cancer.

	#0223 Adjuvant chemotherapy is considered or administered within 4 months (120) days of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer (ACS),	#0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients (AMA-PCPI).
	<ul style="list-style-type: none"> regional lymph node positive for cancer (AJCC Stage III) All or part of 1st course of treatment performed at the reporting facility² Known to be alive within 4 months (120 days) of diagnosis 	
Exclusions	<p>Patients age <18 and >=80; not a first or only cancer diagnosis;</p> <ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Documentation of medical reason(s) for not referring for or prescribing adjuvant chemotherapy (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) 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)
Data Source	Registry and paper records.	Administrative claims, EHR, registry, paper records

MEASURE SPECIFIC ISSUES

Changing Evidence or Guidelines

~~Prior to and during this project, e~~Changing guidelines in the area of screening for breast cancer influenced evaluation of the maintenance measure [#0031 Breast Cancer Screening](#) (The National Committee for Quality Assurance), which captures women age 40 to 69 years who have had a biennial mammogram to screen for breast cancer. In 2009, the [U.S. Preventive Services Task Force](#) (USPSTF) issued the following recommendations related to screening for breast cancer:

- The USPSTF recommends biennial screening mammography for women aged 50 to 74 years.
 - Grade: B recommendation.
- The decision to start regular, biennial screening mammography before the age of 50 years should be an individual one and take patient context into account, including the patient's values regarding specific benefits and harms.
 - Grade: C recommendation.
- The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of screening mammography in women 75 years or older.
 - Grade: I Statement.
- The USPSTF recommends against teaching breast self-examination (BSE).
 - Grade: D recommendation.
- The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of clinical breast examination (CBE) beyond screening mammography in women 40 years or older.
 - Grade: I Statement.
- The USPSTF concludes that the current evidence is insufficient to assess the additional benefits and harms of either digital mammography or magnetic resonance imaging (MRI) instead of film mammography as screening modalities for breast cancer.
 - Grade: I Statement.^{ix}

However, other many oncology societies' national guidelines (e.g., American Cancer Society, American College of Obstetricians and Gynecologists) continue to recommend screening at earlier ages. The Steering Committee did not reach clear consensus on measure #0031 due to concerns about the rationale for the age specified in the measure, given the USPSTF recommendations and conflicting recommendations from oncology-national societies. The Steering Committee ~~felt agreed that~~ the measure addresses an important topic where there is potential for improvement in breast cancer screenings; however, the Steering Committee was concerned that evolving evidence for breast cancer screenings may lessen the impact of this metric for the patient populations that would most benefit from the screenings. The NCQA is currently evaluating the guidelines to determine if and how measure #0031 should be changed. One possibility is that the developer might stratify the measure by different age groups.

~~The Steering Committee is requesting additional input from the membership and the public on this measure, as the Steering Committee was unable to achieve consensus on an endorsement recommendation.~~

Since the Steering Committee was unable to reach consensus on this measure, the Committee requested additional input from the membership and the public on an endorsement recommendation. After considering member and public comment, as well as information presented by the developer on a follow up conference call, the Steering Committee voted against continued endorsement of the measure as it is currently specified.

Comment on the measures provided both support and concern with the measure and the relation to the USPSTF breast cancer screening guidelines. One commenter suggested that the measure might be stratified by women aged 40 to 49, and women aged 50 and older as a way to address concerns about conflicting guideline recommendations regarding the appropriate age to begin biennial screening mammograms. NCQA noted that many professional organizations, including American Congress of

Obstetricians and Gynecologists, American Cancer Society, American College of Radiology, American Society of Breast Surgeons, and the Society of Breast Imaging continued to recommend biennial mammography screening for women aged 40 to 49. NCQA is currently reevaluating the measure and exploring potential changes to the measure, including the possibility of stratifying the measure by age. The measure would remain in use in HEDIS while modifications are made, and changes to the measure are expected to be finalized in spring of 2013. Committee members agreed that measures of accountability must be supported by consistent, high-level evidence supporting the measure focus. The Committee was concerned that stratification of the measure by age groups may not address the issue of conflicting evidence as results on the younger age group may not be meaningful and may be confusing to users of the measure. Steering Committee members suggested that two separate measures addressing these age groups may be the most appropriate action given the need to incorporate patient's family history and preferences for screening for women aged 40 to 49.

NQF would be pleased to review the revised NCQA measure when it is finalized and an appropriate endorsement project is available.

RECOMMENDATIONS FOR FUTURE MEASURE DEVELOPMENT

During the measure evaluation process the Steering Committee identified areas in Phase 2 where additional measure development is needed:

Next Generation Measures

- Measures capturing patient adherence to prescribed medications or therapies, including oral chemotherapies
- Measures capturing treatment of negative side effects from prescribed medications or therapies
- Measures capturing gene mutations and appropriate therapies
- Measures capturing use of biological therapies
- Outcome measures rather than process measures

Quality of Care

- Measures capturing surgical outcomes
- Measures capturing surgical processes linked to outcomes
- Measures assessing the quality of laboratory methodologies
- Measures assessing the quality of laboratory reports
- Measures addressing maintenance of nutritional status throughout the course of treatment
- Measures capturing smoking cessation for patients with lung cancers
- 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
- Measures related to predictive laboratory testing

Unique Patient Populations

- Measures addressing pediatric patients with cancer
- Measures addressing hematological cancers separately from other cancers
- Measures addressing disparities stratified by race/ethnicity, gender, and language

Measure Evaluation Summary

Measures recommended

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Measures Recommended

COLON CANCER MEASURES

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

Status: Maintenance, Original Endorsement: Mar 01, 2007, Most Recent Endorsement: Mar 01, 2007

Description: Percentage of patients under the age of 80 with AJCC III (lymph node positive) colon cancer for whom adjuvant chemotherapy is considered or administered within 4 months (120 days) of diagnosis.

Numerator Statement: Chemotherapy is considered or administered within 4 months (120 days) of diagnosis

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 facility²

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

Adjustment/Stratification: No risk adjustment or risk stratification No stratification applied

Level of Analysis: Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry, Paper Records

Measure Steward: Commission on Cancer, American College of Surgeons **Other organizations:** This measure was harmonized with measure development efforts coordinated between the American Societ

Steering Committee In-Person May 23-24, 2012

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

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-11; M-0; L-0; I-0; 1b. Performance Gap: H-7; M-4; L-0; I-0; 1c. Evidence: Y-11, N-0, I-0

Rationale:

- The Steering Committee agreed the measure focus demonstrates an area of high potential impact as there could be a potential 25 percent difference in survival for patients.
- Overall poor performance on this measure is concerning, given the very strong level 1 evidence of the impact on patient outcomes. A Committee member questioned whether Stage 2b colon cancers should be included in the measure.
 - The developer explained the ability to identify that subset of Stage 2 colon cancers is not yet routinely possible due to the way the staging systems were designed until 2010, and stated the evidence is not settled regarding the appropriateness of adjuvant chemotherapy for Stage 2b disease.

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-6; M-5; L-0; I-0; 2b. Validity: H-6; M-5; L-0; I-0

Rationale:

- The Steering Committee stated that reliability testing was sufficient.
- The face validity of the measure was well demonstrated.
- The denominator exclusions are relevant.

3. Usability: H-7; M-4; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

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

Rationale:

- Reporting the time and administration of chemotherapy is straightforward and easily understood.
- This measure is in use by the Commission on Cancer.

4. Feasibility: H-6; M-5; L-0; I-0

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- Measure appears feasible whether dealing with abstracting data or from EMRs.
- All data elements are available in cancer registries.

Steering Committee Recommendation for Endorsement: Y-11 ; N-0

Public and Member Comment

Comments included:

- Supportive comments for the measure.
- Commenters suggested that the measure can be improved upon by focusing only on administration of chemotherapy and not consideration of chemotherapy, as “considered” is not a precise term.

Developer Response:

- The developer stated that the Commission on Cancer and the American College of Surgeons use cancer registries to implement this measure; the cancer registries have standard definitions for both “administered” and “considered” therapies. Cancer registries record and report this information if it is documented in the patient chart. Further, a review of data has demonstrated consistency in reporting considered therapies over three years.

Steering Committee Response:

- The Steering Committee agreed with the developer’s response, which is consistent with discussions that occurred at the in-person meeting and on related conference calls.

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

Status: Maintenance, Original Endorsement: Mar 01, 2007, Most Recent Endorsement: Mar 01, 2007

Description: Percentage of patients >18yrs of age, who have primary colon tumors (epithelial malignancies only), experiencing their first diagnosis, 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

Known or assumed to be first or only cancer 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; not a first or only cancer diagnosis; non-epithelial and non-invasive tumors; metastatic disease (AJCC Stage IV); not treated surgically at the reporting facility

Adjustment/Stratification: No risk adjustment or risk stratification No stratification applied

Level of Analysis: Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry, Paper Records

0225 At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer.
Measure Steward: Commission on Cancer, American College of Surgeons
Steering Committee In-Person May 23-24, 2012
<p>1. Importance to Measure and Report: <u>The measure meets the Importance criteria.</u> (1a. High Impact; 1b. Performance Gap; 1c. Evidence) 1a. Impact: H-8; M-2; L-1; I-0; 1b. Performance Gap: H-5; M-5; L-0; I-1; 1c. Evidence: Y-7, N-2, I-2</p> <p>Rationale:</p> <ul style="list-style-type: none"> • The Steering Committee agreed the measure focus demonstrates an area of high potential impact as many patients are diagnosed with colon cancer. • The Steering Committee noted that lower level quality of evidence was presented. A large body of observational studies was provided in support of the measure, but no RCTs. • The Steering Committee was concerned that some literature suggests that removal of anywhere from 6 to 17 nodes is the appropriate number. <ul style="list-style-type: none"> ○ The developer noted that was true; however, NCCN guidelines call for 12 lymph nodes. The developer noted that this will be a moving target, and as the literature on the topic improves, the measure will be updated accordingly. • The Steering Committee stated that there are few measures focused on the quality of surgical care, and as such this measure will move the field forward.
<p>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-5; M-6; L-0; I-0; 2b. Validity: H-4; M-5; L-1; I-1</p> <p>Rationale:</p> <ul style="list-style-type: none"> • The Steering Committee stated that reliability testing was sufficient. • The validity of the measure was well demonstrated, though concern about the evolving guidelines was thought to be a possible threat to validity. • The denominator exclusions are relevant.
<p>3. Usability: <u>H-5; M-4; L-1; I-1</u> <i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale:</p> <ul style="list-style-type: none"> • The number of lymph nodes removed and pathologically examined is straightforward. • The measure is currently in use by oncologists for Commission on Cancer.
<p>4. Feasibility: <u>H-6; M-4; L-0; I-1</u> <i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale:</p> <ul style="list-style-type: none"> • Measure appears feasible whether dealing with abstracting data or from EMRs. • All data elements are available in cancer registries.
Steering Committee Recommendation for Endorsement: <u>Y-9 ; N-2</u>
Public and Member Comment No comments were received.

0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients
Status: Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 31, 2008
Description: Percentage of patients aged 18 years and older with Stage IIIA through IIIC colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy or have previously received adjuvant chemotherapy within the 12 month reporting period

0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients

Numerator Statement: Patients who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy* within the 12 month reporting period
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
Denominator Statement: All patients aged 18 years and older with Stage IIIA through IIIC colon cancer
Exclusions: Documentation of medical reason(s) for not referring for or prescribing adjuvant chemotherapy (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)
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)
Adjustment/Stratification: No risk adjustment or risk stratification None We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.
Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Type of Measure: Process
Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Medical Records
Measure Steward: American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) **Other organizations:** This measure is jointly copyrighted by the AMA-PCPI, American Society of Clinical Oncology, and Nati

Steering Committee In-Person May 23-24, 2012

1. Importance to Measure and Report: The measure meets the Importance criteria.
(1a. High Impact; 1b. Performance Gap; 1c. Evidence)
1a. Impact: H-11; M-0; L-0; I-0; 1b. Performance Gap: H-6; M-5; L-0; I-0; 1c. Evidence: Y-10, N-1, I-0
Rationale:

- The Steering Committee agreed the measure focus demonstrates an area of high impact, as many patients are diagnosed with colon cancer.
- There is a demonstrated performance gap on this measure, with 93 percent adherence to the measure in PQRS. The Steering Committee noted that as participants in PQRS are self-selecting and report voluntarily, there is likely greater variation in the field and there is an opportunity for improvement.
- High level evidence was provided to support the measure focus.

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-5; M-6; L-0; I-0; 2b. Validity: H-4; M-5; L-1; I-1
Rationale:

- The Steering Committee stated that reliability testing was sufficient.
- The Steering Committee questioned use of the NCCN list of drugs for adjuvant chemotherapy.
 - The developer noted that the measure specifications will be updated as timely as possible. The developer also stated that the measure has taken a pragmatic approach; reporting of adjuvant chemotherapy is sufficient to meet the measure. The drugs used are not part of the specifications or coding. Instead, the drugs are listed separately.
 - The Steering Committee noted that this in effect means that to get credit for this measure, the provider does

<p>0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients</p> <p>not have to give the patient the “gold standard” chemotherapy drugs.</p> <ul style="list-style-type: none"> • The validity of the measure was well demonstrated. • The denominator exclusions are relevant.
<p>3. Usability: H-8; M-3; L-0; I-0 <i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale:</p> <ul style="list-style-type: none"> • The Steering Committee stated that use of chemotherapy for patients with Stage IIIA through IIIC colon cancer can be easily understood by both providers and the public. • The measure is currently in use in PQRS.
<p>4. Feasibility: H-8; M-3; L-0; I-0 <i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale:</p> <ul style="list-style-type: none"> • The measure appears feasible whether dealing with abstracting data or from EMRs. • All data elements are generated through the process of care.
<p>Steering Committee Recommendation for Endorsement: Y-11 ; N-0</p> <p>Public and Member Comment</p> <p><u>Comments included:</u></p> <ul style="list-style-type: none"> • <u>Commenters suggested that the developer revise the measure numerator to include only patients who have received adjuvant chemotherapy in order to create a more patient-centered measure.</u> <p><u>Developer Response:</u></p> <ul style="list-style-type: none"> • <u>The developer stated that as the measure can be reported on at any time between diagnosis and five years past diagnosis, and because any provider involved in the patient's cancer care may report this measure (including providers who do not administer chemotherapy), the numerator includes those who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12 month reporting period. The goal of the measure is to promote shared responsibility for ensuring that all recommended step for cancer treatment occur, in accordance with patient preference.</u> <p><u>Steering Committee Response:</u></p> <ul style="list-style-type: none"> • <u>The Steering Committee agreed with the developer’s response, which is consistent with discussions that occurred at the in-person meeting and on related conference calls.</u>

<p>0392 Colorectal Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade</p> <p>Status: Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 31, 2008</p> <p>Description: Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade</p> <p>Numerator Statement: Reports that include the pT category, the pN category and the histologic grade</p> <p>Denominator Statement: All colon and rectum cancer resection pathology reports</p> <p>Exclusions: Denominator Exclusion: Documentation of medical reason(s) for not including the pT category, the pN category or the histologic grade (eg; re-excision without residual tumor; non-carcinomasanal canal)</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>Type of Measure: Process</p>

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

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry, Paper Records

Measure Steward: American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) **Other organizations:** College of American Pathologists

Steering Committee In-Person May 23-24, 2012

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

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-12; M-2; L-0; I-0; 1b. Performance Gap: H-9; M-5; L-1; I-1; 1c. Evidence: Y-14, N-2, I-0

Rationale:

- The Steering Committee agreed the measure addresses a high impact area and provides useful and important pieces of information when making therapeutic decisions about patients with colorectal cancer.
- Accurate pathology reporting is very important for determining adjuvant treatments, staging and discriminating between Stage 2 and Stage 3 cancer and possibly in determining eligibility for clinical trials.
- There is not demonstrated evidence that recording stage leads to improved outcomes; however, this can be reasonably inferred as staging provides the basis for treatment decisions.
- There was a demonstrated performance gap, with 25.82 percent of eligible reports missing at least one of the ten CAP-recommended colorectal cancer elements. The Steering Committee was concerned, however that the data for the performance gap data was several years old and that it is unclear what performance gap exists today.

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-10; M-4; L-1; I-1; 2b. Validity: H-4; M-8; L-2; I-1

Rationale:

- The Steering Committee stated that the measure was clearly and precisely specified.
- The Steering Committee stated that reliability of the measure score was high.
- The measure demonstrated validity through queries of an expert panel: 8 out of a 12- member panel agreed the measure was important to report.
- Denominator exclusions, such as recurring cases, are relevant.
- The Steering Committee recommended that margin status and number of lymph nodes evaluated be captured in future iterations of the measure.

3. Usability: H-4; M-8; L-3; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

Rationale:

- The measure is currently in use in PQRS.
- Measure demonstrates high usability as it's a way to look at the quality of the pathology reporting that is delivered by a local institution.
- The measure should be moderately understood by the public and by healthcare providers.

