NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

NQF #: 1855 **NQF Project:** Cancer Project

(for Endorsement Maintenance Review)
Original Endorsement Date: **Most Recent Endorsement Date:**

BRIEF MEASURE INFORMATION

De.1 **Measure Title:** Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

Co.1.1 **Measure Steward:** College of American Pathologists

De.2 **Brief Description of Measure:** 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.

2a1.1 **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 *

2a1.4 **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.")

2a1.8 **Denominator Exclusions:** None

1.1 **Measure Type:** Process
2a1. 25-26 **Data Source:** Administrative claims, Other, Paper Records
2a1.33 **Level of Analysis:** Clinician : Group/Practice, Clinician : Individual

1.2-1.4 **Is this measure paired with another measure?** No

De.3 **If included in a composite, please identify the composite measure** (*title and NQF number if endorsed*)**:**

STAFF NOTES (*issues or questions regarding any criteria*)

Comments on Conditions for Consideration:

Is the measure untested? **Yes**☐ **No**☐ **If untested, explain how it meets criteria for consideration for time-limited endorsement:**

1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (*check De.5*)**:**
5. Similar/related endorsed or submitted measures (*check 5.1*)**:**
Other Criteria:

Staff Reviewer Name(s):

1. IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence.
Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.
(evaluation criteria)

1a. High Impact: H☐ M☐ L☐ I ☐
(*The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.*)

De.4 **Subject/Topic Areas** *(Check all the areas that apply)*: Cancer, Cancer : Breast
De.5 **Cross Cutting Areas** (*Check all the areas that apply)*: Care Coordination, Safety : Medication Safety

1a.1 **Demonstrated High Impact Aspect of Healthcare:** Affects large numbers, A leading cause of morbidity/mortality, Frequently performed procedure, Patient/societal consequences of poor quality

1a.2 **If "Other," please describe:**

1a.3 **Summary of Evidence of High Impact** *(Provide epidemiologic or resource use data)*:
"Besides skin cancer, breast cancer is the most commonly diagnosed cancer among American women. Just under 30% of cancers in women are breast cancers." http://www.breastcancer.org/symptoms/understand_bc/statistics.jsp

Breast cancer is currently the most costly cancer to treat and impacts a very large patient population. HER2 testing assures that appropriate therapies are provided to patients most likely to benefit.

1a.4 **Citations for Evidence of High Impact cited in 1a.3:** U.S. Cancer Statistics Working Group. United States Cancer Statistics: 1999–2007 Incidence and Mortality Web-based Report. Atlanta (GA): Department of Health and Human Services, Centers for Disease Control and Prevention, and National Cancer Institute; 2010. Available at: http://www.cdc.gov/uscs. (full site)

US Breast Cancer statistics - http://www.breastcancer.org/symptoms/understand_bc/statistics.jsp

1b. Opportunity for Improvement: H☐ M☐ L☐ I ☐
(*There is a demonstrated performance gap - variability or overall less than optimal performance*)

1b.1 **Briefly explain the benefits (improvements in quality) envisioned by use of this measure:**
The ASCO/CAP Guideline recommendations for quantitative HER2 IHC evaluation were designed to enhance concordance with FISH assays for HER2 Amplified and Non-amplified tumor status. The recommendations are different from those provided by HER2 antibody manufacturers and compliance is likely to considerably less than 100%. Implementation of Guideline scoring would promote uniformity and quality among interpreting pathologists.

1b.2 **Summary of Data Demonstrating Performance Gap** *(Variation or overall less than optimal performance across providers)*:
[*For Maintenance* – *Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.***]**
A College of American Pathologists Survey of 757 Laboratories indicated that 84% of laboratories (605 of 722) use the ASCO/CAP scoring criteria.

1b.3 **Citations for Data on Performance Gap: [*For Maintenance* –** *Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included***]**
Nakhleh RE, Grimm EE, Idowu MO, Souers RJ, Fitzgibbons PL. Laboratory compliance with the American Society of Clinical Oncology/college of American Pathologists guidelines for human epidermal growth factor receptor 2 testing: a College of American Pathologists survey of 757 laboratories. Arch Pathol Lab Med. 2010 May;134(5):728-34.

