



Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to subcriterion 1b).

Brief Measure Information

NQF #: 1878

Corresponding Measures:

De.2. Measure Title: HER2 testing for overexpression or gene amplification in patients with breast cancer

Co.1.1. Measure Steward: American Society of Clinical Oncology

De.3. Brief Description of Measure: Proportion of female patients (aged 18 years and older) with breast cancer who receive human epidermal growth factor receptor 2 (HER2) testing for overexpression or gene amplification

1b.1. Developer Rationale: Human epidermal growth factor receptor (HER2) gene is amplified and/or overexpressed in approximately 15% to 20% of primary breast cancers. The ASCO/CAP joint guideline on HER2 testing recommends all patients with invasive breast cancer should be tested for HER2 status and only those who test positive for HER2 status should receive HER2 targeted therapies (Giordano, 2014). Results of HER2 testing are imperative to receive guideline concordant treatment. Studies show that tumors of older female patients (15.7%) and Hispanics (20.7%) as well as other race/ethnicities (18.8%) are less likely to be tested for HER2 (Lund, 2010).

Giordano, S.H., Temin, S., et. al., "Systemic Therapy for Patients with Advanced Human Epidermal Growth Factor Receptor 2-Positive Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline." J Clin Onc 32.19 (2014): 2078-099. Available at:<http://jco.ascopubs.org/content/32/19/2078.full.pdf+html>

Lund, M. J., E. N. Butler, et al. (2010). "Age/race differences in HER2 testing and in incidence rates for breast cancer triple subtypes: a population-based study and first report." Cancer 116(11): 2549-2559.

S.4. Numerator Statement: HER2 testing performed

S.7. Denominator Statement: Adult women with breast cancer

S.10. Denominator Exclusions: None

De.1. Measure Type: Process

S.23. Data Source: Registry

S.26. Level of Analysis: Clinician : Group/Practice

IF Endorsement Maintenance – Original Endorsement Date: Oct 22, 2012 **Most Recent Endorsement Date:** Oct 26, 2016

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? Not applicable

1. Evidence, Performance Gap, Priority – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. **Measures must be judged to meet all subcriteria to pass this criterion and be evaluated against the remaining criteria.**

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

[1878_Evidence_MSF5.0_Data-635932990174672035.doc](#)

1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure (e.g., the benefits or improvements in quality envisioned by use of this measure)

Human epidermal growth factor receptor (HER2) gene is amplified and/or overexpressed in approximately 15% to 20% of primary breast cancers. The ASCO/CAP joint guideline on HER2 testing recommends all patients with invasive breast cancer should be tested for HER2 status and only those who test positive for HER2 status should receive HER2 targeted therapies (Giordano, 2014). Results of HER2 testing are imperative to receive guideline concordant treatment. Studies show that tumors of older female patients (15.7%) and Hispanics (20.7%) as well as other race/ethnicities (18.8%) are less likely to be tested for HER2 (Lund, 2010).

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Lund, M. J., E. N. Butler, et al. (2010). "Age/race differences in HER2 testing and in incidence rates for breast cancer triple subtypes: a population-based study and first report." Cancer 116(11): 2549-2559.

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. *(This is required for endorsement maintenance. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included). This information also will be used to address the subcriterion on improvement (4b.1) under Usability and Use.*

This data was produced from the QOPI® registry and data was abstracted for a sample of patients seen with the data collection period. Performance is reported at the clinical practice level.

In 2013, 230 practices were measured, and the total patient population for this measure was 6258.

In 2014, 225 practices were measured, and the total patient population for this measure was 5980.

In 2015, 266 practices were measured, and the total patient population for this measure was 6783.

		2013	2014	2015
Overall	96.94	96.93	98.86	
Mean	98.53	98.77	98.63	
Minimum	68.75	80	50	
Maximum	100	100	100	
Standard Deviation	3.31	2.72	4.26	
Percentiles				
P10	95	96	96.2	
P25	97.56	97.74	100	
P50	100	100	100	
P75	100	100	100	
P90	100	100	100	
P95	100	100	100	

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity,

gender, age, insurance status, socioeconomic status, and/or disability. (This is required for endorsement maintenance. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the subcriterion on improvement (4b.1) under Usability and Use.

This data was produced from the QOPI® registry and data was abstracted for a sample of patients seen with the data collection period. Performance is reported at the chart level.

In 2013, the total patient population for this measure was 6258.

In 2014, the total patient population for this measure was 5980.

In 2015, the total patient population for this measure was 6783.

	2013	2014	2015
Overall	96.94	96.93	98.86
Hispanic	97.69	97.08	98.13
White	96.92	97.10	98.93
Black	96.08	94.96	98.92
Other	95.79	97.77	98.60

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations.