4. Feasibility: H-5; M-8; L-2; I-0

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- The measure testing demonstrates reliable abstraction from paper medical records and from EMRs.
- Steering Committee members questioned whether the information required by the measure would be found in an initial report or an integrated summary report. It was noted that as there are often many reports, it will be difficult for a provider to know which report contains the most significant pathology information.
 - The developer noted that reporting of the measure will be limited to what the pathologist has available-the pathologist may not have information demonstrating metastatic disease, and as such, that would not be

0392 Colorectal Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade
included on the report. <ul style="list-style-type: none"> The Steering Committee noted that the data is generated during the processes of clinical care.
Steering Committee Recommendation for Endorsement: <u>Y-12 ; N-2</u>
<u>Public and Member Comment</u>
Comments included: <ul style="list-style-type: none"> <u>Supportive comments for the measure.</u> <u>Concern that the measure assesses what is considered standard practice.</u>
Developer Response: <ul style="list-style-type: none"> <u>The developer noted that though this should be standard care, there is a documented gap in care, with 25.82 percent of eligible reports missing at least one of the ten CAP-recommended colorectal cancer elements.</u>
Steering Committee Response: <ul style="list-style-type: none"> <u>The Steering Committee agreed with the developer's response, which is consistent with discussions that occurred at the in-person meeting and on related conference calls.</u>

1859 KRAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy
Status: New Submission Description: Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom KRAS gene mutation testing was performed Numerator Statement: KRAS gene mutation testing performed before initiation of anti-EGFR MoAb Denominator Statement: Adult patients with metastatic colorectal cancer who receive anti-EGFR monoclonal antibody therapy Exclusions: Patient transfer to practice after initiation of chemotherapy Adjustment/Stratification: No risk adjustment or risk stratification n/a n/a Level of Analysis: Clinician : Group/Practice, Clinician : Team Type of Measure: Process Data Source: Electronic Clinical Data : Electronic Health Record, Paper Medical Records Measure Steward: American Society of Clinical Oncology
Steering Committee In-Person May 23-24, 2012
1. Importance to Measure and Report: <u>The measure meets the Importance criteria.</u> (1a. High Impact; 1b. Performance Gap; 1c. Evidence) 1a. Impact: H-11; M-0; L-0; I-0; 1b. Performance Gap: H-6; M-5; L-0; I-0; 1c. Evidence: Y-10, N-1, I-0 <u>Rationale:</u> <ul style="list-style-type: none"> The Steering Committee agreed the measure focus demonstrates an area of high impact, as many patients are diagnosed with colorectal cancer. There is a demonstrated performance gap on this measure, with 73 percent mean adherence to the measure in Quality Oncology Practice Initiative. The Steering Committee noted that there is a demonstrated opportunity for improvement. There is consistent evidence demonstrating a lack of benefit in using this therapy for patients with the KRAS mutation, and the therapy is expensive. The measure will be useful for preventing overtreatment of patients who would not benefit from the therapy.
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)

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

2a. Reliability: H-8; M-3; L-0; I-0; 2b. Validity: H-8; M-3; L-0; I-0

Rationale:

- The reliability testing was sufficient.
- The validity of the measure was well demonstrated.
- The denominator exclusions are relevant.
- The Steering Committee asked the developer to specify where the mutations are found, as in the future there may be mutations in the same gene that will be difficult to correlate and understand.
 - The developer made the following modifications to 2a1.7 which sufficiently addressed the Steering Committee's concerns:
 - KRAS mutation testing: KRAS testing for this measure refers to assays that detect mutations in codons 12 and 13 of KRAS only. Do not include results from mutations at other codons (e.g., codons 61 and 146), or assays for other alterations (e.g., BRAF, PI3K, PTEN genes). The College of American Pathologists (CAP) Perspectives on Emerging Technology (POET) Report on KRAS mutation testing provides additional guidance on testing. If multiple KRAS mutation tests have been performed, refer to the most recent test results.

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

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

Rationale:

- An expert panel has supported use of this measure for public reporting.
- The Steering Committee suggested the developer revise the title of the measure to clarify. The measure developer did so and received the Steering Committee's approval.

4. Feasibility: H-6; M-5; L-0; I-0

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- Measure appears feasible whether dealing with abstracting data or from EMRs.
- All data elements are generated through the process of care.

Steering Committee Recommendation for Endorsement: Y-11 ; N-0

Public and Member Comment

Comments included:

- Supportive comments for the measure.
- A request for harmonization and combination with measure 1860, which would capture testing and treatment with appropriate exclusions such as patient preference.

Developer Response:

- The developer states that the measures are reported together by ASCO, but ASCO considers the measures to be independently useful. Neither measure assesses whether testing was given to all metastatic colorectal cancer (CRC) patients, as that is not recommended. Likewise, neither measure assesses whether patients with metastatic CRC receive monoclonal antibodies; thus, exclusion for patient preference is not warranted.

Steering Committee Response:

- The Steering Committee agreed with the developer's response, which is consistent with discussions that occurred at the in-person meeting and on related conference calls.

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

Status: New Submission

Description: Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-EGFR monoclonal antibodies

Numerator Statement: Anti-EGFR monoclonal antibody therapy not received

Denominator Statement: Adult patients with metastatic colorectal cancer who have a KRAS gene mutation

Exclusions: Patient transfer to practice after initiation of chemotherapy
Receipt of anti-EGFR monoclonal antibody therapy as part of a clinical trial protocol

Adjustment/Stratification: No risk adjustment or risk stratification n/a n/a

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

Type of Measure: Process

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

Measure Steward: American Society of Clinical Oncology

Steering Committee In-Person May 23-24, 2012

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

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-10; M-1; L-0; I-0; 1b. Performance Gap: H-6; M-5; L-0; I-0; 1c. Evidence: Y-11, N-0, I-0

Rationale:

- The Steering Committee agreed the measure focus demonstrates an area of high impact, as many patients are diagnosed with colorectal cancer.
- There is a demonstrated performance gap on this measure, with 85 percent mean adherence to the measure in Quality Oncology Practice Initiative. The Steering Committee noted that there is a demonstrated opportunity for improvement.
- The Steering Committee noted that sparing futile or useless therapy is important, particularly as this therapy is very expensive.
- The measure will be useful for preventing overtreatment of patients who would not benefit from the therapy.

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-5; M-6; L-0; I-0; 2b. Validity: H-6; M-4; L-0; I-1

Rationale:

- Reliability testing was sufficient.
- The validity of the measure was well demonstrated.
- The denominator exclusions are relevant.
- The Steering Committee questioned whether there was a clinical trial exclusion for this measure.
 - The developer noted that there was not and added this exclusion to the measure specifications.
- The Steering Committee stated the need for clarification as to when the testing is to be performed.
 - The developer added clarifying instructional information to the measure.
- The Steering Committee asked the developer to specify where the mutations are found, as in the future there may be mutations in the same gene that will be difficult to correlate and understand.
 - The developer made the following modifications to 2a1.7 which sufficiently addressed the Steering Committee's concerns:
 - KRAS mutation testing: KRAS testing for this measure refers to assays that detect mutations in codons 12 and 13 of KRAS only. Do not include results from mutations at other codons (e.g., codons 61 and 146), or assays for other alterations (e.g., BRAF, PI3K, PTEN genes). The College of American Pathologists (CAP) Perspectives on Emerging Technology (POET) Report on KRAS mutation testing provides additional guidance on testing. If multiple KRAS mutation tests have been performed, refer to the most recent test results.

3. Usability: H-7; M-4; L-0; I-0

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

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

Rationale:

- An expert panel has supported use of this measure for public reporting.

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

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- The measure appears feasible whether dealing with abstracting data or from EMRs.
- All data elements are generated through the process of care.

Steering Committee Recommendation for Endorsement: Y-11 ; N-0

Public and Member Comment

Comments included:

- Supportive comments for the measure.
- A request for harmonization and combination with measure 1860, which would capture testing and treatment with appropriate exclusions such as patient preference.

Developer Response:

- The developer states that the measures are reported together by ASCO, but ASCO considers the measures to be independently useful. Neither measure assesses whether testing was given to all metastatic CRC patients, as that is not recommended. Likewise, neither measure assesses whether patients with metastatic CRC receive monoclonal antibodies; thus, exclusion for patient preference is not warranted.

Steering Committee Response:

- The Steering Committee agreed with the developer's response, which is consistent with discussions that occurred at the in-person meeting and on related conference calls.

BREAST CANCER MEASURES

0219 Post breast conservation surgery irradiation

Status: Maintenance, Original Endorsement: Mar 01, 2007, Most Recent Endorsement: Mar 01, 2007

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 treatment by breast conservation surgery (surgical excision less than mastectomy)

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

Known to be alive within 1 year (365 days) of diagnosis

0219 Post breast conservation surgery irradiation

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

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

Adjustment/Stratification: No risk adjustment or risk stratification No stratification applied

Level of Analysis: Facility

Type of Measure: Process

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

Measure Steward: Commission on Cancer, American College of Surgeons **Other organizations:** This measure was harmonized with measure development efforts coordinated between the American Societ

Steering Committee In-Person May 23-24, 2012

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

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-10; M-4; L-0; I-0; 1b. Performance Gap: H-1; M-12; L-1; I-0; 1c. Evidence: Y-13, N-0, I-1

Rationale:

- The Steering Committee agreed the measure focus represents an area of high impact, with many women receiving breast conservation surgery.
- There is a demonstrated opportunity for improvement, with demonstrated variation in the use of radiation with breast conservation surgery. Additionally, there are demonstrated disparities on the basis of age, race/ethnicity, and other factors.
- The Steering Committee noted that this measure is important for both ER negative and ER positive patients, as the measure was initially specified to include only ER negative patients.
 - The developer removed hormone receptor status condition from the numerator.

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-11; M-3; L-0; I-0; 2b. Validity: H-8; M-5; L-0; I-1

Rationale:

- The Steering Committee had noted in a workgroup call prior to the in-person meeting that there were inconsistencies in the denominator specifications related to the Stage 1 category, and were concerned about the specification of receptor status, noting that the measure is important for both ER negative and ER positive patients.
 - The developer corrected the inconsistencies in the denominator specifications to be inclusive of Stage 1 breast cancers, and removed the hormone receptor status condition.
- The Steering Committee questioned the time window of 1 year for the measure.
 - The developer clarified that the time starts at the index diagnosis date, and that typically most patients have started radiation therapy within 1 year of the index diagnosis date.
- The Steering Committee stated that reliability testing was sufficient.
- The validity of the measure is well demonstrated.

3. Usability: H-5; M-9; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

Rationale:

- The measure is currently in use in the American College of Surgeons Commission on Cancer.

0219 Post breast conservation surgery irradiation

- The measure should be easily understood by the public and by healthcare providers.

4. Feasibility: H-8; M-6; L-0; I-0

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- All data elements are available in cancer registries.

Steering Committee Recommendation for Endorsement: Y-14 ; N-0

Public and Member Comment

Comments included:

- Supportive comments for the measure.
- A request for the evidentiary basis for the time window of one year.

Developer Response:

- The developer stated that the standard of care is to provide radiation after the completion of chemotherapy. The time frame to receive chemotherapy, coupled with the time to complete initial diagnostic and second opinions, surgery and chemotherapy may extend through 8 - 10 months. Therefore, radiation will not be administered until this time. For the purpose of a measure, it was felt best to apply the 365 days to accommodate this variation. When this measure was originally specified, sensitivity analyses were performed to evaluate the effect the timing rule for radiation therapy would have on aggregate performance rates. In this analysis of over 90,000 women who had undergone breast conservation surgery it was determined that just over half of those who eventually received radiation therapy did so within 180 days of diagnosis, and three quarters received radiation therapy within 365 days.

Steering Committee Response:

- The Steering Committee agreed with the developer’s response, which is consistent with discussions that occurred at the in-person meeting and on related conference calls.

0220 Adjuvant hormonal therapy

Status: Maintenance, Original Endorsement: Mar 01, 2007, Most Recent Endorsement: Mar 01, 2007

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

Numerator Statement: Hormone therapy is considered or administered within 1 year (365 days) of the date of diagnosis

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 T1c or Stage II or III

Primary tumor is estrogen receptor positive or progesterone receptor positive

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

Known to be alive within 1 year (365 days) of date of diagnosis

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

Men

Under age 18 at time of diagnosis

Second or subsequent cancer diagnosis

0220 Adjuvant hormonal therapy

Tumor not originating in the breast
Non-epithelial malignancies
Stage 0, in-situ tumor
AJCC T1mic, T1a, or T1b 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

Adjustment/Stratification: No risk adjustment or risk stratification No stratification applied

Level of Analysis: Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry, Paper Records

Measure Steward: Commission on Cancer, American College of Surgeons **Other organizations:** This measure was harmonized with measure development efforts coordinated between the American Societ

Steering Committee In-Person May 23-24, 2012

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

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-14; M-3; L-0; I-0; 1b. Performance Gap: H-5; M-10; L-1; I-1; 1c. Evidence: Y-16, N-1, I-0

Rationale:

- The Steering Committee agreed the measure focus represents an area of high impact, with many women receiving a breast cancer diagnosis.
- Evidence supports the selected patient population, as hormone therapy is indicated in patients with receptor positive disease.
- There is a performance gap for this measure.
- Disparities are demonstrated between African American and white females.

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-11; M-6; L-0; I-0; 2b. Validity: H-8; M-9; L-0; I-0

Rationale:

- The Steering Committee questioned why there was no exclusion for pregnancy or planned pregnancy.
 - The developer noted that of the 110,000 women reported on, 63 had a secondary diagnosis code with pregnancy. This equates to one half of one percent. Half of these women did ultimately receive hormonal therapy; it is plausible that those women received the therapy after delivery. Consequently, the number of patients excluded for pregnancy would be extremely minimal. With respect to planned pregnancy, it is not feasible to ascertain planned pregnancy with respect to the measure.
- The Steering Committee stated that reliability testing was sufficient.
- The validity of the measure was well demonstrated.
- The Steering Committee recommended that in future iterations, the measure capture that the patients are receiving the appropriate dose of hormonal therapy.
- The Steering Committee also recommended that the measure capture appropriateness of hormonal therapy based upon menopausal state of the patient.
- The Steering Committee recommended that the measure captured patient adherence to the hormonal therapy through filled prescriptions.

3. Usability: H-10; M-6; L-1; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

Rationale:

- The measure is currently in use in the American College of Surgeons Commission on Cancer.
- The measure should be easily understood by the public and by healthcare providers.

0220 Adjuvant hormonal therapy

4. Feasibility: H-7; M-10; L-0; I-0

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- All data elements are available in cancer registries.

Steering Committee Recommendation for Endorsement: Y-17 ; N-0

Public and Member Comment

Comments included:

- Supportive comments for the measure.
- A request that the measure specifications include race, ethnicity, gender, and language data elements to allow for stratification by these elements.
- A request that the measure have provisions for appropriate hormonal therapy dosage.
- A request for exclusion of small tumors.
- Commenters suggested that the measure can be improved upon by focusing only on administration of chemotherapy and not consideration of chemotherapy, as “considered” is not a precise term.

Developer Response:

- The developer stated that the Commission on Cancer’s Rapid Quality Reporting System allows participating programs to generate comparison reports which stratify measure performance rates by race/ethnicity, age, insurance status, and area-based SES measures.
- The developer stated that it is not certain that ascertainment of the prescribed dosage of the hormonal therapy would enhance our understanding of adherence to this clinical standard of care. NCCN Guidelines simply specify the term or period of time for which hormonal agents should be prescribed, and in contrast to their dose specifications for chemotherapy regimens, don't comment specifically with respect to hormone therapy doses. Further, for the hormone agents that are used in the large majority of cases (tamoxifen and aromatase inhibitors) there is a single dose used. These issues, coupled with the high level of added work effort to confirm and record a dose, suggest that the added value to a quality measure of collecting dose would be limited.
- The developer stated that the full definition of this measure specifies that women with AJCC T1cN0M0 or Stage II or III HR+ breast disease are eligible to be included in this measure. This excludes women with small (Tmic, T1a and T1b) tumors.
- The developer stated that the Commission on Cancer and the American College of Surgeons use cancer registries to implement this measure; the cancer registries have standard definitions for both “administered” and “considered” therapies. Cancer registries record and report this information if it is documented in the patient chart. Further, a review of data has demonstrated consistency in reporting considered therapies over three years.

Steering Committee Response:

- The Steering Committee agreed with the developer’s response, which is consistent with discussions that occurred at the in-person meeting and on related conference calls.

0221 Needle biopsy to establish diagnosis of cancer precedes surgical excision/resection

Status: Maintenance, Original Endorsement: Mar 01, 2007, Most Recent Endorsement: Mar 01, 2007

Description: Percentage of patients presenting with AJCC Stage Group 0, I, II, or III disease, who undergo surgical excision/resection of a primary breast tumor who undergo a needle biopsy to establish diagnosis of cancer preceding surgical excision/resection.

Numerator Statement: Patient whose date of needle biopsy precedes the date of surgery.

0221 Needle biopsy to establish diagnosis of cancer precedes surgical excision/resection

Denominator Statement: Women with AJCC Stage 0, I, II, or III breast cancer undergoing surgery:

- Women
- Age >=18 at time of diagnosis
- Known or assumed first or only cancer diagnosis
- Primary tumors of the breast
- Epithelial invasive malignancy only
- Surgically treated
- Diagnosis and all or part of first course of treatment performed at the reporting facility

Exclusions: Exclusions:

Men; not a first or only cancer diagnosis; non-epithelial tumors; metastatic disease (AJCC Stage IV); not treated surgically; died before surgery

Adjustment/Stratification: No risk adjustment or risk stratification No stratification applied

Level of Analysis: Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry, Paper Records

Measure Steward: Commission on Cancer, American College of Surgeons

Steering Committee In-Person May 23-24, 2012

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

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-2; M-13; L-1; I-0; 1b. Performance Gap: H-3; M-12; L-1; I-0; 1c. Evidence: Y-14, N-1, I-1

Rationale:

- The Steering Committee agreed the measure focus represents an area of high impact given the prevalence of the disease and the benefit to patients of fewer surgical procedures.
- The evidence demonstrates similar accuracy of needle biopsy with open surgical biopsy in the diagnosis of breast cancer.
- There are demonstrated disparities in use of needle biopsy prior to excision, with variation in use dependent upon age, race/ethnicity, provider specialty training, etc.
- The measure is important for addressing continuity of care for the patient.

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-4; M-10; L-2; I-0; 2b. Validity: H-3; M-10; L-3; I-1

Rationale:

- The Steering Committee questioned why cytologic was not separated out from core needle biopsies in the measure.
 - The developer stated that the vast majority of biopsies are core needle; however, the cancer registry confounds these data sets so they cannot be separated out.
 - It was also noted that there are limitations to cytologic testing and it requires very experienced programs to perform this testing.
- The Steering Committee questioned whether the measure was dependent upon obtaining usable diagnostic tissue.
 - The developer clarified that performance of the procedure counts toward the numerator. The measure is not outcome dependent.
- Steering Committee members expressed concern that this technique is not available for use everywhere, given the equipment and training necessary to perform the procedure. In particular, the Steering Committee had concerns about the availability of the technique in rural settings.
 - The developer noted that in the current use of the measure by the Commission on Cancer only has 1 percent of facilities in rural areas, another 12 percent are in urban non metro areas. Of those, 80 percent of the facilities have diagnostic imaging available, and the remaining 20 percent have it available by referral.
- The Steering Committee raised concerns over the issue of attribution with referrals to outside providers for performance of the procedure.