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance –Descriptive statistics for performance results for this measure by population group*]
No data on disparities is available.

1b.5 Citations for Data on Disparities Cited in 1b.4: [*For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
Not applicable.

1c. Evidence (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the measure focus a health outcome? Yes☐ No☐ If not a health outcome, rate the body of evidence.

Quantity: H☐ M☐ L☐ I☐ Quality: H☐ M☐ L☐ I☐ Consistency: H☐ M☐ L☐ I☐

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	**Yes**☐
L	M-H	M	**Yes**☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise **No**☐
M-H	L	M-H	**Yes**☐ IF potential benefits to patients clearly outweigh potential harms: otherwise **No**☐
L-M-H	L-M-H	L	**No** ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	**Does the measure pass subcriterion1c?** **Yes**☐ IF rationale supports relationship

1c.1 Structure-Process-Outcome Relationship *(Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome)*:
The measure is focused on process with the goal of improving health outcomes for the target population (patients with suspected or confirmed breast cancer) by the use of standardized scoring methods.

1c.2-3 Type of Evidence *(Check all that apply)*:
Clinical Practice Guideline

1c.4 Directness of Evidence to the Specified Measure *(State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population)*:
The measure is based on the HER2 guidelines supported by evidence; however, we did not review the evidence used to develop the guideline during the measurement development process. The target of the measure is consistent with the guideline recommendations.

1c.5 Quantity of Studies in the Body of Evidence *(Total number of studies, not articles)*: The measure is based on a guideline.

1c.6 Quality of Body of Evidence (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events*): No information available at this time.

1c.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction of the effect):* No information available at this time.

1c.8 Net Benefit *(Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms)*:
Patients should receive more consistent and appropriate care with a standard approach to scoring the HER2 test results. The ASCO/CAP Guideline recommendations for quantitative HER2 IHC evaluation were designed to enhance concordance with FISH

assays for HER2 Amplified and Non-amplified tumor status. The recommendations are different from those provided by HER2 antibody manufacturers and compliance is likely to considerably less than 100%. Implementation of Guideline scoring would promote uniformity and quality among interpreting pathologists.

1c.9 **Grading of Strength/Quality of the Body of Evidence**. Has the body of evidence been graded? Yes

1c.10 **If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:** ASCO/CAP Update Committee

1c.11 **System Used for Grading the Body of Evidence:** Other

1c.12 **If other, identify and describe the grading scale with definitions:** A modification of the scale developed by the Canadian Task Force on the Periodic Health Examination and Expert Consensus were used

1c.13 **Grade Assigned to the Body of Evidence:** "The Update Committee has attempted to review tumor markers in reference to a Levels of Evidence framework, which defines the quality of the data on a given marker. Most published studies could be designated as Level of Evidence III (evidence from large but retrospective studies), which may generate hypotheses but are insufficient to change clinical practice. The Update Committee attempted, wherever possible, to base the updated recommendations on studies deemed to be Level of Evidence II (prospective therapeutic trials in which marker utility is a secondary study objective), or, ideally, Level of Evidence I (single, high-powered, prospective, randomized controlled trials specifically designed to test the utility of the marker or meta-analyses of well-designed studies)."
http://www.guideline.gov/content.aspx?id=11741&search=her2

1c.14 **Summary of Controversy/Contradictory Evidence:** No information available on controvery or contradictory evidence.

1c.15 **Citations for Evidence other than Guidelines*(Guidelines addressed below)*:**

1c.16 **Quote verbatim, <u>the specific guideline recommendation</u>** *(Including guideline # and/or page #)*:
"Positive HER2 test. – 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 … uniform intense membrane staining of >30% of invasive tumor cells… or FISH result of amplified HER2 gene copy number (average of > six gene copies/nucleus for test systems without internal control probe) or HER2/CEP 17 ratio of more than 2.2, where CEP 17 is a centromeric probe for chromosome 17 on which the HER2 gene resides. The 30% [criterion] for a positive IHC is further discussed in Appendix G."

From Appendix G:
"For IHC assays of HER2 protein expression, the original US Food and Drug Administration-approved interpretation guidelines provide insufficient specificity. Several experts, including those serving as central reviewers on clinical trials, have specified that a threshold of more than 30% of tumor (rather than the originally specified 10%) should show strong circumferential membrane staining for a positive result. This means that according to this guideline, strong circumferential staining of 30% or less of cells would be considered equivocal and be subjected to confirmatory FISH testing."

1c.17 **Clinical Practice Guideline Citation:** 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.

1c.18 **National Guideline Clearinghouse or other URL:** http://www.guideline.gov/content.aspx?id=11741&search=her2

1c.19 **Grading of Strength of Guideline Recommendation.** Has the recommendation been graded? No

1c.20 **If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:**

1c.21 **System Used for Grading the Strength of Guideline Recommendation:** Other

1c.22 If other, identify and describe the grading scale with definitions: Recommendations were not graded.

1c.23 Grade Assigned to the Recommendation: Not applicable.

1c.24 Rationale for Using this Guideline Over Others: The guideline used is the definitive guideline on HER2 testing.

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?
1c.25 Quantity: High **1c.26** Quality: High**1c.27** Consistency**:** High

Was the threshold criterion, *Importance to Measure and Report*, met?
(*1a & 1b must be rated moderate or high and 1c yes*) Yes☐ No☐
Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & 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. **(evaluation criteria)**
Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing.

S.1 Measure Web Page *(In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for this measure can be obtained? Yes

S.2 If yes, provide web page URL: http://www.cap.org/apps/docs/advocacy/pathology_performance_measurement.pdf

2a. RELIABILITY. Precise Specifications and Reliability Testing: H☐ M☐ L☐ I☐

2a1. Precise Measure Specifications. (*The measure specifications precise and unambiguous.*)

2a1.1 Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome)***:**
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 *

2a1.2 Numerator Time Window *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)***:**
Report once per patient per date of service

2a1.3 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, codes with descriptors, and/or specific data collection items/responses***:**
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:

- 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

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)***:**

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.")

2a1.5 Target Population Category *(Check all the populations for which the measure is specified and tested if any)*: Adult/Elderly Care

2a1.6 Denominator Time Window *(The time period in which cases are eligible for inclusion)*:
Each Event

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
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

- 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)

- 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.

- 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),....

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
None

2a1.9 Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
Not applicable

2a1.10 Stratification Details/Variables *(All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses)*:
Not applicable

2a1.11 Risk Adjustment Type *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13)*: No risk adjustment or risk stratification **2a1.12 If "Other," please describe:**

2a1.13 Statistical Risk Model and Variables *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.)*:
Not applicable

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score: Rate/proportion

2a1.19 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

2a1.20 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 Measure:
3394F + 3395F/
Claims identified by CPT code 88360 or 88361 and breast cancer ICD- 9 codes

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

2a1.24 Sampling (Survey) Methodology. If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):
Not applicable

2a1.25 Data Source *(Check all the sources for which the measure is specified and tested*). If other, please describe:
Administrative claims, Other, Paper Records

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): Data can be collectected from Pathology Report/Medical Records, Laboratory procedures and claims forms.

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment:

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested)*: Clinician : Group/Practice, Clinician : Individual

2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)*: Laboratory

2a2. Reliability Testing. (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.*)

2a2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)***:**
To be determined; testing in planning stages.

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)***:**
To be determined; testing in planning stages.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)***:**
To be determined; testing in planning stages.