Studies show that tumors of older female patients (15.7%) and Hispanics (20.7%) as well as other race/ethnicities (18.8%) are less likely to be tested for HER2 (Lund, 2010).

Health disparities between patients with breast cancer according to race/ethnicity, age, insurance status, geographic location, education, and other factors are well documented, however literature addressing disparities specific to patients with HER2-positive metastatic breast cancer is scarce. According to some studies, there are not large (although some suggest modest) differences in the prevalence of HER2 positivity between women with breast cancer of different races/ethnicities. The variation by race is smaller among those with HER2-positive breast cancer than for some other subtypes.

HER2 positivity is not necessarily associated with worse treatment outcomes among African American compared with non-African American patients. However, high-quality data on patients with HER2-positive metastatic disease are still needed to reach conclusions related to outcomes based on ethnicity. Therefore, health disparities may be similar to those faced by patients with metastatic breast cancer generally.

Although ASCO clinical practice guidelines represent expert recommendations the highest level of cancer care, it is important to note that many patients have limited access to medical care. Racial and ethnic disparities in health care contribute significantly to this problem in the United States. Minority racial/ethnic patients with cancer suffer disproportionately from comorbidities, experience more substantial obstacles to receiving care, are more likely to be uninsured, and are at greater risk of receiving care of poor quality than other North Americans. Many other patients lack access to care because of their age, geography, and distance from appropriate treatment facilities. Awareness of these disparities in access to care should be considered in the context of this clinical practice guideline, and health care providers should strive to deliver the highest level of cancer care to these vulnerable populations (Giordano, 2014).

Citations:

Giordano, S.H., Temin, S., et. al., "Systemic Therapy for Patients with Advanced Human Epidermal Growth Factor Receptor 2-Positive Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline." J Clin Onc 32.19 (2014): 2078-099.

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1c. High Priority (previously referred to as High Impact)

The measure addresses:

- a specific national health goal/priority identified by DHHS or the National Priorities Partnership convened by NQF; OR
- a demonstrated high-priority (high-impact) aspect of healthcare (e.g., affects large numbers of patients and/or has a substantial impact for a smaller population; leading cause of morbidity/mortality; high resource use (current and/or future); severity of illness; and severity of patient/societal consequences of poor quality).

1c.1. Demonstrated high priority aspect of healthcare

1c.2. If Other:

1c.3. Provide epidemiologic or resource use data that demonstrates the measure addresses a high priority aspect of healthcare. List citations in 1c.4.

1c.4. Citations for data demonstrating high priority provided in 1a.3

1c.5. If a PRO-PM (e.g. HRQoL/functional status, symptom/burden, experience with care, health-related behaviors), provide evidence that the target population values the measured PRO and finds it meaningful. (Describe how and from whom their input was obtained.)

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. **Measures must be judged to meet the subcriteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.**

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area (check all the areas that apply):

Cancer, Cancer : Breast

De.6. Non-Condition Specific (check all the areas that apply):

S.1. Measure-specific Web Page (Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)

Not applicable

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure Attachment:

S.2b. Data Dictionary, Code Table, or Value Sets (and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)

No data dictionary Attachment:

S.3. For endorsement maintenance, please briefly describe any changes to the measure specifications since last endorsement date and explain the reasons.

Title and description were modified to clarify the measure intent.

No other substantive changes were made.

S.4. Numerator Statement (Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome)

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm.

HER2 testing performed

S.5. Time Period for Data (What is the time period in which data will be aggregated for the measure, e.g., 12 mo, 3 years, look back to August for flu vaccination? Note if there are different time periods for the numerator and denominator.)

Practices are required to order tests within 31 days from first office visit (HER2 test date – first office visit date = 31 days) and if a new test is ordered, it must be within 10 days of original report

S.6. Numerator Details (All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm.

HER-2/neu status = HER2 positive

OR

HER-2/neu status = HER2 negative

OR

HER-2/neu status = Test ordered, results not yet documented

OR

HER-2/neu status = Test ordered, insufficient sample for results

OR

(HER-2 equivocal AND New test ordered within 10 days of report = Yes or N/A (patient died or transferred out of practice))

Practices are required to order tests within 31 days from first office visit (HER2 test date – first office visit date = 31 days) and if a new test is ordered, it must be within 10 days of original report

Numerator definitions:

Select 'Test ordered, results not yet documented' only if there is documentation in the chart that a test that reports HER-2/neu analyses was ordered.

In the absence of any documentation regarding HER-2/neu status, select 'Test not ordered/no documentation.'