0221 Needle biopsy to establish diagnosis of cancer precedes surgical excision/resection
<ul style="list-style-type: none"> ○ The developer clarified that the cancer registries track down the information on the referrals and can determine where the procedures take place. The developer also noted that the denominator specifies that only patients who have all or part of the first course of treatment at the reporting facility are to be counted in the measure. • The Steering Committee stated that reliability testing was sufficient. • The validity of the measure was well demonstrated.
<p>3. Usability: <u>H-4; M-10; L-2; I-0</u> <i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i> Rationale:</p> <ul style="list-style-type: none"> • The measure will be used in the American College of Surgeons Commission on Cancer starting in 2012. • The measure should be easily understood by the public and by healthcare providers.
<p>4. Feasibility: <u>H-3; M-10; L-3; I-0</u> <i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i> Rationale:</p> <ul style="list-style-type: none"> • All data elements are available in cancer registries.
Steering Committee Recommendation for Endorsement: <u>Y-12 ; N-4</u>
<p>Public and Member Comment Comments included:</p> <ul style="list-style-type: none"> • <u>Supportive comments for the measure.</u>

0391 Breast Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade
<p>Status: Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 31, 2008 Description: Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade. Numerator Statement: Reports that include the pT category, the pN category and the histologic grade Denominator Statement: All breast cancer resection pathology reports (excluding biopsies) Exclusions: Documentation of medical reason(s) for not including the pT category, the pN category or the histologic grade (eg; re-excision without residual tumor; non-carcinomas) Adjustment/Stratification: No risk adjustment or risk stratification No risk adjustment or risk stratification. We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected. Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team Type of Measure: Process Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry, Paper Records Measure Steward: American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) Other organizations: College of American Pathologists</p>
Steering Committee In-Person May 23-24, 2012
<p>1. Importance to Measure and Report: <u>The measure meets the Importance criteria.</u> (1a. High Impact; 1b. Performance Gap; 1c. Evidence) 1a. Impact: H-12; M-3; L-1; I-0; 1b. Performance Gap: H-9; M-5; L-1; I-1; 1c. Evidence: Y-14, N-2, I-0 Rationale:</p>

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

- The Steering Committee agreed the measure focus is high impact and is a useful and important piece of information when making therapeutic decisions about patients with breast cancer, as treatment is dependent upon staging.
- There is not demonstrated evidence that recording stage leads to improved outcomes; however, this can be reasonably inferred from the body of literature.
- The Steering Committee raised the concern that a single pathology report will not provide the physician with all of the information necessary diagnostic information. The information may be contained on several different reports, which weakens the outcome link.
- There is a demonstrated performance gap, with 32 percent of eligible reports missing at least one of the ten CAP-recommended breast cancer elements.

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-10; M-4; L-1; I-1; 2b. Validity: H-4; M-8; L-2; I-1

Rationale:

- The Steering Committee stated that the measure was clearly and precisely specified.
- Reliability testing was sufficient.
- The validity of the measure was well demonstrated.
- The Steering Committee stated that there is a need for integrated summary reports containing all available pathological information; if these become available, they should be incorporated in future iterations of the measure.
- The Steering Committee recommended that margin status and number of lymph nodes evaluated be captured in future iterations of the measure.

3. Usability: H-4; M-8; L-3; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

Rationale:

- The measure is currently in use in PQRS.
- The measure should be moderately understood by the public and by healthcare providers.

4. Feasibility: H-5; M-8; L-2; I-0

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- Steering Committee members questioned whether the information required by the measure would be found in an initial report or an integrated summary report. It was noted that as there are often many reports, it will be difficult for a provider to know which report contains the most significant pathology information.
 - The developer noted that reporting of the measure will be limited to what the pathologist has available-the pathologist may not have information demonstrating metastatic disease, which would not be included on the report.
- The Steering Committee noted that the data is generated during the processes of clinical care.

Steering Committee Recommendation for Endorsement: Y-12 ; N-2

Public and Member Comment

Comments included:

- Supportive comments for the measure.
- Concern that the measure assesses what is considered standard practice.

Developer Response:

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

- The developer noted that though this should be standard care, there is a documented gap in care, with 32 percent of eligible reports missing at least one of the ten CAP-recommended breast cancer elements.

Steering Committee Response:

- The Steering Committee agreed with the developer's response, which is consistent with discussions that occurred at the in-person meeting and on related conference calls.

0559 Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer.

Status: Maintenance, Original Endorsement: Mar 01, 2007, Most Recent Endorsement: Mar 01, 2007

Description: Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage T1c, or Stage II, or III, who's primary tumor is progesterone and estrogen receptor negative recommended for multiagent chemotherapy (considered or administered) within 4 months (120 days) of diagnosis.

Numerator Statement: Combination chemotherapy is considered or administered within 4 months (120 days) of the date of diagnosis

Denominator Statement: Women under the age of 70 with AJCC T1cN0M0, or Stage II or 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 malignancy only
- AJCC T1cN0M0, or Stage II or III
- Primary tumor is estrogen receptor negative and progesterone receptor negative
- All or part of first 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:

Men; Age <18 and >=70; not a first or only cancer diagnosis; non-epithelial and non-invasive tumors; tumor size <=1cm and AJCC pN=0; ERA unknown or positive; PRA unknown or positive; metastatic disease (AJCC Stage IV); not treated surgically; died within 4 months (120 days) of diagnosis

Adjustment/Stratification: No risk adjustment or risk stratification No stratification applied

Level of Analysis: Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry, Paper Records

Measure Steward: American College of Surgeons **Other organizations:** This measure was harmonized with measure development efforts coordinated between the American Society

Steering Committee In-Person May 23-24, 2012

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

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-8; M-8; L-1; I-0; 1b. Performance Gap: H-1; M-12; L-3; I-1; 1c. Evidence: Y-12, N-3, I-3

Rationale:

- The Steering Committee agreed the measure focus represents an area of high impact, with many women receiving a breast cancer diagnosis.
- Evidence supports the selected target age and includes RCTs
- There is a performance gap for this measure.
- Disparities are not well documented in this measure.

0559 Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer.

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-7; M-8; L-2; I-0; 2b. Validity: H-7; M-8; L-2; I-0

Rationale:

- The Steering Committee noted that the measure doesn't specify that the patient receive the gold standard for combination chemotherapy; as such, patients could be getting less mainstream combination chemotherapy and that would still count toward the numerator.
- The Steering Committee questioned how neoadjuvant chemotherapy is captured.
 - The developer clarified that the date of service of the chemotherapy and the clinical and pathological staging are all captured.
- The Steering Committee questioned what an acceptable performance rate for the measure is.
 - The developer stated that the target rate is 90 percent, knowing that there should be some flexibility. It was also noted that this measure captures consideration of or administration of combination chemotherapy, making it somewhat easier to achieve the numerator.
- The Steering Committee stated that reliability testing was sufficient.
- The validity of the measure was well demonstrated.
- The Steering Committee expressed a desire to see a more nuanced iteration of the measure in the future to capture whether the chemotherapy administered was appropriate.

3. Usability: H-6; M-6; L-5; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

Rationale:

- The measure is currently in use in the American College of Surgeons Commission on Cancer.
- The measure should be easily understood by the public and by healthcare providers.

4. Feasibility: H-3; M-9; L-5; I-0

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- All data elements are available in cancer registries.

Steering Committee Recommendation for Endorsement: Y-14 ; N-3

Public and Member Comment

Comments included:

- Supportive comments for the measure.

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

Status: Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 31, 2008

Description: 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

Numerator Statement: Patients who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12 month reporting period

Definition: Prescribed may include prescription given to the patient for tamoxifen or aromatase inhibitor (AI) at one or more

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

visits in the 12-month period OR patient already taking tamoxifen or aromatase inhibitor (AI) as documented in the current medication list.

Denominator Statement: All female patients aged 18 years and older with Stage IC through IIIC, estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer

Exclusions: 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)

Adjustment/Stratification: No risk adjustment or risk stratification None We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.

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

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Medical Records

Measure Steward: American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) **Other organizations:** This measure is jointly copyrighted by the AMA-PCPI, American Society of Clinical Oncology and Natio

Steering Committee In-Person May 23-24, 2012

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

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-10; M-1; L-0; I-0; 1b. Performance Gap: H-7; M-4; L-0; I-0; 1c. Evidence: Y-10, N-0, I-1

Rationale:

- The Steering Committee agreed the measure focus represents an area of high impact, with many women receiving a breast cancer diagnosis.
- The ASCO Quality Oncology Practice Initiative (QOPI) study demonstrated a performance rate of 93.9 percent; however, another study reported an 80 percent performance rate, so there is room for improvement.
- Disparities in measure performance for low income and minority patients were cited and were significant.
- The evidence presented is robust.

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-10; M-1; L-0; I-0; 2b. Validity: H-11; M-0; L-0; I-0

Rationale:

- The measure was clearly and precisely specified.
- The denominator exclusions are appropriate.
- The Steering Committee stated that reliability of the measure score was high.
- Validity was demonstrated.
- The Steering Committee recommended that in the future, compliance with hormonal therapy be captured through prescription data.

3. Usability: H-11; M-0; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

Rationale:

- The measure is currently in use in PQRS.
- The measure should be moderately understood by the public and by healthcare providers.

4. Feasibility: H-9; M-2; L-0; I-0

0387 Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
<i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i>
Rationale: <ul style="list-style-type: none"> The measure is feasible as it can be captured through electronic data. The Steering Committee noted that the data is generated during the processes of clinical care.
Steering Committee Recommendation for Endorsement: <u>Y-11 ; N-0</u>
Public and Member Comment Comments included: <ul style="list-style-type: none"> <u>Supportive comments for the measure.</u>

1857 Patients with breast cancer and negative or undocumented human epidermal growth factor receptor 2 (HER2) status who are spared treatment with trastuzumab
Status: New Submission
Description: Percentage of adult patients (aged 18 or over) with invasive breast cancer that is HER2/neu negative who are not administered trastuzumab
Numerator Statement: Trastuzumab not administered during the initial course of treatment
Denominator Statement: Adult women with AJCC stage I (T1c) – III breast cancer that is HER-2 negative or HER-2 undocumented/unknown
Exclusions: Patient transfer to practice after initiation of chemotherapy
Adjustment/Stratification: No risk adjustment or risk stratification n/a n/a
Level of Analysis: Clinician : Group/Practice, Clinician : Team
Type of Measure: Process
Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records
Measure Steward: American Society of Clinical Oncology
Steering Committee In-Person May 23-24, 2012
1. Importance to Measure and Report: <u>The measure meets the Importance criteria.</u> (1a. High Impact; 1b. Performance Gap; 1c. Evidence) 1a. Impact: H-9; M-3; L-4; I-0; 1b. Performance Gap: H-2; M-6; L-7; I-1; 1c. Evidence: Y-13, N-2, I-1 Rationale: <ul style="list-style-type: none"> Steering Committee members expressed concern with the presented performance gap showing concordance of 99 percent with the measure and questioned the opportunity for improvement. <ul style="list-style-type: none"> The developer stated that the participants on the measure are a self-selected group participating in the quality Oncology Practice Initiative and performance may be higher for this group. The developer also noted that several unpublished studies suggest overuse of trastuzumab. The Steering Committee questioned whether this intervention would happen without HER2 testing or with a negative HER2 result. <ul style="list-style-type: none"> The developer stated that this can and does happen, according to feedback from payers. The measure focus represents an area of high impact, with many women receiving a breast cancer diagnosis. Evidence supports the selected patient population, as trastuzumab is not indicated in women with HER2 negative disease.
2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria.</u>

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

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

2a. Reliability: H-6; M-7; L-3; I-0; 2b. Validity: H-4; M-8; L-4; I-0

Rationale:

- The Steering Committee stated that the measure was clearly and precisely specified.
- Reliability testing was sufficient.
- The validity of the measure was well demonstrated.
- The Steering Committee recommended that the developer revise the title of the measure to clarify the intent of the measure. The measure developer did so and received the Steering Committee’s approval.
- The Steering Committee suggested that future iterations of the measure capture:
 - whether patients are receiving the appropriate dose of hormonal therapy.
 - the appropriateness of hormonal therapy based upon menopausal state of the patient, and patient adherence to the hormonal therapy through prescription data.

3. Usability: H-5; M-8; L-3; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

Rationale:

- The measure is planned for use in public reporting.
- The measure should be moderately understood by the public and by healthcare providers.

4. Feasibility: H-6; M-6; L-4; I-0

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- The Steering Committee raised concerns that extraction of this data may be burdensome as it may require chart abstractions.
- Eventual use of this measure through EHRs will lessen this burden.

Steering Committee Recommendation for Endorsement: Y-9 ; N-7

Rationale:

- Steering Committee members expressed concern that several measures had high rates of performance, indicating a small gap in performance; however, the developer clarified that the performance gap data came from the American Society for Clinical Oncology’s Quality Oncology Practice Initiative (QOPI), which included self-selecting practices voluntarily reporting on measures. As such, the developer stated that it is likely that there is more variation in performance than was demonstrated through QOPI.
- The Steering Committee agreed with the developer that it is likely that there is variation in use of trastuzumab and in HER2 testing, given the self-selecting nature of the practices participating with QOPI. Taken in conjunction with several studies suggesting overuse of trastuzumab, the Steering Committee recommended the measure for endorsement.

Public and Member Comment

Comments included:

- A recommendation that references to the specific therapy, trastuzumab, be changed to “FDA-approved HER2 therapy.”
- A recommendation against endorsement of the measure due to limited utility in improving quality, citing a 2009 study where 98 percent of patients had HER2 testing and 100 percent of patients receiving trastuzumab had documented HER2 testing prior to receiving trastuzumab.
- A recommendation that a HER2 composite measure be developed, comprised of measures 1857, 1855, 1858, and 1878.

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

Developer Response:

- The developer stated that the measure is reviewed and, if necessary, updated every six months. If an alternate therapy is approved and considered appropriate for inclusion in this measure, the measure will be updated.
- The developer stated that the preponderance of available data suggest room for improvement. The developer noted that oncologists need to know the result of HER2 testing that was accomplished prior to oncologist engagement. HER2 status should be captured in a way that can be located/retrieved from the medical record. The developer stated that given the large numbers of women affected, modest improvements can have a significant national impact. Lastly, the developer noted that if ongoing use of this measure - or the underuse of trastuzumab measure - reveals in future years that no quality gap exists, ASCO will retire the measure.
- The developer stated that ASCO and CAP, the developers of the referenced measures, have discussed the concept of a composite measure, and neither organization believes that it is advantageous at this time. These measures are designed for different providers and levels of accountability, and have different denominators. Measure 1855 was developed to measure the performance of individual pathologists, while measures 1857, 1858, and 1878 are for medical oncologists/clinical oncology practices. It may be beneficial to implement all of these measures within certain settings, such as accountable care organizations or Cancer Care Centers. ASCO reports measures 1857, 1858, and 1878 together in their quality programs; however, they believe that the measures are independently useful. The developer will consider paired or composite measures in the future.

Steering Committee Response:

- The Steering Committee agreed with the developer's response, which is consistent with discussions that occurred at the in-person meeting and on related conference calls.
- The Steering Committee noted that currently the evidence demonstrates that trastuzumab is the appropriate therapy for HER2 positive patients and is an inappropriate therapy for HER2 negative patients; as such, it should be explicitly named in the measure. The Steering Committee noted that as ASCO has a review system in place for updating the measure as the evidence evolves, the measure should remain unchanged at this time.
- The Steering Committee agreed that as the measures are currently specified for different levels of analysis, a composite measure would not be feasible. Further, the Steering Committee agreed that the measures capture discrete steps in care.

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

Status: New Submission **Time-limited**

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 ASCO/CAP guidelines.

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 *

Denominator Statement: All breast cancer patients with quantitative breast tumor evaluation by HER2 IHC
ICD-9 diagnosis codes for breast cancer: 174.0, 174.1, 174.2, 174.3, 174.4, 174.5, 174.6, 174.7, 174.8, 174.9, 175.0, 175.9
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.")

Exclusions: None

1855 Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines
Adjustment/Stratification: No risk adjustment or risk stratification Not applicable Not applicable
Level of Analysis: Clinician : Group/Practice, Clinician : Individual
Type of Measure: Process
Data Source: Administrative claims, Other, Paper Records
Measure Steward: College of American Pathologists
Steering Committee In-Person May 23-24, 2012
<p>1. Importance to Measure and Report: <u>The measure meets the Importance criteria.</u> (1a. High Impact; 1b. Performance Gap; 1c. Evidence) 1a. Impact: H-11; M-4; L-1; I-0; 1b. Performance Gap: H-5; M-11; L-0; I-0; 1c. Evidence: Y-14, N-2, I-0 Rationale:</p> <ul style="list-style-type: none"> • The Steering Committee agreed high quality evidence was presented. • The measure is high impact and is a useful and important piece of information when making therapeutic decisions about patients with breast cancer. • The measure is supported by the ASCO/CAP guidelines, and the quantity, quality and consistency of the evidence was sufficient. • Regarding the performance gap, the Steering Committee noted that the FDA indications differ from the ASCO/CAP guidelines. Committee members noted ASCO/CAP guidelines currently require that 30 percent of the cells subjected to ImmunoHistoChemistry testing (IHC) test positive; if less than that, fluorescence in situ hybridization (FISH) testing is recommended. It was noted that this may be a reason for the current performance gap, with only 84 percent of laboratories meeting the measure. • The Steering Committee noted that the current version of the ASCO/CAP scoring system will be updated in 2012. <ul style="list-style-type: none"> ○ The developer clarified that the cited guideline does not specify which version of the ASCO/CAP scoring system is to be used. It simply requires use of the ASCO/CAP scoring system, so if the scoring system changes, the measure will still be accurate.
<p>2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability requirement for untested measures.</u> (2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity) Precise Specifications: Y-15; N-0 Rationale:</p> <ul style="list-style-type: none"> • The measure is eligible for time limited endorsement, as reliability and validity testing have yet to be undertaken. • The Steering Committee stated that the measure was clearly and precisely specified. • The Steering Committee recommended that future iterations of the measure capture accuracy of the tests at a facility level (laboratories). This will address whether laboratories are compliant with the ASCO/CAP guideline.
<p>3. Usability: <u>H-6; M-5; L-2; I-2</u> <i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i> Rationale:</p> <ul style="list-style-type: none"> • The measure is planned for use in PQRS 2012. • The measure should be moderately understood by the public and by healthcare providers.
<p>4. Feasibility: <u>H-4; M-11; L-1; I-0</u> <i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i> Rationale:</p> <ul style="list-style-type: none"> • The Steering Committee raised concerns that extraction of this data may be burdensome as it may require chart abstractions. • Eventual use of this measure through EHRs will lessen this burden.
Steering Committee Recommendation for Endorsement: <u>Y-15 ; N-1</u>

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

Public and Member Comments

Comments included:

- Supportive comments for the measure.
- A recommendation that a HER2 composite measure be developed, comprised of measures 1857, 1855, 1858, and 1878.