2b. VALIDITY. Validity, Testing, including all Threats to Validity: H☐ M☐ L☐ I ☐

2b1.1 Describe how the measure specifications *(measure focus, target population, and exclusions)* **are consistent with the evidence cited in support of the measure focus (***criterion 1c)* **and identify any differences from the evidence:**
The measure is focused on providing results in a standardized manner to provide the clearest information for patient´s therapeutic decision-making.

2b2. Validity Testing. (*Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)*

2b2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)***:**
To be determined; testing in planning stages.

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)***:**
To be determined; testing in planning stages.

2b2.3 Testing Results *(Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment)***:**
To be determined; testing in planning stages.

POTENTIAL THREATS TO VALIDITY. (*All potential threats to validity were appropriately tested with adequate results.*)

2b3. Measure Exclusions. (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.*)

2b3.1 Data/Sample for analysis of exclusions *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)***:**
To be determined; testing in planning stages.

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference)***:**
To be determined; testing in planning stages.

2b3.3 Results *(Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):*
To be determined; testing in planning stages.

2b4. Risk Adjustment Strategy. (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

2b4.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)***:**
Not applicable.

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables)***:**
Not applicable.

2b4.3 **Testing Results** (*Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata*)**:**
Not applicable.

2b4.4 **If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment:** Not applicable.

2b5. Identification of Meaningful Differences in Performance. (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

2b5.1 **Data/Sample** (*Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*)**:**
To be determined.

2b5.2 **Analytic Method** (*Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance*)**:**
To be determined.

2b5.3 **Results** (*Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance*):
To be determined.

2b6. Comparability of Multiple Data Sources/Methods. (*If specified for more than one data source, the various approaches result in comparable scores.*)

2b6.1 **Data/Sample** (*Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*)**:**
To be determined.

2b6.2 **Analytic Method** (*Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure*)**:**
To be determined.

2b6.3 **Testing Results** (*Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted*)**:**
To be determined.

2c. Disparities in Care: H☐ M☐ L☐ I ☐ NA☐ (*If applicable, the measure specifications allow identification of disparities.*)

2c.1 **If measure is stratified for disparities, provide stratified results** (*Scores by stratified categories/cohorts*)**:** Not applicable.

2c.2 **If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:**
Not applicable.

2.1-2.3 **Supplemental Testing Methodology Information:**

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met?
(*Reliability and Validity must be rated moderate or high*) Yes☐ No☐
Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. **(evaluation criteria)**

C.1 **Intended Purpose/ Use** *(Check all the purposes and/or uses for which the measure is intended)*: Payment Program, Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

3.1 **Current Use** *(Check all that apply; for any that are checked, provide the specific program information in the following questions)*: Not in use

3a. Usefulness for Public Reporting: H☐ M☐ L☐ I ☐
(*The measure is meaningful, understandable and useful for public reporting.*)

3a.1. **Use in Public Reporting - disclosure of performance results to the public at large** *(If used in a public reporting program, provide name of program(s), locations, Web page URL(s)).* If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: **[*For Maintenance* –** *If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.***]**
The measure is also included in the CMS 2012 PQRS - https://www.cms.gov/PQRS/15_MeasuresCodes.asp#TopOfPage

CMS plans to use PQRS measures for public reporting.

3a.2.**Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting**. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results**:** This measure performance results provide meaningful information on whether standardized testing procedures are being used so that more consistent results are obtained.

3.2 **Use for other Accountability Functions (payment, certification, accreditation).** If used in a public accountability program, provide name of program(s), locations, Web page URL(s)**:** Three areas in the guidelines were also addressed with the addition of new CAP Laboratory Accreditation Program (LAP) checklist questions (ANP.22997, ANP.22998, and ANP.22999).6,9 These standards require laboratories to use the ASCO/CAP scoring criteria. However, the LAP does not use the particular specifications in the submitted measure.

CAP Laboratory Accreditation Program (LAP)
http://www.cap.org/apps/cap.portal?_nfpb=true&_pageLabel=accreditation

3b. Usefulness for Quality Improvement: H☐ M☐ L☐ I ☐
(*The measure is meaningful, understandable and useful for quality improvement.*)

3b.1. **Use in QI.** If used in quality improvement program, provide name of program(s), locations, Web page URL(s):
[*For Maintenance* – *If not used for QI, indicate the reasons and describe progress toward using performance results for improvement***]**.
The measure is included in the CMS 2012 PQRS - https://www.cms.gov/PQRS/15_MeasuresCodes.asp#TopOfPage

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated *(e.g., QI initiative),* describe the data, method and results:
CMS PQRS provides participating eligible professionals feedback reports on their performance.

Overall, to what extent was the criterion, *Usability*, met? H☐ M☐ L☐ I ☐
Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. **(evaluation criteria)**

4a. Data Generated as a Byproduct of Care Processes: H☐ M☐ L☐ I ☐

4a.1-2 How are the data elements needed to compute measure scores generated? *(Check all that apply).*
Data used in the measure are**:**
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition, Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry), Other Specified in laboratory protocols

4b. Electronic Sources: H☐ M☐ L☐ I ☐

4b.1 Are the data elements needed for the measure as specified available electronically *(Elements that are needed to compute measure scores are in defined, computer-readable fields)***:** Some data elements are in electronic sources

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources: CAP measure development team is working with SNOMED Terminology Solutions staff to determine how to electronically specify this measure.

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H☐ M☐ L☐ I ☐

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:
To be determined; testing in planning stages.

4d. Data Collection Strategy/Implementation: H☐ M☐ L☐ I ☐

A.2 Please check if either of the following apply (*regarding proprietary measures*)**:** Proprietary measure
4d.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 *(e.g., fees for use of proprietary measures)***:**
To be determined; testing in planning stages.

Overall, to what extent was the criterion, *Feasibility*, met? H☐ M☐ L☐ I ☐
Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes☐ No☐
Rationale:

If the Committee votes No, STOP.
If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND 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 before a final recommendation is made.

5.1 If there are related measures *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population)*, list the NQF # and title of all related and/or competing measures:
0391 : Breast Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade

5a. Harmonization

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

Are the measure specifications completely harmonized? No

5a.2 **If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:**
The CPT codes used to identify the denominator of the measure are different; the measures apply to differnet tests on the same target population.

5b. **Competing Measure(s)**

5b.1 **If this measure has 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)*:
No competing measures.

CONTACT INFORMATION

Co.1 **Measure Steward (Intellectual Property Owner):** College of American Pathologists, 1350 I St. NW Suite 590, Washington, District Of Columbia, 20005

Co.2 **Point of Contact:** Fay, Shamanski, PhD, fshaman@cap.org, 202-354-7113-

Co.3 **Measure Developer if different from Measure Steward:** College of American Pathologists, 1350 I St. NW Suite 590, Washington, District Of Columbia, 20005

Co.4 **Point of Contact:** Fay, Shamanski, PhD, fshaman@cap.org, 202-354-7113-

Co.5 **Submitter:** Fay, Shamanski, PhD, fshaman@cap.org, 202-354-7113-, College of American Pathologists

Co.6 **Additional organizations that sponsored/participated in measure development:**

Co.7 **Public Contact:** Fay, Shamanski, PhD, fshaman@cap.org, 202-354-7113-, College of American Pathologists

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 **Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**
David Witte, MD, PhD, FCAP (Chair)
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CAP Staff

Lynn Boyd
Janemarie Mulvey, PhD
Fay Shamanski, PhD
Ayanna Wooding

CAP Molecular Oncology Committee

Ad.2 **If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward:**

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.3 **Year the measure was first released:** 2008
Ad.4 **Month and Year of most recent revision:** 08, 2010
Ad.5 **What is your frequency for review/update of this measure?** The measure will be reviewed when new data or guidelines are available or every three years, whichev
Ad.6 **When is the next scheduled review/update for this measure?** 01, 2013

Ad.8 **Disclaimers:** 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.

Ad.9 **Additional Information/Comments:**

Date of Submission (*MM/DD/YY*)**:** 01/13/2012