Enter information from the most recent test report.

Patients are classified as having HER-2 positive disease based on positive results with either test.

If the most recent report indicates insufficient sample, select 'Test ordered, insufficient sample for results.'

If a physician note and the HER-2/neu report differ in results, report the status in the physician note if the note explains the discrepancy. Otherwise, report the status from the HER-2/neu report.

Use the following definitions to determine HER-2/neu status:

Positive:

- IHC 3+ cell surface protein expression (defined as uniform intense membrane staining of >30% of invasive tumor cells) or
- FISH ratio >2.2 or
- HER2 gene copy >6.0

Equivocal:

- Not positive according to any of the criteria above, AND
- (IHC with scores 2+ AND FISH ratio 1.8-2.2) or
- HER2 gene copy 4.0-6.0

Negative:

- Not positive according to any of the criteria above, AND
- IHC 0 or 1+ or
- FISH ratio 1.8 or
- HER2 gene copy <4.0
- If the results indicate 'non-amplified', choose HER-2/neu negative.
- If the results indicate 'weakly positive', choose HER-2/neu positive.

New test ordered within 10 days of report of equivocal result: Respond 'Yes' if a new test was ordered within 10 days of oncologist review of the report with inconclusive results. Choose 'N/A' if the patient died or transferred out of the practice within 10 days of review of the report with inconclusive results or fewer than 10 days have passed.
If the chart documents that the pathologist has ordered a new test, respond 'Yes.'

S.7. Denominator Statement (Brief, narrative description of the target population being measured)

Adult women with breast cancer

S.8. Target Population Category (Check all the populations for which the measure is specified and tested if any):

S.9. Denominator Details (All information required to identify and calculate the target population/denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

Female

And

2 or more encounters at the reporting site

And

Age at diagnosis greater than or equal to 18 years

And

Breast cancer diagnosis [C50.01-, C50.11-, C50.21-, C50.31-, C50.41-, C50.51-, C50.61-, C50.81-, C50.91-]

Definitions

Encounter: Patients must have been first seen in the office by a medical oncology or hematology oncology practitioner for the cancer diagnosis eligible for inclusion within the 1-year time frame of the reporting period. Enter the most recent visit that occurred during the 6-month visit window before the abstraction date. This can include visits to other office sites within the practice only if the practice uses a common medical record and shares management of care for the patient. This does not include visits during which a practitioner wasn't seen (e.g., laboratory testing), inpatient consults/visits, phone or email consults, or visits to a surgeon or radiation oncologist.

S.10. Denominator Exclusions (Brief narrative description of exclusions from the target population)

None

S.11. Denominator Exclusion Details (All information required to identify and calculate exclusions from the denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

None

S.12. Stratification Details/Variables (All information required to stratify the measure results including the stratification variables, definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b)

Not applicable

S.13. Risk Adjustment Type (Select type. Provide specifications for risk stratification in S.12 and for statistical model in S.14-15)

No risk adjustment or risk stratification

If other:

S.14. Identify the statistical risk model method and variables (Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development and testing should be addressed with measure testing under Scientific Acceptability)

Not applicable

S.15. Detailed risk model specifications (must be in attached data dictionary/code list Excel or csv file. Also indicate if available at measure-specific URL identified in S.1.)

Note: Risk model details (including coefficients, equations, codes with descriptors, definitions), should be provided on a separate worksheet in the suggested format in the Excel or csv file with data dictionary/code lists at S.2b.

S.15a. Detailed risk model specifications (if not provided in excel or csv file at S.2b)

Not applicable

S.16. Type of score:

Rate/proportion

If other:

S.17. Interpretation of Score (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)

Better quality = Higher score

S.18. Calculation Algorithm/Measure Logic (Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)

Performance is calculated as:

1. Identify those patients that meet the denominator criteria defined in the measure.
2. Subtract those patients with a denominator exclusion from the denominator. Note: this measure does not have exclusions.
3. From the patients who qualify for the denominator (after any exclusions are removed), identify those who meet the numerator criteria.
4. Calculation: Numerator/Denominator-Denominator Exclusions

S.19. Calculation Algorithm/Measure Logic Diagram URL or Attachment (You also may provide a diagram of the Calculation Algorithm/Measure Logic described above at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)

No diagram provided

S.20. Sampling (If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)

IF a PRO-PM, identify whether (and how) proxy responses are allowed.