Developer Response:

- The developer stated that ASCO and CAP, the developers of the referenced measures, have discussed the concept of a composite measure, and neither organization believes that it is advantageous at this time. These measures are designed for different providers and levels of accountability, and have different denominators. Measure 1855 was developed to measure the performance of individual pathologists, while measures 1857, 1858, and 1878 are for medical oncologists/clinical oncology practices. It may be beneficial to implement all of these measures within certain settings, such as -accountable care organizations or Cancer Care Centers.

Steering Committee Response:

- The Steering Committee agreed with the developer's response, which is consistent with discussions that occurred at the in-person meeting and on related conference calls.
- The Steering Committee agreed that as the measures are currently specified for different levels of analysis, a composite measure would not be feasible. Further, the Steering Committee agreed that the measures capture discrete steps in care.

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

Status: New Submission

Description: Percentage of adult patients (aged 18 or over) with invasive breast cancer that is HER2/neu positive who are administered trastuzumab

Numerator Statement: Trastuzumab administered within 12 months of diagnosis

Denominator Statement: Adult women with AJCC stage I (T1c) –III, HER2/neu positive breast cancer who receive chemotherapy

- Exclusions:**
- Patient history of metastatic cancer
 - Multiple primaries prior to or within the measurement period
 - Patient metastatic at diagnosis
 - Patient transfer to practice after initiation of chemotherapy
 - Patient still receiving anthracycline-based chemotherapy
 - Patient declined
 - Patient died or transferred within 12 months of diagnosis
 - Contraindication or other clinical exclusion

Adjustment/Stratification: No risk adjustment or risk stratification n/a n/a

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

Type of Measure: Process

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

Measure Steward: American Society of Clinical Oncology

Steering Committee In-Person May 23-24, 2012

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

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-14; M-2; L-0; I-0; **1b. Performance Gap:** H-3; M-9; L-2; I-2; **1c. Evidence:** Y-15, N-0, I-1

Rationale:

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

- The Steering Committee agreed high quality evidence was presented.
- Steering Committee members expressed concern with the presented performance gap showing concordance of 97 percent with the measure and questioned the opportunity for improvement.
 - The developer stated that the participants on the measure are a self-selected group participating in the Quality Oncology Practice Initiative and performance may be higher for this group.
- The Steering Committee questioned whether this intervention would happen without HER2 testing or with a negative HER2 result.
 - The developer stated that this can and does happen, according to feedback from payers.
- The measure focus represents an area of high impact, with many women being diagnosed with breast cancer.
- Evidence supports the selected patient population, as trastuzumab is only indicated in women with HER2 positive disease.

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-6; M-8; L-2; I-0; 2b. Validity: H-5; M-7; L-4; I-0

Rationale:

- In a workgroup call prior to the in-person meeting, the Steering Committee asked the developer to clarify that trastuzumab should be administered within one year of diagnosis.
 - The developer had made this change.
- The Steering Committee was raised concerns about a possible cardiac exclusion, as trastuzumab can cause cardiac toxicity.
 - The developer noted that “contraindication or other clinical exclusion” is listed as exclusion to the denominator and would cover a cardiac exclusion.
- The measure was clearly and precisely specified.
- Reliability testing was sufficient.
- The validity of the measure was well demonstrated.
- The Steering Committee suggested the developer revise the title of the measure to clarify the intent of the measure. The measure developer did so and received the Steering Committee’s approval.

3. Usability: H-4; M-8; L-4; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

Rationale:

- The measure is planned for use in public reporting.
- The measure should be moderately understood by the public and by healthcare providers.

4. Feasibility: H-5; M-9; L-1; I-1

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- The Steering Committee raised concerns that extraction of this data may be burdensome as it may require chart abstractions.
- Eventual abstraction of this measure through EHRs will lessen this burden.

Steering Committee Recommendation for Endorsement: Y-13 ; N-3

Rationale:

- Steering Committee members expressed concern that several measures had high rates of performance, indicating a small gap in performance; however, the developer clarified that the performance gap data came from the American Society for Clinical Oncology’s Quality Oncology Practice Initiative (QOPI), which included self-selecting practices voluntarily reporting on measures. As such, the developer stated that it is likely that there is more variation in performance than was demonstrated through QOPI.

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

- The Steering Committee agreed with the developer that it is likely that there is variation in use of trastuzumab and in HER2 testing, given the self-selecting nature of the practices participating with QOPI. Taken in conjunction with several studies suggesting overuse of trastuzumab, the Steering Committee recommended the measure for endorsement.

Public and Member Comment

Comments included:

- A recommendation that references to the specific therapy, trastuzumab, be changed to “FDA-approved HER2 therapy.”
- A recommendation that a HER2 composite measure be developed, comprised of measures 1857, 1855, 1858, and 1878.

Developer Response:

- The developer stated that the measure is reviewed and, if necessary, updated every six months. If an alternate therapy is approved and considered appropriate for inclusion in this measure, the measure will be updated.
- The developer stated that ASCO and CAP, the developers of the referenced measures, have discussed the concept of a composite measure, and neither organization believes that it is advantageous at this time. These measures are designed for different providers and levels of accountability, and have different denominators. Measure 1855 was developed to measure the performance of individual pathologists, while measures 1857, 1858, and 1878 are for medical oncologists/clinical oncology practices. It may be beneficial to implement all of these measures within certain settings, such as -accountable care organizations or Cancer Care Centers. ASCO reports measures 1857, 1858, and 1878 together in their quality programs; however, they believe that the measures are independently useful. The developer will consider paired or composite measures in the future.

Steering Committee Response:

- The Steering Committee agreed with the developer’s response, which is consistent with discussions that occurred at the in-person meeting and on related conference calls.
- The Steering Committee noted that currently the evidence demonstrates that trastuzumab is the appropriate therapy for HER2 positive patients and is an inappropriate therapy for HER2 negative patients; as such, it should be explicitly named in the measure. The Steering Committee noted that as ASCO has a review system in place for updating the measure as the evidence evolves, the measure should remain unchanged.
- The Steering Committee agreed that as the measures are currently specified for different levels of analysis, a composite measure would not be feasible. Further, the Steering Committee agreed that the measures capture discrete steps in care.

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

Status: New Submission

Description: Percentage of adult patients (aged 18 or over) with invasive breast cancer who receive human epidermal growth factor receptor 2 (HER2) testing

Numerator Statement: HER2/neu testing performed

Denominator Statement: Adult women with invasive breast cancer

Exclusions: Patient history of metastatic cancer

Multiple primaries prior to or within the measurement period

Adjustment/Stratification: No risk adjustment or risk stratification n/a n/a

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

Type of Measure: Process

1878 Human epidermal growth factor receptor 2 (HER2) testing in breast cancer
Data Source: Electronic Clinical Data : Electronic Health Record, Paper Medical Records Measure Steward: American Society of Clinical Oncology
Steering Committee In-Person May 23-24, 2012
<p>1. Importance to Measure and Report: <u>The measure meets the Importance criteria.</u> (1a. High Impact; 1b. Performance Gap; 1c. Evidence) 1a. Impact: H-13; M-3; L-0; I-0; 1b. Performance Gap: H-4; M-7; L-4; I-1; 1c. Evidence: Y-16, N-0, I-0</p> <p>Rationale:</p> <ul style="list-style-type: none"> • The Steering Committee agreed high quality evidence was presented. • Steering Committee members expressed concern with the presented performance gap stating concordance of 98 percent with the measure and questioned the opportunity for improvement. <ul style="list-style-type: none"> ○ The developer noted that the participants on the measure are a self-selected group participating in the Quality Oncology Practice Initiative and performance may be higher for this group; there is likely greater variation in practice outside this group. • The measure focus represents an area of high impact, with many women receiving a breast cancer diagnosis. • The Steering Committee noted that HER2 testing is both prognostic and predictive of patient response to treatment therapies.
<p>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-10; M-6; L-0; I-0; 2b. Validity: H-9; M-6; L-1; I-0</p> <p>Rationale:</p> <ul style="list-style-type: none"> • Steering Committee members questioned whether patients with small tumor sizes should be excluded from the measure. <ul style="list-style-type: none"> ○ The developer noted that insufficient sample size, as would result from a small tumor size, is included as a data element within the numerator. Further, the workgroup members agreed that an explicit exclusion of small tumor sizes may wrongly imply that HER2 testing on them is not necessary. • The measure was clearly and precisely specified. • Reliability testing was sufficient. • The validity of the measure was well demonstrated.
<p>3. Usability: <u>H-7; M-8; L-1; I-0</u> (<i>Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement</i>)</p> <p>Rationale:</p> <ul style="list-style-type: none"> • The measure is planned for use in public reporting. • The measure should be moderately understood by the public and by healthcare providers.
<p>4. Feasibility: <u>H-10; M-5; L-1; I-0</u> (<i>4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented</i>)</p> <p>Rationale:</p> <ul style="list-style-type: none"> • The Steering Committee raised concerns that extraction of this data may be burdensome as it may require chart abstractions. • Eventual abstraction of this measure through EHRs will lessen this burden.
<p>Steering Committee Recommendation for Endorsement: <u>Y-15 ; N-1</u></p> <p>Rationale:</p> <ul style="list-style-type: none"> • Steering Committee members expressed concern that several measures had high rates of performance, indicating a small gap in performance; however, the developer clarified that the performance gap data came from the American Society for Clinical Oncology’s Quality Oncology Practice Initiative (QOPI), which included self-selecting practices voluntarily reporting on measures. As such, the developer stated that it is likely that there is more variation in performance than was demonstrated through QOPI.

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

- The Steering Committee agreed with the developer that it is likely that there is variation in use of trastuzumab and in HER2 testing, given the self-selecting nature of the practices participating with QOPI. Taken in conjunction with several studies suggesting overuse of trastuzumab, the Steering Committee recommended the measure for endorsement.

Public and Member Comment

Comments included:

- A recommendation that a HER2 composite measure be developed, comprised of measures 1857, 1855, 1858, and 1878.
- A recommendation that exclusion of de novo patients from testing to determine HER2 status be removed.

Developer Response:

- The developer stated that ASCO and CAP, the developers of the referenced measures, have discussed the concept of a composite measure, and neither organization believes that it is advantageous at this time. These measures are designed for different providers and levels of accountability, and have different denominators. Measure 1855 was developed to measure the performance of individual pathologists, while measures 1857, 1858, and 1878 are for medical oncologists/clinical oncology practices. It may be beneficial to implement all of these measures within certain settings, such as -accountable care organizations or Cancer Care Centers. ASCO reports measures 1857, 1858, and 1878 together in their quality programs; however, they believe that the measures are independently useful. The developer will consider paired or composite measures in the future.
- The developer stated that the measure does not recommend against testing among patients who are excluded from the denominator (patients with metastatic disease or multiple primaries prior to or within the measurement period). Future development work could consider measurement to address HER2 re-testing, if supported sufficiently by evidence and if feasibility/burden were considered appropriate.

Steering Committee Response:

- The Steering Committee agreed with the developer's response, which is consistent with discussions that occurred at the in-person meeting and on related conference calls.
- The Steering Committee agreed that as the measures are currently specified for different levels of analysis, a composite measure would not be feasible. Further, the Steering Committee agreed that the measures capture discrete steps in care.

MEASURES WHERE CONSENSUS NOT YET REACHED

BREAST CANCER MEASURES

0031 Breast Cancer Screening

Status: Maintenance, Original Endorsement: Aug 10, 2009, Most Recent Endorsement: May 24, 2012

Description: Percentage of women 40-69 years of age who had a mammogram to screen for breast cancer

Numerator Statement: One or more mammograms during the measurement year or the year prior to the measurement year

Denominator Statement: Women 42-69 years of age as of Dec 31 of the measurement year (note: this denominator statement captures women age 40-69 years)

Exclusions: Exclusion: Women who had a bilateral mastectomy or for whom there is evidence of two unilateral mastectomies. Look for evidence of a bilateral mastectomy as far back as possible in the member's history through Dec 31 of the measurement year.

Adjustment/Stratification: No risk adjustment or risk stratification - NA None

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Health Plan, Population : State

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record

Measure Steward: National Committee for Quality Assurance

Steering Committee In Person May 23-24, 2012

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

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-8; M-2; L-0; I-1; 1b. Performance Gap: H-4; M-4; L-2; I-1; 1c. Evidence: Y-2, N-1, I-8

Rationale:

- The Steering Committee agreed the measure focus represents an area of high impact; breast cancer is a leading cause of cancer deaths.
- Data presented showed variability in performance rate particularly in the public plan for lower income Medicaid plans, which have a somewhat significantly lower rate at 52 percent compared to Medicare and commercial plans; commercial plans are only at a 71 percent performance rate.
- Disparities data presented show some room for improvement.
- The Steering Committee was concerned that currently there are differences in national guidelines regarding the age at which breast cancer screening should begin.
 - The Steering Committee stated that screening should be a shared decision between patients and providers.
 - The Steering Committee noted that many commercial plans use the USPSTF guidelines (screenings begin at age 50); however, HHS was instructed to disregard the USPSTF guideline. This adds to the confusion.
 - The developer noted that this could possibly be addressed by stratifying the reporting by age group.
 - The developer stated that this measure is being reevaluated this summer, but the finalization of the measure won't be complete until the summer of 2013.
 - The developer stated that most oncology societies are endorsing biennial mammograms beginning at age 40, which is in line with this measure.

The Steering Committee was concerned that the inclusion of the 40 to 50 year old patient population in the measure may distract from the importance of the intervention for the 50 to 70 year old patient population, where there is clear consensus that the screening intervention is warranted and the median age of breast cancer is 65.

- The Steering Committee moved to vote on all criteria for the measure even though it did not meet subcriteria 1c. Evidence for Importance to Measure and Report. The Steering Committee acknowledged that the measure focus is important and the intervention is crucial for many patients in this patient population. Steering Committee concern with the evidence for the measure focused solely on the disparities between guideline recommendations for the age when mammography screening should begin. The Steering Committee wanted to seek input from the NQF members and the public as to what patient population should be captured by this measure.

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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 6; M 3; L 0; I 2; 2b. Validity: H 0; M 6; L 2; I 3	
Rationale:	
<ul style="list-style-type: none"> • The Steering Committee agreed the measure is reliable. • The validity is an issue with respect to the age captured by the measure. The Committee was concerned that if providers are following different guidelines, the measure may not be a valid representation of the quality of care. 	
3. Usability: H 2; M 5; L 2; I 2 (Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)	
Rationale:	
<ul style="list-style-type: none"> • The measure is in use in the Healthcare Effectiveness Data and Information Set (HEDIS). • The measure is easily understood by the public, although there is some concern that there may be confusion because the measure includes age ranges that differ from the USPSTF recommendation. 	
4. Feasibility: H 9; M 2; L 0; I 0 (4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/unintended consequences identified 4d. Data collection strategy can be implemented)	
Rationale:	
<ul style="list-style-type: none"> • The measure is in the HEDIS measure set and would be captured easily. 	
Steering Committee Recommendation for Endorsement: Y 2; N 9	
The Steering Committee requests NQF Member and Public comment on this measure.	
Rationale:	
<ul style="list-style-type: none"> • The measure is high impact and a significant performance gap has been demonstrated. It is not clear which guidelines the measure should be conformed to, but the Steering Committee feels the intervention is very important. • The measure did not pass subcriteria 1c. Evidence for Importance to Measure and Report. The Steering Committee acknowledged that the measure focus is important and the intervention is crucial for many patients in this patient population. Steering Committee concern with the evidence for the measure focused solely on the disparities between guideline recommendations for the age when mammography screening should begin. • The measure passed all other major criteria for NQF endorsement. 	
Public and Member Comment	
Comments included:	
<ul style="list-style-type: none"> • While there were relatively few comments on this measure, some were supportive of the measure as specified, while another expressed concern that the measure was not consistent with the U.S. Preventive Services Task Force (USPSTF) cancer screening guidelines. • One commenter suggested that the measure might be stratified by women aged 40 to 49, and women aged 50 and older as a way to address concerns about conflicting guideline recommendations regarding the appropriate age to begin biennial screening mammograms. 	
Developer Response:	
<ul style="list-style-type: none"> • The developer stated that NCQA currently is re-evaluating this measure under its HEDIS measures process. Per this process, they are obtaining feedback from multiple stakeholder groups, including breast cancer experts, practicing physicians, consumers and health plans. The developer is working to understand how the measure can best represent the full picture of evidence-based guidelines, as the current U.S. Preventives Services Task Force guideline 	

0031 Breast Cancer Screening

recommends biennial screening for women aged 50 to 74, noting that screening before age 50 should be an individual decision that takes into account patient context and values. The developer is cognizant that many organizations currently recommend screening begin at age 40. One option the developer is exploring is to stratify the measure by age. Per the measure developer's process changes to the measure, including stratification by age, would be made available for public comment in spring of 2013.

The developer stated that many professional organizations, including American Congress of Obstetricians and Gynecologists, American Cancer Society, American College of Radiology, American Society of Breast Surgeons, and the Society of Breast Imaging recommend biennial mammography screening for women aged 40 to 49.

Steering Committee Response:

Steering Committee members stated that there is incontrovertible evidence regarding the utility of this measure for women aged 50 to 74; however, at present the benefits for women aged 40 to 49 are unclear.

The Steering Committee stated that quality measures are perceived by providers and patients to be supported by consistent, high-level evidence demonstrating that the focus of the measure is recommended, quality care.

The Steering Committee noted that there is a difference between a quality metric and good clinical practice. Though many providers still recommend biennial screening for women aged 40 to 49, quality metrics should be based on high-level evidence rather than the current state of clinical care.

The Steering Committee raised concerns that stratification of the measure by women aged 40 to 49, and 50 to 74, would not address the issue of conflicting evidence. Stratifying the measure will result in the reported measure data on women aged 40 to 49 not being meaningful, and users of the measure will be unclear as to how to use the data. Steering Committee members suggested that two separate measures addressing these age groups may be the most appropriate action to take, as guidelines indicate that providers for women aged 40 to 49 need to take into account variables such as the patient's family history and preferences for screening.

