

**Quality ID #251 (NQF 1855): Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients – National Quality Strategy**  
**Domain: Effective Clinical Care**

**2018 OPTIONS FOR INDIVIDUAL MEASURES:**  
**REGISTRY ONLY**

**MEASURE TYPE:**  
Process

**DESCRIPTION:**

This is a measure based on whether quantitative evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) by immunohistochemistry (IHC) uses the system recommended in the current ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer

**INSTRUCTIONS:**

This measure should be submitted **each time** a quantitative HER2 IHC pathology examination is performed during the performance period for patients with breast cancer; however, only one quality-data code (QDC) per date of service for a patient is required. This measure may be submitted by eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

**Measure Submission:**

The listed denominator criteria is used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions allowed by the measure. The quality-data codes listed do not need to be submitted for registry submissions; however, these codes may be submitted for those registries that utilize claims data.

**DENOMINATOR:**

All breast cancer patients with quantitative breast tumor evaluation by HER2 IHC

**Denominator Criteria (Eligible Cases):**

**Diagnosis for breast cancer (ICD-10-CM):** C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929

**AND**

**Patient procedure during the performance period (CPT):** 88360, 88361

**AND NOT**

**DENOMINATOR EXCLUSION:**

Quantitative non-HER2 IHC evaluation (eg, testing for estrogen or progesterone receptors, [ER/PR]) performed: 3395F

**NUMERATOR:**

Breast cancer patients receiving quantitative breast tumor HER2 IHC evaluation using the ASCO/CAP recommended manual system or a computer-assisted system consistent with the optimal algorithm for HER2 testing as described in the current ASCO/CAP guideline

**Numerator Options:**

***Performance Met:***

Quantitative HER2 by IHC evaluation consistent with scoring system defined in the ASCO/CAP guidelines (3394F)

**OR**

***Performance Not Met:***

Quantitative evaluation of HER2 did not use the system recommended in the ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer, reason not otherwise specified (3394F *with 8P*)

**RATIONALE:**

Through a cooperative effort with the American Society of Clinical Oncologists (ASCO) and the CAP, new guidelines for Human Epidermal Growth Factor 2 testing in breast cancer were published in January 2007 and then revised in 2013.

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 be considerably less than 100%. Implementation of Guideline scoring would promote uniformity and quality among interpreting pathologists.

- **Positive HER2 test. (p.2):** Must report a HER2 test result as positive if: (a) IHC 3p positive or (b) ISH positive using either a single-probe ISH or dual-probe ISH (Table 1; Figs 1 to 3). This assumes that there is no apparent histopathologic discordance observed by the pathologist (Table 2). (Wolff, A.C.,2013)
- **Equivocal HER2 test. (p.2):** Must report a HER2 test result as equivocal and order reflex test on the same specimen (unless the pathologist has concerns about the specimen) using the alternative test if: (a) IHC 2p equivocal or (b) ISH equivocal using single-probe ISH or dual-probe ISH (Table 1; Figs 1 to 3). This assumes that there is no apparent histopathologic discordance observed by the pathologist (Table 2). Note that there are some rare breast cancers (e.g., gland-forming tumors, micropapillary carcinomas) that show IHC 1p staining that is intense but incomplete (basolateral or U shaped) and that are found to be HER2 amplified. The pathologist should consider also reporting these specimens equivocal and request reflex testing using the alternative test. (Wolff, A.C.,2013)
- **Negative HER2 test. (p.2):** Must report a HER2 test result as negative if a single test (or all tests) performed on a tumor specimen show: (a) IHC 1p negative or IHC 0 negative or (b) ISH negative using single-probe ISH or dual-probe ISH (Table 1; Figs 1 to 3). This assumes that there is no apparent histopathologic discordance observed by the pathologist (Table 2). (Wolff, A.C.,2013)
- **Indeterminate HER2 test (p.2):** Must report a HER2 test result as indeterminate if technical issues prevent one or both tests (IHC and ISH) performed on a tumor specimen from being reported as positive, negative, or equivocal. This may occur if specimen handling was inadequate, if artifacts (crush or edge artifacts) make interpretation difficult, or if the analytic testing failed. Another specimen should be requested for testing, if possible, and a comment should be included in the pathology report documenting intended action. (Wolff, A.C.,2013)

**CLINICAL RECOMMENDATION STATEMENTS:**

"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".