QOPI registry abstraction is offered twice a year to participating Medical Oncology and Hematology Oncology Practices. The minimum sample size for each data abstraction period is based on the number of med-onc and hem-onc FTEs at the practice and/or site level. For breast cancer, patients must be female, 18 years and older with a diagnosis of [C50.01-, C50.11-, C50.21-, C50.31-, C50.41-, C50.51-, C50.61-, C50.81-, C50.91-] within the one year diagnosis window applicable to the round. The practices follow a chart selection methodology which identify patients who had a diagnosis date within one year of the abstraction period start date AND had two office visits with a practitioner in the office within three months of the abstraction data period start date.

S.21. Survey/Patient-reported data (If measure is based on a survey, provide instructions for conducting the survey and guidance on minimum response rate.)

IF a PRO-PM, specify calculation of response rates to be reported with performance measure results.

Not applicable

S.22. Missing data (specify how missing data are handled, e.g., imputation, delete case.)

Required for Composites and PRO-PMs.

This measure is specified with defined criteria and data elements. If a patient record does not include one or more of these components for the initial patient population or denominator, then patients are not considered eligible for the measure and not

included.

If data to determine whether a patient should be considered for the numerator or exclusions is missing, then the numerator or exclusions not considered to be met and the practice will not get credit for meeting performance for that patient.

S.23. Data Source (Check ONLY the sources for which the measure is SPECIFIED AND TESTED).

If other, please describe in S.24.

Registry

S.24. Data Source or Collection Instrument (Identify the specific data source/data collection instrument e.g. name of database, clinical registry, collection instrument, etc.)

If a PRO-PM, identify the specific PROM(s); and standard methods, modes, and languages of administration.

ASCO Quality Oncology Practice Initiative (QOPI®)

S.25. Data Source or Collection Instrument (available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)

No data collection instrument provided

S.26. Level of Analysis (Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)

Clinician : Group/Practice

S.27. Care Setting (Check ONLY the settings for which the measure is SPECIFIED AND TESTED)

Clinician Office/Clinic

If other:

S.28. COMPOSITE Performance Measure - Additional Specifications (Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)

Not applicable

2a. Reliability – See attached Measure Testing Submission Form

2b. Validity – See attached Measure Testing Submission Form

1878_MeasureTesting_MS5.0_Data_Update.doc

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields? (i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields)

ALL data elements are in defined fields in electronic clinical data (e.g., clinical registry, nursing home MDS, home health OASIS)

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources.

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL.

[No feasibility assessment](#) Attachment:

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

IF a PRO-PM, consider implications for both individuals providing PROM data (patients, service recipients, respondents) and those whose performance is being measured.

[The measure and its specifications have been in place for several years and ASCO continues to monitor and ensure that the measure and its specifications are up-to-date for widespread use.](#)

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm).

[Not applicable](#)

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Planned	Current Use (for current use provide URL)
	Payment Program CMS Physician Quality Reporting Program Qualified Clinical Data Registry http://www.institutequality.org/qopi/pqrs-measures-0 Professional Certification or Recognition Program QOPI® Certification Program http://www.institutequality.org/qcp/qopi-certification-measures

4a.1. For each CURRENT use, checked above, provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included

[Quality Oncology Practice Initiative:](#)

[In 2002, the American Society of Clinical Oncology established the Quality Oncology Practice Initiative \(QOPI®\). QOPI® is a practice-based quality assessment and improvement program designed to foster a culture of self-examination and improvement in oncology.](#)

Collection rounds are offered twice per year, in spring and fall, for an eight week period. QOPI® continues to be a successful program in the United States and 12 other countries, with 441, 313, 361 and 256 unique practices participating in Fall 2013, Spring 2014, Spring 2015 and Fall 2015 respectively.

QOPI® Certification Program:

The QOPI® Certification Program provides a three-year certification for outpatient hematology-oncology practices. To obtain Certification, a practice must achieve an aggregate score above 75% adherence on 26 measures that count toward the overall Quality Score. Please see a description of the QOPI® program above for details.

PQRS Qualified Clinical Data Registry:

In addition to the current use for quality improvement with benchmarking in the QOPI® registry, this measure has been reported to CMS by the registry as a Qualified Clinical Data Registry. QOPI® was deemed as a registry for oncology measures group reporting and as a QCDR to report to PQRS in 2015 and 2016. Eligible professionals will be considered to have satisfactorily participated in PQRS if they submit quality measures data or results to CMS via a qualified clinical data registry. In Fall 2015, 36 practices and 3,124 patient charts were submitted to PQRS through QOPI. 2015 QCDR data will be publicly reported at the individual eligible professional level as a performance rate in the form of a percent for each measure. Beginning with 2016 data, both individual and group-level QCDR performance rates will be publicly reported.

4a.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?)

As described above, CMS is planning to publicly report QCDR data.