The developer responded that stratifying the measure would allow programs to choose how to implement the measure, allowing the programs to use the measure for patients aged 50 to 74 for accountability or public reporting purposes while still tracking mammography screening in patients aged 40 to 49.

The developer stated that this is a long-standing measure currently used in HEDIS. It will continue to be used in HEDIS while modifications to the measure are being made. These modifications may include stratification by age; however, the developer was unsure that this would be the final outcome. The developer stated that an expert group will be convened to modify the measure in Fall 2012; the modifications will be posted for public comment in early 2013. The modifications to the measure will be finalized in Spring 2013.

NQF staff noted that after the measure is finalized by NCQA it may be reviewed in a project focusing on Cancer scheduled for 2014; they will also look for opportunities for the measure to be reviewed earlier in a different project if possible.

Taking into consideration the information presented on the follow-up conference call, Steering Committee members re-voted on the measure. The voting results are presented below:

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

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H ; M ; L ; I ; 1b. Performance Gap: H ; M ; L ; I ; 1c. Evidence: Y ; N ; I

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 ; M ; L ; I ; 2b. Validity: H ; M ; L ; I

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3. Usability: H ; M ; L ; I

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

4. Feasibility: H ; M ; L ; I

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Steering Committee Recommendation for Endorsement: Y ; N-

MEASURES NOT RECOMMENDED

BREAST CANCER MEASURES

0031 Breast Cancer Screening

Status: Maintenance, Original Endorsement: Aug 10, 2009, Most Recent Endorsement: May 24, 2012

Description: Percentage of women 40-69 years of age who had a mammogram to screen for breast cancer

Numerator Statement: One or more mammograms during the measurement year or the year prior to the measurement year

Denominator Statement: Women 42–69 years of age as of Dec 31 of the measurement year (note: this denominator statement captures women age 40-69 years)

Exclusions: Exclusion: Women who had a bilateral mastectomy or for whom there is evidence of two unilateral mastectomies. Look for evidence of a bilateral mastectomy as far back as possible in the member's history through Dec 31 of the measurement year.

Adjustment/Stratification: No risk adjustment or risk stratification NA None

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Health Plan, Population : State

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record

Measure Steward: National Committee for Quality Assurance

Steering Committee In-Person May 23-24, 2012

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

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-8; M-2; L-0; I-1; 1b. Performance Gap: H-4; M-4; L-2; I-1; 1c. Evidence: Y-2, N-1, I-8

Rationale:

- The Steering Committee agreed the measure focus represents an area of high impact; breast cancer is a leading cause of cancer deaths.
- Data presented showed variability in performance rate particularly in the public plan for lower-income Medicaid plans, which have a somewhat significantly lower rate at 52 percent compared to Medicare and commercial plans; commercial plans are only at a 71 percent performance rate.
- Disparities data presented show some room for improvement.
- The Steering Committee was concerned that currently there are differences in national guidelines regarding the age at which breast cancer screening should begin.
 - The Steering Committee stated that screening should be a shared decision between patients and providers.
 - The Steering Committee noted that many commercial plans use the USPSTF guidelines (screenings begin at age 50).
 - The developer noted that this could possibly be addressed by stratifying the reporting by age group.
 - The developer stated that this measure is being reevaluated this summer, but the finalization of the measure won't be complete until the summer of 2013.
 - The developer stated that most oncology societies are endorsing biennial mammograms beginning at age 40, which is in line with this measure.

The Steering Committee was concerned that the inclusion of the 40 to 50 year old patient population in the measure may distract from the importance of the intervention for the 50 to 70 year old patient population, where there is clear consensus that the screening intervention is warranted and the median age of breast cancer is 65.

- The Steering Committee moved to vote on all criteria for the measure even though it did not meet subcriteria 1c. Evidence for Importance to Measure and Report. The Steering Committee acknowledged that the measure focus is important and the intervention is crucial for many patients in this patient population. Steering Committee concern with the evidence for the measure focused solely on the disparities between guideline recommendations for the age when mammography screening should begin. The Steering Committee wanted to seek input from the NQF members and the public as to what patient population should be captured by this measure.

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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-6; M-3; L-0; I-2; 2b. Validity: H-0; M-6; L-2; I-3	
Rationale:	
<ul style="list-style-type: none"> The Steering Committee agreed the measure is reliable. The validity is an issue with respect to the age captured by the measure. The Committee was concerned that if providers are following different guidelines, the measure may not be a valid representation of the quality of care. 	
3. Usability: H-2; M-5; L-2; I-2 (Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)	
Rationale:	
<ul style="list-style-type: none"> The measure is in use in the Healthcare Effectiveness Data and Information Set (HEDIS). The measure is easily understood by the public, although there is some concern that there may be confusion because the measure includes age ranges that differ from the USPSTF recommendation. 	
4. Feasibility: H-9; M-2; L-0; I-0 (4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)	
Rationale:	
<ul style="list-style-type: none"> The measure is in the HEDIS measure set and would be captured easily. 	
Steering Committee Recommendation for Endorsement: Y-2 ; N-9	
The Steering Committee requests NQF Member and Public comment on this measure.	
Rationale:	
<ul style="list-style-type: none"> The measure is high impact and a significant performance gap has been demonstrated. It is not clear which guidelines the measure should be conformed to, but the Steering Committee feels the intervention is very important. The measure did not pass subcriteria 1c. Evidence for Importance to Measure and Report. The Steering Committee acknowledged that the measure focus is important and the intervention is crucial for many patients in this patient population. Steering Committee concern with the evidence for the measure focused solely on the disparities between guideline recommendations for the age when mammography screening should begin. The measure passed all other major criteria for NQF endorsement. 	
Public and Member Comment	
Comments included:	
<ul style="list-style-type: none"> While there were relatively few comments on this measure, some were supportive of the measure as specified, while another expressed concern that the measure was not consistent with the U.S. Preventive Services Task Force (USPSTF) cancer screening guidelines. One commenter suggested that the measure might be stratified by women aged 40 to 49, and women aged 50 and older as a way to address concerns about conflicting guideline recommendations regarding the appropriate age to begin biennial screening mammograms. 	
Developer Response:	
<ul style="list-style-type: none"> The developer stated that NCQA currently is re-evaluating this measure under its HEDIS measures process. Per this process, they are obtaining feedback from multiple stakeholder groups, including breast cancer experts, practicing physicians, consumers and health plans. The developer is working to understand how the measure can best represent the full picture of evidence-based guidelines, as the current U.S. Preventives Services Task Force guideline 	

0031 Breast Cancer Screening

recommends biennial screening for women aged 50 to 74, noting that screening before age 50 should be an individual decision that takes into account patient context and values. The developer is cognizant that many organizations currently recommend screening begin at age 40. One option the developer is exploring is to stratify the measure by age. Per the measure developer's process changes to the measure, including stratification by age, would be made available for public comment in spring of 2013.

- The developer stated that many professional organizations, including American Congress of Obstetricians and Gynecologists, American Cancer Society, American College of Radiology, American Society of Breast Surgeons, and the Society of Breast Imaging recommend biennial mammography screening for women aged 40 to 49.

Steering Committee Response:

- Steering Committee members stated that there is incontrovertible evidence regarding the utility of this measure for women aged 50 to 74; however, at present the benefits for women aged 40 to 49 are unclear.
- The Steering Committee agreed that quality measures must be supported by consistent, high-level evidence demonstrating that the focus of the measure is recommended, quality care. At present, there is conflicting evidence for which age range of women should receive biennial mammogram screenings. The Steering Committee stated concern that given the conflicting guidelines, it would be difficult to endorse this measure for use for accountability purposes.
- The Steering Committee noted that there is a difference between a quality measure and good clinical practice; though, many providers still recommend biennial screening for women aged 40 to 49, quality measures (particularly those used for accountability purposes) should be based on consistent evidence rather than the current state of clinical care.
- The Steering Committee raised concerns that stratification of the measure by age, 40 to 49 and 50 to 74, does not address the issue of conflicting evidence. Stratifying the measure will result in the reported measure data on women aged 40 to 49 not being meaningful, and users of the measure will be unclear as to how to use the data. Steering Committee measures suggested that two separate measures addressing these age groups may be the most appropriate action to take, as guidelines indicate that providers for women aged 40 to 49 need to take into account variables such as the patient's family history and preferences for screening.
 - The developer responded that stratifying the measure would allow programs to choose how to implement the measure, allowing the programs to use the measure for patients aged 50 to 74 for accountability or public reporting purposes while still tracking mammography screening in patients aged 40 to 49.
 - The developer stated that this is a long-standing measure currently used in HEDIS. It will continue to be used in HEDIS while modifications to the measure are being made. These modifications may include stratification by age; however, the developer was unsure that this would be the final outcome. The developer stated that an expert group will be convened to modify the measure in Fall 2012; the modifications will be posted for public comment in early 2013. The modifications to the measure will be finalized in Spring 2013.
 - NQF would be pleased to review the revised NCQA measure when it is finalized and an appropriate endorsement project is available.

Taking into consideration the information presented on the follow up conference call, Steering Committee members re-voted on the measure. The voting results are presented below:

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

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-9; M-4; L-1; I-1; 1b. Performance Gap: H-3; M-11; L-0; I-1; 1c. Evidence: Y-4; N-3; I-8

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-8; M-3; L-1; I-3; 2b. Validity: H-2; M-6; L-4; I-3

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3. Usability: H-4; M-9; L-1; I-1

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

4. Feasibility: H-6; M-5; L-2; I-2

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Steering Committee Recommendation for Endorsement: Y-2; N-13

The measure did not meet the Importance criteria. The Steering Committee did not recommend measure 0031 for endorsement.

0623 History of Breast Cancer - Cancer Surveillance

Status: Maintenance, Original Endorsement: Dec 04, 2009, Most Recent Endorsement: Sep 02, 2011

Description: The percentage of women with a history of breast cancer treated with curative intent who had breast cancer surveillance for local regional recurrence (LRR) annually.

Numerator Statement: Women with a history of breast cancer treated with curative intent who had surveillance for breast LRR annually.

Denominator Statement: Women with a history of non-metastatic invasive breast cancer who have been treated with curative intent more than one year ago.

Exclusions: 1. Bilateral mastectomy

2. Evidence of metastatic disease

3. Provider or patient feedback stating patient does not have a diagnosis of breast cancer

5. General exclusions:

a. Patients who have been in a skilled nursing facility in the past 3 months

b. Patients who are terminally ill

c. Active treatment of malignancy (chemotherapy or radiation therapy) in the last 6 months

Adjustment/Stratification: No risk adjustment or risk stratification. No risk adjustment is done with our measure, therefore, we do not have a risk model. This measure addresses all patients with a history of breast cancer who have been treated with curative intent. Using our highly specific algorithms, women with a history of breast cancer treated surgically are included in the denominator. This measure

Level of Analysis: Population : National

Type of Measure: Process

Data Source: Administrative claims, Healthcare Provider Survey, Patient Reported Data/Survey

Measure Steward: ActiveHealth Management

Steering Committee In-Person May 23-24, 2012

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

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-0; M-4; L-6; I-3; 1b. Performance Gap: H-1; M-4; L-1; I-7; 1c. Evidence: Y-0, N-7, I-6

Rationale:

- The evidence is unclear whether lumpectomy plus radiation therapy has led to the improved survival, rather than increased surveillance.
- The Steering Committee was concerned that the evidence does not demonstrate improved outcomes from this intervention. Data show the same rate of survival for patients who received surveillance and those who did not.

0623 History of Breast Cancer - Cancer Surveillance
<ul style="list-style-type: none"> ○ The developer stated that incidence of relapse free survival is not the same, and that early detection leads to salvage therapy. ○ The Steering Committee noted that local recurrence risks are in the low single digits, and the false positive rate is higher in this patient population. <ul style="list-style-type: none"> ● The vast majority of patients captured by this measure would be captured by other measures for mammography. ● Multiple data sets show that the breast conservation population has a poor prognosis with recurrence.
<p>2. Scientific Acceptability of Measure Properties: <u>N/A</u> (2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity) 2a. Reliability: H-; M-; L-; I-; 2b. Validity: H-; M-; L-; I- <u>Rationale:</u></p> <ul style="list-style-type: none"> ○
<p>3. Usability: <u>N/A</u> <i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i> <u>Rationale:</u></p>
<p>4. Feasibility: <u>N/A</u> <i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i> <u>Rationale:</u></p> <ul style="list-style-type: none"> ●
Steering Committee Recommendation for Endorsement: The measure failed the Importance criteria.
<p><u>Public and Member Comments</u> <u>Comments included:</u></p> <ul style="list-style-type: none"> ● <u>One supportive comment for the measure.</u>

MEASURES WITHDRAWN FROM CONSIDERATION

Three measures previously endorsed by NQF have not been re-submitted or have been withdrawn from consideration for endorsement maintenance. The following measures will be requested to have endorsement removed.

Measure	Reason for Withdrawal
0222 Patients with early stage breast cancer who have evaluation of the axilla	No measure steward
0224 Completeness of pathology reporting	Retirement of a maintenance measure
0572 Follow-up after initial diagnosis and treatment of colorectal cancer: colonoscopy	Retirement of a maintenance measure

NOTES

ⁱ U.S. Department of Health and Human Services (DHHS), National Institutes of Health (NIH), National Cancer Institute (NCI), Defining Cancer. Updated 07/12/2010. Bethesda, MD:NCI, 2010. Available at www.cancer.gov/cancertopics/cancerlibrary/what-is-cancer. Last accessed February 2011.

ⁱⁱ American Cancer Society. Cancer Facts & Figures 2010. Atlanta, GA. 2009. Last Medical Review: 05/20/2009. Last Revised: 05/20/2009. Available at <http://www.cancer.org/Research/CancerFactsFigures/CancerFactsFigures/cancer-facts-and-figures-2010>. Last accessed February 2011.

ⁱⁱⁱ Ibid. Available at <http://www.cancer.org/Research/CancerFactsFigures/CancerFactsFigures/cancer-facts-and-figures-2010>. Last accessed February 2011.

^{iv} McGlynn EA, Asch SM, Adams J, et al. The quality of health care delivered to adults in the United States. [see comment]. *New England Journal of Medicine*. 2003;348(26):2635-2645, and Harlan LC, Greene AL, Clegg LX, Mooney M, Stevens JL, Brown ML. Insurance status and the use of guideline therapy in the treatment of selected cancers. [see comment]. *Journal of Clinical Oncology*. 2005;23(36):9079-9088, as cited in National Quality Forum (NQF). *The Current State of Cancer Quality Measurement 2008: A White Paper*. Washington, DC: NQF; 2008.

^v Du XL, Lin CC, Johnson NJ et al., Effects of individual-level socioeconomic factors on racial disparities in cancer treatment and survival: findings from the National Longitudinal Mortality Study, 1979-2003, *Cancer*, 2011.

^{vi} Byers T, Two decades of declining cancer mortality: progress with disparity, *Annu Rev Public Health*, 2010;31:121-132.

^{vii} Sherr DL, Stessin AM, Demographic disparities in patterns of care and survival outcomes for patients with resected gastric adenocarcinoma. *Cancer Epidemiol Biomarkers Prev*. 2011 Mar;20(2):223-33.

^{viii} Slatore CG, Au DH, Gould MK; American Thoracic Society Disparities in Healthcare Group, An official American Thoracic Society systematic review: insurance status and disparities in lung cancer practices and outcomes. *Am J Respir Crit Care Med*. 2010 Nov 1;182(9):1195-205.

^{ix} Screening for Breast Cancer, Topic Page. July 2010. U.S. Preventive Services Task Force.

<http://www.uspreventiveservicestaskforce.org/uspstf/uspsbrca.htm>. Last accessed June 2012.

Appendix A: Measure Specifications

0219 Post breast conservation surgery irradiation	A-2
0220 Adjuvant hormonal therapy.....	A-3
0221 Needle biopsy to establish diagnosis of cancer precedes surgical excision/resection	A-4
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	A-5
0225 At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer.	A-6
0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients	A-7
0387 Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer	A-10
0391 Breast Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade.....	A-13
0392 Colorectal Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade.....	A-15
0559 Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer.	A-17
1855 Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines	A-18
1857 Patients with breast cancer and negative or undocumented human epidermal growth factor receptor 2 (HER2) status who are spared treatment with trastuzumab.....	A-20
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	A-22
1859 KRAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy.....	A-24
1860 Patients with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies.....	A-26
1878 Human epidermal growth factor receptor 2 (HER2) testing in breast cancer	A-27

	0219 Post breast conservation surgery irradiation
Status	Maintenance, Original Endorsement: Mar 01, 2007, Most Recent Endorsement: Mar 01, 2007
Steward	Commission on Cancer, American College of Surgeons Other organizations: This measure was harmonized with measure development efforts coordinated between the American Societ
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	Electronic Clinical Data : Registry, Paper Medical Records Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base URL http://www.naacr.org/StandardsandRegistryOperations/Volumell.aspx URL http://www.facs.org/cancer/coc/fordsmanual.html
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	Time Window: 1 year (365 days) 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 treatment by breast conservation surgery (surgical excision less than mastectomy) All or part of 1st course of treatment performed at the reporting facility Known to be alive within 1 year (365 days) of diagnosis
Denominator Details	Time Window: Typically a 12 month, calendar year, time period 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 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
Exclusion Details	See: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf

	0219 Post breast conservation surgery irradiation
Risk Adjustment	No risk adjustment or risk stratification
Stratification	No stratification applied
Type Score	Rate/proportion better quality = higher score
Algorithm	See: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf URL http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf
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	0220 Adjuvant hormonal therapy
Status	Maintenance, Original Endorsement: Mar 01, 2007, Most Recent Endorsement: Mar 01, 2007
Steward	Commission on Cancer, American College of Surgeons Other organizations: This measure was harmonized with measure development efforts coordinated between the American Society
Description	Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage I, II, or III, who's primary tumor is progesterone or estrogen receptor positive recommended for tamoxifen or third generation aromatase inhibitor (considered or administered) within 1 year (365 days) of diagnosis.
Type	Process
Data Source	Electronic Clinical Data : Registry, Paper Records Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base URL http://www.naaccr.org/StandardsandRegistryOperations/Volumell.aspx URL http://www.facs.org/cancer/coc/fordsmanual.html
Level	Facility
Setting	Hospital/Acute Care Facility
Numerator Statement	Hormone therapy is considered or administered within 1 year (365 days) of the date of diagnosis
Numerator Details	Time Window: 1 year (365 days) Hormone Therapy [NAACCR Item#1400]=82-87 OR; Hormone Therapy [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 T1c or Stage II or III Primary tumor is estrogen receptor positive or progesterone receptor positive All or part of 1st course of treatment performed at the reporting facility Known to be alive within 1 year (365 days) of date of diagnosis
Denominator Details	Time Window: Typically a 12 month, calendar year, time period Sex [NAACCR Item#220]=2; CS Tumor Size [NAACCR Item#2800]= 010 and AJCC pN [NAACCR Item#890]=0, OR AJCC pN [NAACCR Item#890]=1, 2, or 3; 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

0220 Adjuvant hormonal therapy	
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 Stage 0, in-situ tumor AJCC T1mic, T1a, or T1b 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
Exclusion Details	See: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf
Risk Adjustment	No risk adjustment or risk stratification
Stratification	No stratification applied
Type Score	Rate/proportion better quality = higher score
Algorithm	See: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf URL http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf
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0221 Needle biopsy to establish diagnosis of cancer precedes surgical excision/resection	
Status	Maintenance, Original Endorsement: Mar 01, 2007, Most Recent Endorsement: Mar 01, 2007
Steward	Commission on Cancer, American College of Surgeons
Description	Percentage of patients presenting with AJCC Stage Group 0, I, II, or III disease, who undergo surgical excision/resection of a primary breast tumor who undergo a needle biopsy to establish diagnosis of cancer preceding surgical excision/resection.
Type	Process
Data Source	Electronic Clinical Data : Registry, Paper Records Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base URL http://www.naaccr.org/StandardsandRegistryOperations/Volumell.aspx URL http://www.facs.org/cancer/coc/fordsmanual.html
Level	Facility
Setting	Hospital/Acute Care Facility
Numerator Statement	Patient whose date of needle biopsy precedes the date of surgery.
Numerator Details	Time Window: Prior to, but not including, the day of surgical treatment Surgical Diagnostic And Staging and Procedure [NAACCR Item#1350]=2; AND Date of Surgical Diagnostic And Staging and Procedure [NAACCR Item#1280] < Date of First Surgical Procedure [NAACCR Item#1200]
Denominator Statement	Women with AJCC Stage 0, I, II, or II breast cancer undergoing surgery: <ul style="list-style-type: none"> • Women • Age >=18 at time of diagnosis

0221 Needle biopsy to establish diagnosis of cancer precedes surgical excision/resection	
	<ul style="list-style-type: none"> • Known or assumed first or only cancer diagnosis • Primary tumors of the breast • Epithelial invasive malignancy only • Surgically treated • Diagnosis and all or part of first course of treatment performed at the reporting facility
Denominator Details	Time Window: Typically a 12 month, calendar year, time period Sex [NAACCR Item#220]=2; Pathologic Stage Group [NAACCR Item#910] = IA, IB, IIA, IIB, IIIA, IIIB or IIIC, AND Surgical Procedure of the Primary Site at This Facility [NAACCR Item#670] = 20–90
Exclusions	Exclusions: Men; not a first or only cancer diagnosis; non-epithelial tumors; metastatic disease (AJCC Stage IV); not treated surgically; died before surgery
Exclusion Details	See: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf
Risk Adjustment	No risk adjustment or risk stratification
Stratification	No stratification applied
Type Score	Rate/proportion better quality = higher score
Algorithm	See: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf URL See: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf
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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	
Status	Maintenance, Original Endorsement: Mar 01, 2007, Most Recent Endorsement: Mar 01, 2007
Steward	Commission on Cancer, American College of Surgeons Other organizations: This measure was harmonized with measure development efforts coordinated between the American Society
Description	Percentage of patients under the age of 80 with AJCC III (lymph node positive) colon cancer for whom adjuvant chemotherapy is considered or administered within 4 months (120 days) of diagnosis.
Type	Process
Data Source	Electronic Clinical Data : Registry, Paper Records Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base URL http://www.naacr.org/StandardsandRegistryOperations/Volumell.aspx URL http://www.facs.org/cancer/coc/fordsmanual.html
Level	Facility
Setting	Hospital/Acute Care Facility
Numerator Statement	Chemotherapy is considered or administered within 4 months (120 days) of diagnosis
Numerator Details	Time Window: 4 months (120 days) Chemotherapy [NAACCR Item#1390]=82-87 OR; Chemotherapy [NAACCR Item#1390]=3, and Date Chemotherapy Started (NAACCR Item#1220) <=120 days following Date of Diagnosis [NAACCR Item# 340]
Denominator	Include, if all of the following characteristics are identified:

	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
r Statement	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 ² Known to be alive within 4 months (120 days) of diagnosis
Denominator Details	Time Window: Typically a 12 month, calendar year, time period Age at Diagnosis [NAACCR Item#230] < 80, 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
Exclusion Details	See: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf
Risk Adjustment	No risk adjustment or risk stratification
Stratification	No stratification applied
Type Score	Rate/proportion better quality = higher score
Algorithm	See: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf URL http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf
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	0225 At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer.
Status	Maintenance, Original Endorsement: Mar 01, 2007, Most Recent Endorsement: Mar 01, 2007
Steward	Commission on Cancer, American College of Surgeons
Description	Percentage of patients >18yrs of age, who have primary colon tumors (epithelial malignancies only), experiencing their first diagnosis, 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	Electronic Clinical Data : Registry, Paper Records Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base URL http://www.naaccr.org/StandardsandRegistryOperations/Volumell.aspx URL http://www.facs.org/cancer/coc/fordsmanual.html
Level	Facility
Setting	Hospital/Acute Care Facility
Numerator Statement	>=12 regional lymph nodes pathologically examined.
Numerator Details	Time Window: Not applicable

	0225 At least 12 regional lymph nodes are removed and pathologically examined for resected colon cancer.
	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 Known or assumed to be first or only cancer diagnosis Primary tumors of the colon Epithelial malignancy only AJCC Stage I, II, or III Surgical resection performed at the reporting facility
Denominator Details	Time Window: Typically a 12 month, calendar year, time period 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; not a first or only cancer diagnosis; non-epithelial and non-invasive tumors; metastatic disease (AJCC Stage IV); not treated surgically at the reporting facility
Exclusion Details	See: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf
Risk Adjustment	No risk adjustment or risk stratification
Stratification	No stratification applied
Type Score	Rate/proportion better quality = higher score
Algorithm	
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	0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients
Status	Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 31, 2008
Steward	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) Other organizations: This measure is jointly copyrighted by the AMA-PCPI, American Society of Clinical Oncology, and Nati
Description	Percentage of patients aged 18 years and older with Stage IIIA through IIIC 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
Data Source	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Medical Records Not applicable. Zip file for data dictionary/code table to be sent separately (cannot be attached to 2a1.30).
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Ambulatory Care : Clinician Office/Clinic, Other Oncology/Outpatient Clinic; Radiation Oncology Dept/Clinic
Numerator Statement	Patients who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy* within the 12 month reporting period 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

0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients	
	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
Numerator Details	Time Window: At least once during the measurement period. For EHR: eMeasure (See attached) Administrative claims Report the CPT Category II code: 4180F - Adjuvant chemotherapy referred, prescribed, or previously received for Stage IIIA through IIIC colon cancer
Denominator Statement	All patients aged 18 years and older with Stage IIIA through IIIC colon cancer
Denominator Details	Time Window: 12 consecutive months. For EHR: eMeasure (See attached) Administrative claims data: AGE: >= 18 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	Documentation of medical reason(s) for not referring for or prescribing adjuvant chemotherapy (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) 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	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

0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients	
	<p>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:</p> <p>For EHR: eMeasure (See attached)</p> <p>Administrative claims: Denominator Exceptions:</p> <ul style="list-style-type: none"> 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 None
Stratification	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = higher score
Algorithm	<p>To calculate performance rates:</p> <ol style="list-style-type: none"> 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, 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)(eg, patient is currently enrolled in a clinical trial that precludes prescription of chemotherapy). If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. <p>--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.</p> <p>If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure.</p> <p>See calculation algorithm in attachment 2a1.21. Attachment Generic Measure Logic-634620633024859689.pdf</p>
Copyright/Disclaimer	<p>Physician Performance Measures (Measures) and related data specifications, developed by the Physician Consortium for Performance Improvement® (the Consortium), are intended to facilitate quality improvement activities by physicians.</p> <p>These Measures are intended to assist physicians in enhancing quality of care. Measures are designed for use by any physician who manages the care of a patient for a specific condition or for prevention. These performance Measures are not clinical guidelines and do not establish a standard of medical care. The Consortium has not tested its Measures for all potential applications. The Consortium encourages the testing and evaluation of its Measures.</p> <p>Measures are subject to review and may be revised or rescinded at any time by the Consortium. The Measures may not be altered without the prior written approval of the Consortium. Measures developed by the</p>

	0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients
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	0387 Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
Status	Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 31, 2008
Steward	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) Other organizations: This measure is jointly copyrighted by the AMA-PCPI, American Society of Clinical Oncology and Natio
Description	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
Data Source	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Medical Records Not applicable. Zip file for data dictionary/code table to be sent separately (cannot be attached to 2a1.30).
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Ambulatory Care : Clinician Office/Clinic, Other Oncology/Outpatient Clinic
Numerator Statement	Patients who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12 month reporting period 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.
Numerator Details	Time Window: At least once during the measurement period For EHR: eMeasure (see attached). Administrative claims: Report the CPT Category II code: 4179F - Tamoxifen or aromatase inhibitor (AI) prescribed
Denominator Statement	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	Time Window: 12 consecutive months For EHR: eMeasure (see attached).

0387 Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer	
	<p>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</p>
Exclusions	<p>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)</p>
Exclusion Details	<p>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:</p>

	0387 Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
	For EHR: eMeasure (see attached). 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 None
Stratification	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, 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 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. Attachment AMA-PCPI_Measure Calculation-Standard Measures-634620676683828729.pdf
Copyright/Disclaimer	Physician Performance Measures (Measures) and related data specifications, developed by the Physician Consortium for Performance Improvement® (the Consortium), are intended to facilitate quality improvement activities by physicians. These Measures are intended to assist physicians in enhancing quality of care. Measures are designed for use by any physician who manages the care of a patient for a specific condition or for prevention. These performance Measures are not clinical guidelines and do not establish a standard of medical care. The Consortium has not tested its Measures for all potential applications. The Consortium encourages the testing and evaluation of its Measures. Measures are subject to review and may be revised or rescinded at any time by the Consortium. The Measures may not be altered without the prior written approval of the Consortium. Measures developed by the Consortium, while copyrighted, can be reproduced and distributed, without modification, for noncommercial purposes, e.g., use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of the Measures into a product or service that is sold, licensed or distributed for commercial gain. Commercial uses of the Measures

	0387 Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
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	0391 Breast Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade
Status	Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 31, 2008
Steward	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) Other organizations: College of American Pathologists
Description	Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade.
Type	Process
Data Source	Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry, Paper Records Not Applicable Attachment AMA-PCPI_0391_PATH BreastCancerResectionPathologyReporting_DataElements_1 2012.pdf
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Ambulatory Care : Clinician Office, Laboratory
Numerator Statement	Reports that include the pT category, the pN category and the histologic grade
Numerator Details	<p>Time Window: Each final report during measurement period</p> <p>For EHR: eSpecification currently under development. Data elements (using Quality Data Model) required for the measure attached.</p> <p>For Claims Specifications CPT Category II code: 3260F – pT (primary tumor), pN (regional lymph node), and histologic grade documented in pathology report</p>
Denominator Statement	All breast cancer resection pathology reports (excluding biopsies)
Denominator Details	<p>Time Window: 12 consecutive months</p> <p>For EHR: eSpecification currently under development. Data elements (using Quality Data Model) required for the measure attached.</p> <p>For Claims/Administrative: ICD-9-CM diagnosis codes: 174.0, 174.1, 174.2, 174.3, 174.4, 174.5, 174.6 , 174.8, 174.9, 175.0, 175.9</p>

	0391 Breast Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade
	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, C50.021, C50.022, C50.029, C50.121, C50.122, C50.129, C50.221, C50.222, C50.229, C50.321, C50.322, C50.329, C50.421, C50.422, C50.429, C50.521, C50.522, C50.529, C50.621, C50.622, C50.629, C50.821, C50.822, C50.829, C50.921, C50.922, C50.929 AND CPT Codes: 88307, 88309
Exclusions	Documentation of medical reason(s) for not including the pT category, the pN category or the histologic grade (eg; re-excision without residual tumor; non-carcinomas)
Exclusion Details	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 documentation of medical reason(s) for not including the pT category, the pN category or the histologic grade (eg; re-excision without residual tumor). 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: eSpecification currently under development. Data elements (using Quality Data Model) required for the measure attached. For Claims/Administrative: Documentation of medical reason(s) for not including the pT category, the pN category or the histologic grade (eg; re-excision without residual tumor) Append modifier to CPT Category II code: 3260F-1P OR If the specimen is not primary breast tissue (e.g., liver, lung) report: CPT II 3250F: Specimen site other than anatomic location of primary tumor
Risk Adjustment	No risk adjustment or risk stratification
Stratification	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, 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 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

	0391 Breast Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade
	<p>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: exceptions may include documentation of medical reason(s) for not including the pT category, the pN category or the histologic grade (eg; re-excision without residual tumor)].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.</p> <p>If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure.</p> <p>See calculation algorithm attached in 2a1.21. Attachment AMA-PCPI_Measure Calculation-634626514390218943.pdf</p>
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	0392 Colorectal Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade
Status	Maintenance, Original Endorsement: Jul 31, 2008, Most Recent Endorsement: Jul 31, 2008
Steward	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) Other organizations: College of American Pathologists
Description	Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade
Type	Process
Data Source	Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry, Paper Records Attachment AMA-PCPI_0392_PATH ColorectalCancerResectionPathology_DataElements_1 2012.pdf
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Ambulatory Care : Ambulatory Surgery Center (ASC), Laboratory
Numerator Statement	Reports that include the pT category, the pN category and the histologic grade
Numerator Details	<p>Time Window: Each final report during measurement period</p> <p>For EHR: eSpecification currently under development. Data elements (using Quality Data Model) required for the measure attached.</p> <p>For Claims/Administrative: CPT Category II code 3260F: pT (primary tumor), pN (regional lymph node), and histologic grade documented in pathology report</p>
Denominator Statement	All colon and rectum cancer resection pathology reports
Denominator Details	<p>Time Window: 12 consecutive months</p> <p>For EHR: eSpecification currently under development. Data elements (using Quality Data Model) required for the measure attached.</p> <p>For Claims/Administrative:</p>

	0392 Colorectal Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade
	ICD-9-CM diagnosis codes: 153.0, 153.1, 153.2, 153.3, 153.4, 153.5, 153.6, 153.7, 153.8, 153.9, 154.0, 154.1, 154.8 ICD-10-CM diagnosis codes: C18.0, C18.1, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C18.9, C19, C20, C21.2, C21.8 AND CPT Codes: 88309
Exclusions	Denominator Exclusion: Documentation of medical reason(s) for not including the pT category, the pN category or the histologic grade (eg; re-excision without residual tumor; non-carcinomasanal canal)
Exclusion Details	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 Documentation of medical reason(s) for not including the pT category, the pN category or the histologic grade. 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: eSpecification currently under development. Data elements (using Quality Data Model) required for the measure attached. For Claims/Administrative: Documentation of medical reason(s) for not including the pT category, the pN category or the histologic grade <ul style="list-style-type: none"> • Append modifier to CPT Category II code: 3260F-1P OR If the specimen is not primary breast tissue (e.g., liver, lung) report: CPT II 3250F: Specimen site other than anatomic location of primary tumor
Risk Adjustment	No risk adjustment or risk stratification
Stratification	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.
Type Score	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

	0392 Colorectal Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade
	measure: documentation of medical reason(s) for not including the pT category, the pN category or the histologic grade]. 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. Calculation algorithm is included in data dictionary/code table attachment 2a1.30. Attachment AMA-PCPI_Measure Calculation.pdf
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	0559 Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer.
Status	Maintenance, Original Endorsement: Mar 01, 2007, Most Recent Endorsement: Mar 01, 2007
Steward	American College of Surgeons Other organizations: This measure was harmonized with measure development efforts coordinated between the American Society
Description	Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage T1c, or Stage II, or III, who's primary tumor is progesterone and estrogen receptor negative recommended for multiagent chemotherapy (considered or administered) within 4 months (120 days) of diagnosis.
Type	Process
Data Source	Electronic Clinical Data : Registry, Paper Records Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base URL http://www.naacr.org/StandardsandRegistryOperations/Volumell.aspx URL http://www.facs.org/cancer/coc/fordsmanual.html
Level	Facility
Setting	Hospital/Acute Care Facility
Numerator Statement	Combination chemotherapy is considered or administered within 4 months (120 days) of the date of diagnosis
Numerator Details	Time Window: 4 months (120 days) Chemotherapy [NAACCR Item#1390]=82-87 OR; Chemotherapy [NAACCR Item#1390]=3, and Date Chemotherapy Started (NAACCR Item#1220) <=120 days following Date of Diagnosis [NAACCR Item# 340]
Denominator Statement	Women under the age of 70 with AJCC T1cN0M0, or Stage II or III hormone receptor negative breast cancer: <ul style="list-style-type: none"> • Women • Age 18-69 at time of diagnosis • Known or assumed first or only cancer diagnosis • Primary tumors of the breast • Epithelial invasive malignancy only • AJCC T1cN0M0, or Stage II or III • Primary tumor is estrogen receptor negative and progesterone receptor negative • All or part of first course of treatment performed at the reporting facility • Known to be alive within 4 months (120 days) of diagnosis
Denominator Details	Time Window: Typically a 12 month, calendar year, time period

	0559 Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer.
	Sex [NAACCR Item#220]=2; Age at Diagnosis [NAACCR Item#230] < 80; CS Tumor Size [NAACCR Item#2800]= 010 and AJCC pN [NAACCR Item#890]=0, OR AJCC pN [NAACCR Item#890]=1, 2, or 3; AND CS SSF1 (ERA) [NAACCR Item#2880]=020 or 030; 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; tumor size <=1cm and AJCC pN=0; ERA unknown or positive; PRA unknown or positive; metastatic disease (AJCC Stage IV); not treated surgically; died within 4 months (120 days) of diagnosis
Exclusion Details	See: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf
Risk Adjustment	No risk adjustment or risk stratification
Stratification	No stratification applied
Type Score	Rate/proportion better quality = higher score
Algorithm	See: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf URL http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf
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	1855 Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines
Status	New Submission Time-Limited
Steward	College of American Pathologists
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 ASCO/CAP guidelines.
Type	Process
Data Source	Administrative claims, Other, Paper Records Data can be collected from Pathology Report/Medical Records, Laboratory procedures and claims forms.
Level	Clinician : Group/Practice, Clinician : Individual
Setting	Laboratory
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 *
Numerator Details	Time Window: Report once per patient per date of service 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 Report one of the following CPT Category II codes to confirm the use of the recommended scoring system: <ul style="list-style-type: none"> • 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

	1855 Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines
Denominator Statement	All breast cancer patients with quantitative breast tumor evaluation by HER2 IHC ICD-9 diagnosis codes for breast cancer: 174.0, 174.1, 174.2, 174.3, 174.4, 174.5, 174.6, 174.7, 174.8, 174.9, 175.0, 175.9 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.”)
Denominator Details	Time Window: Each Event ICD-9 diagnosis codes for breast cancer: 174.0, 174.1, 174.2, 174.3, 174.4, 174.5, 174.6, 174.7, 174.8, 174.9, 175.0, 175.9 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.”) Also, from Wolff, A.C., et al. American Society of Clinical Oncology/College of American Pathologists Guideline Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer. Arch Pathol Lab Med. 2007;131:18-43 <ul style="list-style-type: none"> Positive HER2 test. (p.25) Based on a literature review of clinical trials, international studies and protocols, expert consensus, and US Food and Drug Administration Panel findings, a positive HER2 test is defined as either IHC result of 3+ cell surface protein expression (defined as uniform intense membrane staining of > 30% of invasive tumor cells) <ul style="list-style-type: none"> Equivocal HER2 test. (p.26) The equivocal range for IHC consists of samples scored 2+, and this may include up to 15% of samples. An equivocal result (2+) is complete membrane staining that is either non-uniform or weak in intensity but with obvious circumferential distribution in at least 10% of cells. Very rarely, in the experience of panel members, invasive tumors can show intense, complete membrane staining of 30% or fewer tumor cells. These are also considered to be equivocal in this guideline. <ul style="list-style-type: none"> Negative HER2 test. (p.27) A negative HER2 test is defined as either an IHC result of 0 or 1+ for cellular membrane protein expression (no staining or weak, incomplete membrane staining in any proportion of tumor cells),....
Exclusions	None
Exclusion Details	Not applicable
Risk Adjustment	No risk adjustment or risk stratification Not applicable
Stratification	Not applicable
Type 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
Copyright/Disclaimer	© 2007 College of American Pathologists. All Rights Reserved Limited proprietary coding is contained in the Measure specifications for convenience. Users of the proprietary code sets should obtain all necessary licenses from the owners of these code sets. The College of American Pathologists disclaims all liability for use or accuracy of any Current Procedural Terminology (CPT®) or other coding contained in the specifications.

	1857 Patients with breast cancer and negative or undocumented human epidermal growth factor receptor 2 (HER2) status who are spared treatment with trastuzumab
Status	New Submission
Steward	American Society of Clinical Oncology
Description	Percentage of adult patients (aged 18 or over) with invasive breast cancer that is HER2/neu negative who are not administered trastuzumab
Type	Process
Data Source	Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records QOPI data are entered via a case report form accessed via a secure web portal. The case report form includes logic and data validation. URL http://qopi.asco.org
Level	Clinician : Group/Practice, Clinician : Team
Setting	Ambulatory Care : Clinician Office/Clinic
Numerator Statement	Trastuzumab not administered during the initial course of treatment
Numerator Details	Time Window: Initial course of treatment. The initial course of treatment is defined as: The treatment course for the initial diagnosis, which may include elements of chemotherapy (any route), hormonal therapy, radiation, or additional surgery. Do not include treatment Trastuzumab (Herceptin) administered during initial treatment course = Trastuzumab NOT administered OR (Trastuzumab (Herceptin) administered during initial treatment course = Trastuzumab administered AND Trastuzumab administered according to clinical trial protocol = Yes)
Denominator Statement	Adult women with AJCC stage I (T1c) – III breast cancer that is HER-2 negative or HER-2 undocumented/unknown
Denominator Details	Time Window: Implementation in QOPI specifies a time window of less than or equal to two years since diagnosis with invasive cancer; however, shorter time windows (e.g., 12 months) can be specified for individual analyses. 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 (174.xx) 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

	1857 Patients with breast cancer and negative or undocumented human epidermal growth factor receptor 2 (HER2) status who are spared treatment with trastuzumab
	<p>Encounter: new patient visit (CPT 99201 -99205) or established patient (CPT 99211-99215), not consult (CPT 99241-99245 office consult or inpatient consult CPT 99251-99255)</p> <p>HER2 status:</p> <p>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.</p> <p>In the absence of any documentation regarding HER-2/neu status, select 'Test not ordered/no documentation.'</p> <p>Enter information from the most recent test report.</p> <p>Patients are classified as having HER-2 positive disease based on positive results with either test.</p> <p>If the most recent report indicates insufficient sample, select 'Test ordered, insufficient sample for results.'</p> <p>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.</p> <p>Use the following definitions to determine HER-2/neu status:</p> <p>Positive:</p> <ul style="list-style-type: none"> • 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 <p>Equivocal:</p> <ul style="list-style-type: none"> • 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 <p>Negative:</p> <ul style="list-style-type: none"> • 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. <p>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.</p> <p>If the chart documents that the pathologist has ordered a new test, respond 'Yes.'</p>
Exclusions	Patient transfer to practice after initiation of chemotherapy
Exclusion Details	<ul style="list-style-type: none"> • Patient transferred to reporting practice during the initial course of medical oncology treatment or <ul style="list-style-type: none"> • Patient transferred to reporting practice following completion of initial course of medical oncology treatment
Risk Adjustment	No risk adjustment or risk stratification n/a
Stratification	n/a
Type Score	Rate/proportion better quality = higher score
Algorithm	This measure is a proportion with exclusions; thus, the calculation algorithm is: Patients meeting the numerator/(Patients in the denominator – Patients with valid exclusions) x 100
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	1857 Patients with breast cancer and negative or undocumented human epidermal growth factor receptor 2 (HER2) status who are spared treatment with trastuzumab
	<p>physician judgment with respect to particular patients or clinical situations. Patient care is always subject to the independent professional judgment of the treating physician.</p> <p>Accordingly, QOPI participants' adherence to quality measures contained in this research report is strictly voluntary and discretionary, with the ultimate determination regarding their application to be made by the treating physician in his or her professional judgment and in light of each patient's individual circumstances. ASCO does not endorse the QOPI® measures as guidelines for standards of practice or 'best practices.'</p>

	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
Status	New Submission
Steward	American Society of Clinical Oncology
Description	Percentage of adult patients (aged 18 or over) with invasive breast cancer that is HER2/neu positive who are administered trastuzumab
Type	Process
Data Source	Electronic Clinical Data : Electronic Health Record, Paper Medical Records QOPI data are entered via a case report form accessed via a secure web portal. The case report form includes logic and data validation. URL http://qopi.asco.org/
Level	Clinician : Group/Practice, Clinician : Team
Setting	Ambulatory Care : Clinician Office/Clinic
Numerator Statement	Trastuzumab administered within 12 months of diagnosis
Numerator Details	<p>Time Window: Within 12 months (365 days) of diagnosis</p> <p>Definition:</p> <p>Date of diagnosis: Refer to the pathology/hemato-pathology or cytology report and record the date of the report (not the date of the specimen). If there are multiple reports, enter the first date. In</p> <p>(Trastuzumab (Herceptin) administered during initial treatment course = Trastuzumab administered AND Trastuzumab administration start date – diagnosis date < = 365 days) OR (Trastuzumab (Herceptin) administered during initial treatment course = Trastuzumab NOT administered AND Alternative treatment according to clinical trial protocol)</p> <p>Numerator definitions:</p> <p>Initial Course of Treatment is defined as the treatment course for the initial diagnosis, which may include elements of chemotherapy (any route), hormonal therapy, radiation, or additional surgery. If a section or item refers to the initial course of treatment, do not abstract data related to treatment provided for recurrence or disease progression.</p> <p>In the absence of any documentation regarding trastuzumab, select 'NOT administered.' Select 'Contraindication or other clinical exclusion documented' only if there is documentation of a medical reason why a patient who would otherwise be recommended trastuzumab is not given that recommendation.</p> <p>Trastuzumab administered according to clinical trial protocol: respond 'Yes', if the patient received trastuzumab according to a clinical trial protocol without documentation of HER-2/neu positive tumor.</p>
Denominator Statement	Adult women with AJCC stage I (T1c) –III, HER2/neu positive breast cancer who receive chemotherapy
Denominator	Time Window: Implementation in QOPI specifies a time window of less than or equal to two years since

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	
r Details	<p>diagnosis with invasive cancer; however, shorter time windows (e.g., 12 months) can be specified for individual analyses.</p> <p>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 (174.xx) And Breast chemotherapy administered AND HER-2/neu status = Positive AND [(AJCC stage at breast cancer diagnosis =II or III) OR (AJCC stage at breast cancer diagnosis = I (IA or IB) and T-Stage at breast cancer diagnosis =T1c) OR (T-Stage at breast cancer diagnosis = T1c, T2-T4d and N-Stage at breast cancer diagnosis =N0) OR (N-Stage at breast cancer diagnosis = N1-N3c)]</p> <p>Definitions Encounter: new patient visit (CPT 99201 -99205) or established patient (CPT 99211-99215), not consult (CPT 99241-99245 office consult or inpatient consult CPT 99251-99255) HER2 status: 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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 </p>

	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
	<ul style="list-style-type: none"> • If the results indicate ‘non-amplified’, choose HER-2/neu negative. • If the results indicate ‘weakly positive’, choose HER-2/neu positive. <p>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.</p> <p>If the chart documents that the pathologist has ordered a new test, respond ‘Yes.’</p>
Exclusions	<ul style="list-style-type: none"> • Patient history of metastatic cancer • Multiple primaries prior to or within the measurement period • Patient metastatic at diagnosis • Patient transfer to practice after initiation of chemotherapy • Patient still receiving anthracycline-based chemotherapy • Patient declined • Patient died or transferred within 12 months of diagnosis • Contraindication or other clinical exclusion
Exclusion Details	
Risk Adjustment	No risk adjustment or risk stratification n/a
Stratification	n/a
Type Score	Rate/proportion better quality = higher score
Algorithm	This measure is a proportion with exclusions; thus, the calculation algorithm is: Patients meeting the numerator / (Patients in the denominator – Patients with valid exclusions) x 100
Copyright/Disclaimer	<p>Copyright © 2012 American Society of Clinical Oncology. All rights reserved.</p> <p>These clinical indicators and quality measures are not intended to and should never supplant independent physician judgment with respect to particular patients or clinical situations. Patient care is always subject to the independent professional judgment of the treating physician.</p> <p>Accordingly, QOPI participants’ adherence to quality measures contained in this research report is strictly voluntary and discretionary, with the ultimate determination regarding their application to be made by the treating physician in his or her professional judgment and in light of each patient’s individual circumstances. ASCO does not endorse the QOPI® measures as guidelines for standards of practice or ‘best practices.’</p>

	1859 KRAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy
Status	New Submission
Steward	American Society of Clinical Oncology
Description	Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom KRAS gene mutation testing was performed
Type	Process
Data Source	Electronic Clinical Data : Electronic Health Record, Paper Medical Records QOPI data are entered via a case report form accessed via a secure web portal. The case report form includes logic and data validation. URL http://qopi.asco.org/
Level	Clinician : Group/Practice, Clinician : Team
Setting	Ambulatory Care : Clinician Office/Clinic

	1859 KRAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy
Numerator Statement	KRAS gene mutation testing performed before initiation of anti-EGFR MoAb
Numerator Details	<p>Time Window: Time period between date of diagnosis with colorectal cancer and date of anti-EGFR MoAb initiation.</p> <p>KRAS gene mutation testing = KRAS mutation detected OR KRAS gene mutation testing = No KRAS mutation detected (wildtype) AND KRAS gene mutation testing date</p> <p>Numerator definitions:</p> <p>In the absence of any documentation regarding testing for the KRAS gene mutation, select 'Test not ordered/no documentation.'</p> <p>Refer to the interpretive report for the KRAS test. The report will indicate if a mutation within codon 12 or 13 of the KRAS gene was detected in the DNA extracted from the colon tumor specimen.</p>
Denominator Statement	Adult patients with metastatic colorectal cancer who receive anti-EGFR monoclonal antibody therapy
Denominator Details	<p>Time Window: Implementation in QOPI specifies a time window of less than or equal to two years since diagnosis with invasive cancer; however, shorter time windows (e.g., 12 months) can be specified for individual analyses. The denominator time window should not extend</p> <p>Age at diagnosis greater than or equal to 18 years AND 2 or more encounters at the reporting site AND Initial colon or rectal cancer diagnosis (153.x, 154.0, 154.0, 154.1, 154.8) AND Presence of metastatic disease documented AND Anti-EGFR monoclonal antibody therapy received</p> <p>Definitions</p> <p>Encounter: new patient visit (CPT 99201-99205) or established patient (CPT 99211-99215), not consult (CPT 99241-99245) office consult or inpatient consult CPT 99251-99255)</p> <p>KRAS mutation testing: KRAS testing for this measure refers to assays that detect mutations in codons 12 and 13 of KRAS only. Do not include results from mutations at other codons (e.g., codons 61 and 146), or assays for other alterations (e.g., BRAF, PI3K, PTEN genes). The College of American Pathologists (CAP) Perspectives on Emerging Technology (POET) Report on KRAS mutation testing provides additional guidance on testing. If multiple KRAS mutation tests have been performed, refer to the most recent test results.</p>
Exclusions	Patient transfer to practice after initiation of chemotherapy
Exclusion Details	n/a
Risk Adjustment	No risk adjustment or risk stratification n/a
Stratification	n/a
Type Score	Rate/proportion better quality = higher score

	1859 KRAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy
Algorithm	This measure is a proportion with exclusions; thus, the calculation algorithm is: Patients meeting the numerator/(Patients in the denominator – Patients with valid exclusions) x 100
Copyright/Disclaimer	Copyright © 2012 American Society of Clinical Oncology. All rights reserved. These clinical indicators and quality measures are not intended to and should never supplant independent physician judgment with respect to particular patients or clinical situations. Patient care is always subject to the independent professional judgment of the treating physician. Accordingly, QOPI participants' adherence to quality measures contained in this research report is strictly voluntary and discretionary, with the ultimate determination regarding their application to be made by the treating physician in his or her professional judgment and in light of each patient's individual circumstances. ASCO does not endorse the QOPI® measures as guidelines for standards of practice or 'best practices.'

	1860 Patients with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies
Status	New Submission
Steward	American Society of Clinical Oncology
Description	Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-EGFR monoclonal antibodies
Type	Process
Data Source	Electronic Clinical Data : Electronic Health Record, Paper Medical Records QOPI data are entered via a case report form accessed via a secure web portal. The case report form includes logic and data validation. URL http://qopi.asco.org/
Level	Clinician : Group/Practice, Clinician : Team
Setting	Ambulatory Care : Clinician Office/Clinic
Numerator Statement	Anti-EGFR monoclonal antibody therapy not received
Numerator Details	Time Window: Time period between date of diagnosis with metastatic colorectal cancer (initial metastatic diagnosis or progression to metastatic disease) and (date of data collection or date of death) Anti-EGFR monoclonal antibody therapy status = No Anti-EGFR monoclonal antibody therapy received
Denominator Statement	Adult patients with metastatic colorectal cancer who have a KRAS gene mutation
Denominator Details	Time Window: Implementation in QOPI specifies a time window of less than or equal to two years since diagnosis with invasive cancer; however, shorter time windows (e.g., 12 months) can be specified for individual analyses. The denominator time window should not extend Age at diagnosis greater than or equal to 18 years And 2 or more encounters at the reporting site And Initial colon or rectal cancer diagnosis (153.x, 154.0, 154.0, 154.1, 154.8) And Presence of metastatic disease documented And KRAS gene mutation detected Definitions Encounter = new patient visit (CPT 99201 -99205) or established patient (CPT 99211-99215), not consult (CPT

	1860 Patients with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies
	99241-99245 office consult or inpatient consult CPT 99251-99255) KRAS mutation testing: KRAS testing for this measure refers to assays that detect mutations in codons 12 and 13 of KRAS only. Do not include results from mutations at other codons (e.g., codons 61 and 146), or assays for other alterations (e.g., BRAF, PI3K, PTEN genes). The College of American Pathologists (CAP) Perspectives on Emerging Technology (POET) Report on KRAS mutation testing provides additional guidance on testing. If multiple KRAS mutation tests have been performed, refer to the most recent test results.
Exclusions	Patient transfer to practice after initiation of chemotherapy Receipt of anti-EGFR monoclonal antibody therapy as part of a clinical trial protocol
Exclusion Details	n/a
Risk Adjustment	No risk adjustment or risk stratification n/a
Stratification	n/a
Type Score	Rate/proportion better quality = higher score
Algorithm	This measure is a proportion with exclusions; thus, the calculation algorithm is: Patients meeting the numerator/(Patients in the denominator – Patients with valid exclusions) x 100
Copyright/Disclaimer	Copyright © 2012 American Society of Clinical Oncology. All rights reserved. These clinical indicators and quality measures are not intended to and should never supplant independent physician judgment with respect to particular patients or clinical situations. Patient care is always subject to the independent professional judgment of the treating physician. Accordingly, QOPI participants' adherence to quality measures contained in this research report is strictly voluntary and discretionary, with the ultimate determination regarding their application to be made by the treating physician in his or her professional judgment and in light of each patient's individual circumstances. ASCO does not endorse the QOPI® measures as guidelines for standards of practice or 'best practices.'

	1878 Human epidermal growth factor receptor 2 (HER2) testing in breast cancer
Status	New Submission
Steward	American Society of Clinical Oncology
Description	Percentage of adult patients (aged 18 or over) with invasive breast cancer who receive human epidermal growth factor receptor 2 (HER2) testing
Type	Process
Data Source	Electronic Clinical Data : Electronic Health Record, Paper Medical Records QOPI data are entered via a case report form accessed via a secure web portal. The case report form includes logic and data validation. URL http://qopi.asco.org/
Level	Clinician : Group/Practice, Clinician : Team
Setting	Ambulatory Care : Clinician Office/Clinic
Numerator Statement	HER2/neu testing performed
Numerator Details	Time Window: Within 4 weeks (28 days) of diagnosis Date of diagnosis: [Refer to the pathology/hemato-pathology or cytology report and record the date of the report (not the date of the specimen). If there are multiple reports, enter the first date. In the absence of HER-2/neu status = HER2 positive OR OR

1878 Human epidermal growth factor receptor 2 (HER2) testing in breast cancer	
	<p>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))</p> <p>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:</p> <p>Positive:</p> <ul style="list-style-type: none"> • 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 <p>Equivocal:</p> <ul style="list-style-type: none"> • 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 <p>Negative:</p> <ul style="list-style-type: none"> • 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. <p>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.'</p>
Denominator Statement	Adult women with invasive breast cancer
Denominator Details	<p>Time Window: None specified; should be specific to the periodicity of analysis.</p> <p>Female And 2 or more encounters at the reporting site And Age at diagnosis greater than or equal to 18 years And</p>

1878 Human epidermal growth factor receptor 2 (HER2) testing in breast cancer	
	Breast cancer diagnosis (174.xx) Definitions Encounter = new patient visit (CPT 99201 -99205) or established patient (CPT 99211-99215), not consult (CPT 99241-99245) office consult or inpatient consult (CPT 99251-99255)
Exclusions	Patient history of metastatic cancer Multiple primaries prior to or within the measurement period
Exclusion Details	'Multiple primaries' is defined as two or more distinct cancer diagnoses. This includes patients with simultaneous bilateral breast cancer or two distinct cancers in one breast.
Risk Adjustment	No risk adjustment or risk stratification n/a
Stratification	n/a
Type Score	Rate/proportion better quality = higher score
Algorithm	This measure is a proportion with exclusions; thus, the calculation algorithm is: Patients meeting the numerator/(Patients in the denominator – Patients with valid exclusions) x 100.
Copyright/Disclaimer	Copyright © 2012 American Society of Clinical Oncology. All rights reserved. These clinical indicators and quality measures are not intended to and should never supplant independent physician judgment with respect to particular patients or clinical situations. Patient care is always subject to the independent professional judgment of the treating physician. Accordingly, QOPI participants' adherence to quality measures contained in this research report is strictly voluntary and discretionary, with the ultimate determination regarding their application to be made by the treating physician in his or her professional judgment and in light of each patient's individual circumstances. ASCO does not endorse the QOPI® measures as guidelines for standards of practice or 'best practices.'

Appendix B: Project Steering Committee and NQF Staff

STEERING COMMITTEE

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NATIONAL QUALITY FORUM

NQF VOTING DRAFT—DO NOT CITE OR QUOTE. NQF Member votes due by August 31, 2012 by 6:00 PM ET

Memphis, TN

Jerod Loeb, PhD

The Joint Commission
Oakbrook Terrace, IL

Bryan Loy, MD, MBA

Humana Inc.
Louisville, KY

Jennifer Malin, MD, PhD

WellPoint
Santa Monica, CA

Lawrence Marks, MD, FASTRO

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Eugene Cunningham, MS

Project Manager
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Appendix C: Measures Endorsed in Cancer Since July 2008

NQF Number	Title	Steward
1628	Patients with Advanced Cancer Screened for Pain at Outpatient Visits	RAND Corporation
1626	Patients Admitted to ICU who Have Care Preferences Documented	RAND Corporation
1625	Hospitalized Patients Who Die an Expected Death with an ICD that Has Been Deactivated	RAND Corporation
1617	Patients Treated with an Opioid who are Given a Bowel Regimen	RAND Corporation
0579	Annual Cervical Cancer Screening for High-Risk Patients	Resolution Health, Inc.
0460	Risk-adjusted morbidity and mortality for esophagectomy for cancer	The Society of Thoracic Surgeons
0459	Risk-adjusted Morbidity and Lobectomy for Lung cancer	The Society of Thoracic Surgeons
0457	Recording of Performance Status (Zubrod, Karnofsky, WHO or ECOG Performance Status) Prior to Lung or Esophageal Cancer Resection	The Society of Thoracic Surgeons
0455	Recording of Clinical Stage for Lung Cancer and Esophageal Cancer Resection	The Society of Thoracic Surgeons
0365	Pancreatic Resection Mortality Rate (IQI 9) (risk adjusted)	Agency for Healthcare Research and Quality
0360	Esophageal Resection Mortality Rate (IQI 8)	Agency for Healthcare Research and Quality
0209	Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment	National Hospice and Palliative Care Organization
0208	Family Evaluation of Hospice Care	National Hospice and Palliative Care Organization
0139	National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome	Centers for Disease Control and Prevention
0138	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI)	Centers for Disease Control and Prevention
0034	Colorectal Cancer Screening	National Committee for Quality Assurance
0032	Cervical Cancer Screening	National Committee for Quality Assurance

Appendix D: Related and Competing Measures

Comparison of NQF #0220 and NQF #0387

	Measure 0220: Adjuvant hormonal therapy	Measure 0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
Steward	Commission on Cancer, American College of Surgeons	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)
Description	Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage I, II, or III, who's primary tumor is progesterone or estrogen receptor positive recommended for tamoxifen or third generation aromatase inhibitor (considered 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	Electronic Clinical Data : Registry, Paper Records Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base URL http://www.naacr.org/StandardsandRegistryOperations/Volumell.aspx URL http://www.facs.org/cancer/coc/fordsmanual.html	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records Not applicable. Zip file for data dictionary/code table to be sent separately (cannot be attached to 2a1.30).
Level	Facility	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Hospital/Acute Care Facility	Ambulatory Care : Clinician Office, Other Oncology/Outpatient Clinic
Numerator Statement	Hormone therapy is considered or administered within 1 year (365 days) of the date of diagnosis	Patients who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12 month reporting period 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.
Numerator Details	Time Window: 1 year (365 days) Hormone Therapy [NAACCR Item#1400]=82-87 OR; Hormone Therapy [NAACCR Item#1400]=1, AND Date Hormone Therapy Started [NAACCR Item#710] <=365 days following Date of Diagnosis [NAACCR Item# 340]	Time Window: At least once during the measurement period For EHR: eMeasure (see attached). Administrative claims: Report the CPT Category II code: 4179F - Tamoxifen or aromatase

	Measure 0220: Adjuvant hormonal therapy	Measure 0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
		inhibitor (AI) prescribed
Denominator Statement	<p>Include if all of the following characteristics are identified:</p> <p>Women</p> <p>Age >=18 at time of diagnosis</p> <p>Known or assumed to be first or only cancer diagnosis</p> <p>Epithelial malignancy only</p> <p>Primary tumors of the breast</p> <p>AJCC T1c or Stage II or III</p> <p>Primary tumor is estrogen receptor positive or progesterone receptor positive</p> <p>All or part of 1st course of treatment performed at the reporting facility</p> <p>Known to be alive within 1 year (365 days) of date of diagnosis</p>	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	<p>Time Window: Typically a 12 month, calendar year, time period</p> <p>Sex [NAACCR Item#220]=2; CS Tumor Size [NAACCR Item#2800]= 010 and AJCC pN [NAACCR Item#890]=0, OR AJCC pN [NAACCR Item#890]=1, 2, or 3; 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</p>	<p>Time Window: 12 consecutive months</p> <p>For EHR: eMeasure (see attached).</p> <p>Administrative claims:</p> <p>AGE:>= 18 years and older</p> <p>Gender:>Female</p> <p>Diagnosis: Breast Cancer with Stage IC through IIIC, estrogen receptor (ER) or progesterone receptor (PR)</p> <p>AND</p> <p>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)</p> <p>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</p> <p>AND</p> <p>CPT® Codes:</p> <p>99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215,</p>

	Measure 0220: Adjuvant hormonal therapy	Measure 0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
		<p>AND</p> <p>CPT II 3374F: AJCC Breast Cancer Stage I: TIC (tumor size > 1 cm to 2 cm), documented</p> <p>OR</p> <p>CPT II 3376F: AJCC Breast Cancer Stage II, documented</p> <p>OR</p> <p>CPT II 3378F: AJCC Breast Cancer Stage III, documented</p> <p>AND</p> <p>CPT II 3315F: Estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer</p>
Exclusions	<p>Exclude, if any of the following characteristics are identified:</p> <p>Men</p> <p>Under age 18 at time of diagnosis</p> <p>Second or subsequent cancer diagnosis</p> <p>Tumor not originating in the breast</p> <p>Non-epithelial malignancies</p> <p>Stage 0, in-situ tumor</p> <p>AJCC T1mic, T1a, or T1b tumor</p> <p>Stage IV, metastatic tumor</p> <p>Primary tumor is estrogen receptor negative and progesterone receptor negative</p> <p>None of 1st course therapy performed at reporting facility</p> <p>Died within 1 year (365 days) of diagnosis</p>	<p>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)</p> <p>Documentation of patient reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient refusal)</p> <p>Documentation of system reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient is currently enrolled in a clinical trial)</p>
Exclusion Details	<p>See: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf</p>	<p>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,</p>

	Measure 0220: Adjuvant hormonal therapy	Measure 0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
		<p>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: eMeasure (see attached). 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</p>
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, gender, and primary language, 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: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf URL http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf	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).

	Measure 0220: Adjuvant hormonal therapy	Measure 0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
		<p>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.</p> <p>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</p> <p>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. Attachment AMA-PCPI_Measure Calculation-Standard Measures-634620676683828729.pdf</p>
Submission items	5.1 Identified measures:	5.1 Identified measures: 0220 : 0220: Adjuvant hormonal therapy

	Measure 0220: Adjuvant hormonal therapy	Measure 0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
	<p>5a.1 Are specs completely harmonized?</p> <p>5a.2 If not completely harmonized, identify difference, rationale, impact:</p> <p>5b.1 If competing, why superior or rationale for additive value:</p>	<p>5a.1 Are specs completely harmonized? No</p> <p>5a.2 If not completely harmonized, identify difference, rationale, impact: No related measures; See competing measures section below regarding the harmonization of measure specifications.</p> <p>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.</p>
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	Measure 0220: Adjuvant hormonal therapy	Measure 0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer

Comparison of NQF #0385 and NQF #0223

	Measure 0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients	Measure 0223: Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer
Steward	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)	Commission on Cancer, American College of Surgeons
Description	Percentage of patients aged 18 years and older with Stage IIIA through IIIC colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy or have previously received adjuvant chemotherapy within the 12 month reporting period	Percentage of patients under the age of 80 with AJCC III (lymph node positive) colon cancer for whom adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery.
Type	Process	Process
Data Source	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Medical Records Not applicable. Zip file for data dictionary/code table to be sent separately (cannot be attached to 2a1.30).	Electronic Clinical Data : Registry, Paper Records Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base URL http://www.naacr.org/StandardsandRegistryOperations/Volumell.aspx URL http://www.facs.org/cancer/coc/fordsmanual.html
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team	Facility
Setting	Ambulatory Care : Clinician Office/Clinic, Other Oncology/Outpatient Clinic; Radiation Oncology Dept/Clinic	Hospital/Acute Care Facility
Numerator Statement	Patients who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy* within the 12 month reporting period 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	Chemotherapy is considered or administered within 4 months (120 days) of diagnosis

	Measure 0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients	Measure 0223: Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer
	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	
Numerator Details	<p>Time Window: At least once during the measurement period.</p> <p>For EHR: eMeasure (See attached) Administrative claims Report the CPT Category II code: 4180F - Adjuvant chemotherapy referred, prescribed, or previously received for Stage IIIA through IIIC colon cancer</p>	<p>Time Window: 4 months (120 days)</p> <p>Chemotherapy [NAACCR Item#1390]=82-87 OR; Chemotherapy [NAACCR Item#1390]=3, and Date Chemotherapy Started (NAACCR Item#1220) <=120 days following Date of Diagnosis [NAACCR Item#340]</p>
Denominator Statement	All patients aged 18 years and older with Stage IIIA through IIIC colon cancer	<p>Include, if all of the following characteristics are identified:</p> <ul style="list-style-type: none"> 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 facility² Known to be alive within 4 months (120 days) of diagnosis
Denominator Details	<p>Time Window: 12 consecutive months.</p> <p>For EHR: eMeasure (See attached) Administrative claims data: AGE: >= 18 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</p>	<p>Time Window: Typically a 12 month, calendar year, time period</p> <p>Age at Diagnosis [NAACCR Item#230] < 80, AND Surgical Procedure of the Primary Site [NAACCR Item#1290] = 30–90, AND Regional Lymph Nodes Positive [NAACCR Item#820] = 1-90, 95, 97</p>

	Measure 0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients	Measure 0223: Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer
	AND CPT® Codes: 99201, 99202, 99203, 99204, 99205 99212, 99213, 99214, 99215	
Exclusions	Documentation of medical reason(s) for not referring for or prescribing adjuvant chemotherapy (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) 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)	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
Exclusion Details	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	See: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf

	Measure 0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients	Measure 0223: Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer
	<p>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</p>	
Risk Adjustment	No risk adjustment or risk stratification None	No risk adjustment or risk stratification
Stratification	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.	No stratification applied
Type 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 patient population (ie, the general group of patients that the	See: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf URL http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf

	Measure 0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients	Measure 0223: Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer
	<p>performance measure is designed to address).</p> <p>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.</p> <p>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</p> <p>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, 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)(eg, patient is currently enrolled in a clinical trial that precludes prescription of chemotherapy). If the patient meets any exception criteria, they should be removed from the denominator for performance calculation.</p> <p>--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.</p> <p>If the patient does not meet the numerator and a valid</p>	

	Measure 0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients	Measure 0223: Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer
	exception is not present, this case represents a quality failure. See calculation algorithm in attachment 2a1.21. Attachment Generic Measure Logic-634620633024859689.pdf	
Submission items	<p>5.1 Identified measures: 0223 : 0223: Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer</p> <p>5a.1 Are specs completely harmonized? No</p> <p>5a.2 If not completely harmonized, identify difference, rationale, impact: No related measures; See competing measures section below regarding the harmonization of measure specifications.</p> <p>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.</p>	<p>5.1 Identified measures:</p> <p>5a.1 Are specs completely harmonized?</p> <p>5a.2 If not completely harmonized, identify difference, rationale, impact:</p> <p>5b.1 If competing, why superior or rationale for additive value:</p>
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	Measure 0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients	Measure 0223: Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer

	Measure 0220: Adjuvant hormonal therapy	Measure 0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
Steward	Commission on Cancer, American College of Surgeons	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)
Description	Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage I, II, or III, who's primary tumor is progesterone or estrogen receptor positive recommended for tamoxifen or third generation aromatase inhibitor (considered 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	Electronic Clinical Data : Registry, Paper Records Hospital cancer registry data, reported to the American College of Surgeons, Commission on Cancer, National Cancer Data Base URL http://www.naaccr.org/StandardsandRegistryOperations/Volumell.aspx	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records Not applicable. Zip file for data dictionary/code table to be sent separately (cannot be attached to 2a1.30).

	Measure 0220: Adjuvant hormonal therapy	Measure 0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
	URL http://www.facs.org/cancer/coc/fordsmanual.html	
Level	Facility	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Hospital/Acute Care Facility	Ambulatory Care : Clinician Office, Other Oncology/Outpatient Clinic
Numerator Statement	Hormone therapy is considered or administered within 1 year (365 days) of the date of diagnosis	Patients who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12 month reporting period 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.
Numerator Details	Time Window: 1 year (365 days) Hormone Therapy [NAACCR Item#1400]=82-87 OR; Hormone Therapy [NAACCR Item#1400]=1, AND Date Hormone Therapy Started (NAACCR Item#710) <=365 days following Date of Diagnosis [NAACCR Item# 340]	Time Window: At least once during the measurement period For EHR: eMeasure (see attached). Administrative claims: Report the CPT Category II code: 4179F - Tamoxifen or aromatase inhibitor (AI) prescribed
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 T1c or Stage II or III Primary tumor is estrogen receptor positive or progesterone receptor positive All or part of 1st course of treatment performed at the reporting facility Known to be alive within 1 year (365 days) of date of diagnosis	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	Time Window: Typically a 12 month, calendar year, time period Sex [NAACCR Item#220]=2; CS Tumor Size [NAACCR Item#2800]= 010 and AJCC pN [NAACCR Item#890]=0, OR AJCC pN [NAACCR Item#890]=1, 2, or 3; 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	Time Window: 12 consecutive months For EHR: eMeasure (see attached). 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,

	Measure 0220: Adjuvant hormonal therapy	Measure 0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
		<p>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</p>
Exclusions	<p>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 Stage 0, in-situ tumor AJCC T1mic, T1a, or T1b 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</p>	<p>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)</p>
Exclusion Details	<p>See: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf</p>	<p>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;</p>

	Measure 0220: Adjuvant hormonal therapy	Measure 0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
		<p>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:</p> <p>For EHR: eMeasure (see attached). 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</p>
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, gender, and primary language, 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: http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf URL http://www.facs.org/cancer/ncdb/cp3rv2-measurespecs-1211.pdf	To calculate performance rates: 1) Find the patients who meet the initial patient population (ie, the

	Measure 0220: Adjuvant hormonal therapy	Measure 0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
		<p>general group of patients that the performance measure is designed to address).</p> <p>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.</p> <p>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</p> <p>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. Attachment AMA-PCPI_Measure Calculation-Standard Measures-634620676683828729.pdf</p>
Submission items	<p>5.1 Identified measures:</p> <p>5a.1 Are specs completely harmonized?</p> <p>5a.2 If not completely harmonized, identify difference, rationale, impact:</p>	<p>5.1 Identified measures: 0220 : 0220: Adjuvant hormonal therapy</p> <p>5a.1 Are specs completely harmonized? No</p> <p>5a.2 If not completely harmonized, identify difference, rationale, impact: No related measures; See competing measures section below regarding the</p>

	Measure 0220: Adjuvant hormonal therapy	Measure 0387: Oncology: Hormonal therapy for stage IC through IIIC, ER/PR positive breast cancer
	5b.1 If competing, why superior or rationale for additive value:	<p>harmonization of measure specifications.</p> <p>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.</p>
SC Evaluation		