"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.

#### ADD Reference

<sup>1</sup>Wolff, A.C., et al. American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Update Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer. *Arch Pathol Lab Med.* 31:3997 -4014, 2013)

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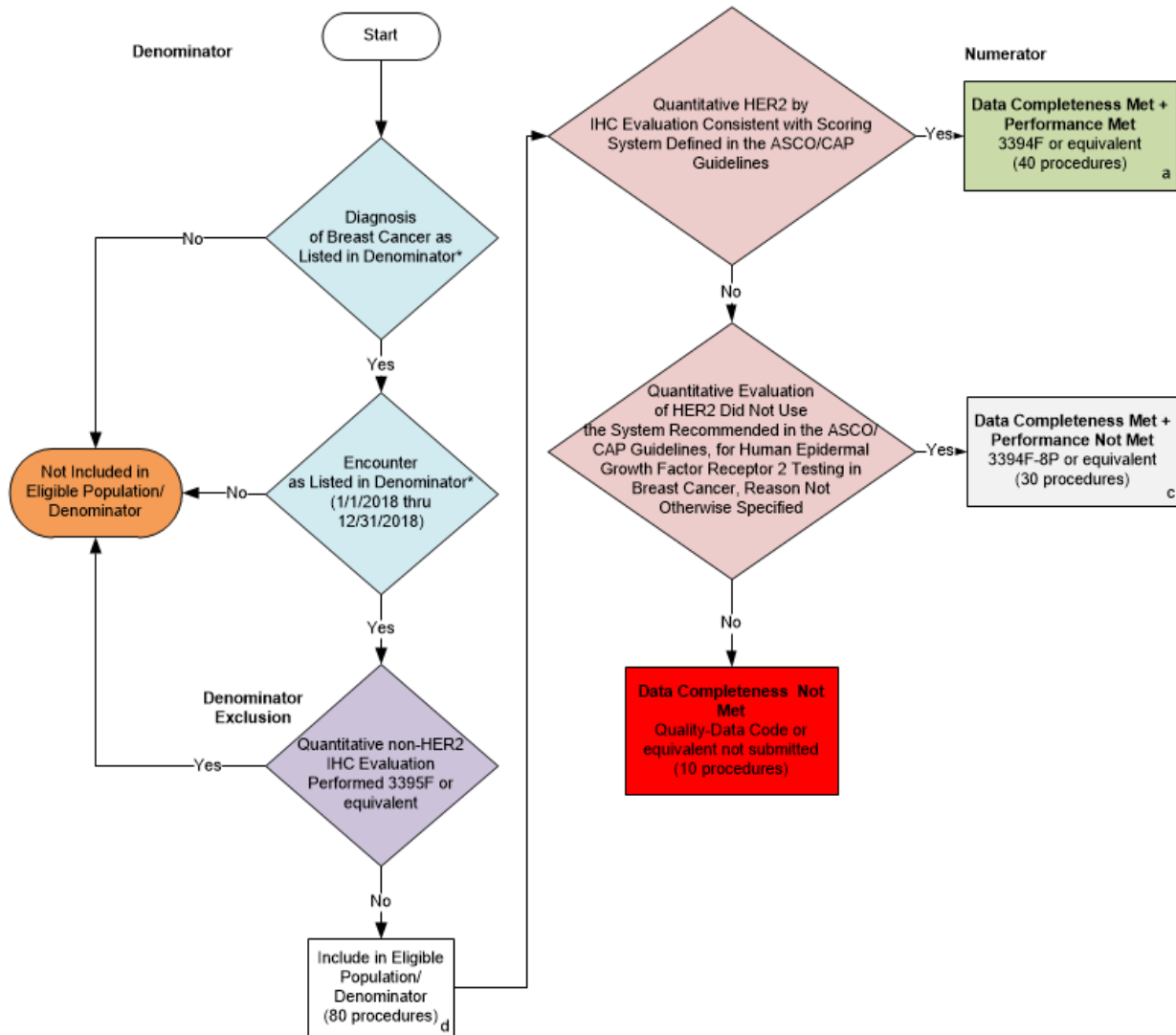
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**2018 Registry Flow for Quality ID #251 NQF #1855:  
Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2  
Testing (HER2) for Breast Cancer Patients**



**SAMPLE CALCULATIONS:**

**Data Completeness=**  

$$\frac{\text{Performance Met (a=40 procedures)} + \text{Performance Not Met (c=30 procedures)}}{\text{Eligible Population / Denominator (d=80 procedures)}} = \frac{70 \text{ procedures}}{80 \text{ procedures}} = 87.50\%$$

**Performance Rate=**  

$$\frac{\text{Performance Met (a=40 procedures)}}{\text{Data Completeness Numerator (70 procedures)}} = \frac{40 \text{ procedures}}{70 \text{ procedures}} = 57.14\%$$

\*See the posted Measure Specification for specific coding and instructions to submit this measure.

NOTE: Submission Frequency: Procedure

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The measure diagrams were developed by CMS as a supplemental resource to be used in conjunction with the measure specifications. They should not be used alone or as a substitution for the measure specification.

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## 2018 Registry Flow for Quality ID

### #251 NQF #1855: Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients

Please refer to the specific section of the specification to identify the denominator and numerator information for use in submitting this Individual Specification. This flow is for registry data submission.

1. Start with Denominator
2. Check Patient Diagnosis:
  - a. If Diagnosis of Breast Cancer as Listed in the Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
  - b. If Diagnosis of Breast Cancer as Listed in the Denominator equals Yes, proceed to check Procedure Performed.
3. Check Procedure Performed:
  - a. If Procedure as Listed in the Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
  - b. If Procedure as Listed in the Denominator equals Yes, proceed to check Quantitative non-HER2 by IHC Evaluation Performed, Denominator Exclusion.
4. Check Quantitative non-HER2 by IHC Evaluation Performed, Denominator Exclusion:
  - a. If Quantitative non-HER2 IHC Evaluation Performed equals Yes, do not include in Eligible Patient Population. Stop Processing.
  - b. If Quantitative non-HER2 IHC Evaluation Performed equals No, include in the Eligible Population.
5. Denominator Population
  - a. Denominator population is all Eligible Patients in the denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d equals 80 procedures in the Sample Calculation.
6. Start Numerator
7. Check Quantitative HER2 by IHC Evaluation Consistent with Scoring System Defined in the ASCO/CAP Guidelines:
  - a. If Quantitative HER2 by IHC Evaluation Consistent with Scoring System Defined in the ASCO/CAP Guidelines equals Yes, include in Data Completeness Met and Performance Met.
  - b. Data Completeness Met and Performance Met letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a equals 40 procedures in Sample Calculation.
  - c. If Quantitative HER2 by IHC Evaluation Consistent with Scoring System Defined in the ASCO/CAP Guidelines equals No, proceed to Check Quantitative Evaluation of HER2 Did Not Use the System Recommended in the ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer, Reason Not Specified.

8. Check Quantitative Evaluation of HER2 Did Not Use the System Recommended in the ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer, Reason Not Specified
  - a. If Quantitative Evaluation of HER2 Did Not Use the System Recommended in the ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer, Reason Not Specified equals Yes, include in the Data Completeness Met and Performance Not Met.
  - b. If Data Completeness Met and Performance Not Met letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c equals 30 procedures in the Sample Calculation.
  - c. If Quantitative Evaluation of HER2 Did Not Use the System Recommended in the ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer, Reason Not Specified equals No, proceed to Data Completeness Not Met.
9. Check Data Completeness Not Met
  - a. If Data Completeness Not Met equals No, Quality Data Code or equivalent not submitted. 10 procedures have been subtracted from Data Completeness Numerator in the Sample Calculation.