Additionally, although the measure is currently in use, we will continue to seek opportunities to advocate for expanded use of this measure in government or other programs.

4a.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.)

4b. Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b.1. Progress on Improvement. (Not required for initial endorsement unless available.)

Performance results on this measure (current and over time) should be provided in 1b.2 and 1b.4. Discuss:

- Progress (trends in performance results, number and percentage of people receiving high-quality healthcare)
- Geographic area and number and percentage of accountable entities and patients included

While performance continues to be generally high, some variation still remains as evidenced by the performance ranges by year and from the time of the last NQF endorsement review. The data available are based on QOPI® self selecting practices that voluntarily report data and may not be reflective of care provided outside of the QOPI® program.

Studies show that tumors of older female patients (15.7%) and Hispanics (20.7%) as well as other race/ethnicities (18.8%) are less likely to be tested for HER2 (Lund, 2010). In addition, data from reporting in the CMS PQRS program is not yet available but may provide additional information on overall performance scores on this measure in the near future.

Lund, M. J., E. N. Butler, et al. (2010). "Age/race differences in HER2 testing and in incidence rates for breast cancer triple subtypes: a population-based study and first report." *Cancer* 116(11): 2549-2559.

4b.2. If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of

initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

While performance continues to be generally high, some variation still remains as evidenced by the performance ranges by year and from the time of the last NQF endorsement review. The data available are based on QOPI® self selecting practices that voluntarily report data and may not be reflective of care provided outside of the QOPI® program.

Studies show that tumors of older female patients (15.7%) and Hispanics (20.7%) as well as other race/ethnicities (18.8%) are less likely to be tested for HER2 (Lund, 2010). In addition, data from reporting in the CMS PQRS program is not yet available but may provide additional information on overall performance scores on this measure in the near future.

Lund, M. J., E. N. Butler, et al. (2010). "Age/race differences in HER2 testing and in incidence rates for breast cancer triple subtypes: a population-based study and first report." *Cancer* 116(11): 2549-2559.

4c. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4c.1. Were any unintended negative consequences to individuals or populations identified during testing; OR has evidence of unintended negative consequences to individuals or populations been reported since implementation? If so, identify the negative unintended consequences and describe how benefits outweigh them or actions taken to mitigate them.

There have been no reports of unintended consequences with this measure.

5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

Yes

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

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

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

5a. Harmonization

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications completely harmonized?

Yes

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

Measure #1878 assesses whether HER2 testing was completed within 31 days of a breast cancer diagnosis. Meanwhile, NQF endorsed measure #1855 focuses on whether HER2 testing was completed according to current ASCO/CAP standards in the laboratory setting. As such, these measures address two complimentary components related to appropriate identification and treatment of breast cancer patients.

These measures also differ by data source. Measure #1878 is suited for registry data while Measure #1855 is suited for administrative claims and paper medical records data sources.

Because each measure has a different intent and uses a different data source, both measures should maintain their endorsement.

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

[Attachment](#) **Attachment:** [QOPI_Adoption_of_ICD10_020916.docx](#)

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): [American Society of Clinical Oncology](#)

Co.2 Point of Contact: [Tayyaba, Shehzadi](#), Tayyaba.Shehzadi@asco.org, 571-483-1673-

Co.3 Measure Developer if different from Measure Steward: [American Society of Clinical Oncology](#)

Co.4 Point of Contact: [Tayyaba, Shehzadi](#), Tayyaba.Shehzadi@asco.org, 571-483-1673-

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

[ASCO Breast Cancer Measure Development Panel](#)

The panel is responsible for reviewing and maintaining breast cancer measures

[Gary Lyman, MD, MPH, FASCO, FRCP](#)

Co-Chair

[Fred Hutchinson Cancer Research Center](#)

[Gabrielle Rocque, MD](#)

Co-Chair

[University of Alabama](#)

[Banu Arun, MD](#)

[University of Texas](#)

[MD Anderson Cancer Center](#)

[Gary Cohen, MD, FASCO](#)

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Michael Soble, MD
North Shore Oncology/Hematology Associates

Ann Von Gehr, MD
Permanente Medical Group Inc.

Antonio Wolff, MD, FACP, FASCO
Johns Hopkins Kimmel Cancer Center

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2007

Ad.3 Month and Year of most recent revision: 02, 2016

Ad.4 What is your frequency for review/update of this measure? q3years

Ad.5 When is the next scheduled review/update for this measure? 02, 2017

Ad.6 Copyright statement: The Measures are not clinical guidelines, do not establish a standard of medical care, and have not been tested for all potential applications.

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Ad.7 Disclaimers:

Ad.8 Additional Information/Comments: