Measure #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

2016 PQRS OPTIONS FOR INDIVIDUAL MEASURES:
CLAIMS, REGISTRY

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

Measure Reporting via Claims:
ICD-10-CM diagnosis codes and CPT codes are used to identify patients who are included in the measure's denominator. CPT Category II codes are used to report the numerator of the measure.

When reporting the measure via claims, submit the listed ICD-10-CM diagnosis codes, CPT codes, and the appropriate CPT Category II code OR the CPT Category II code with the modifier. The modifiers allowed for this measure is: 8P- reason not otherwise specified. All measure-specific coding should be reported on the claim(s) representing the eligible encounter.

Measure Reporting via Registry:
ICD-10-CM diagnosis codes and CPT codes are used to identify patients who are included in the measure's denominator. The listed numerator options are used to report the numerator of the measure.

The quality-data codes listed do not need to be submitted for registry-based 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 encounter during the reporting period (CPT): 88360, 88361

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 NOTE: *Report CPT II quality data codes once per patient for each date-of-service.*

Numerator Quality-Data Coding Options for Reporting Satisfactorily:
Quantitative Evaluation of HER2 by IHC Performed
Performance Met: **CPT II 3394F:** Quantitative HER2 by IHC evaluation consistent with scoring system defined in the ASCO/CAP guidelines

OR

If patient is not eligible for this measure because quantitative non-HER2 IHC evaluation was performed (eg, testing for estrogen or progesterone, receptors, [ER/PR]) report:
Other Performance Exclusion: **CPT II 3395F:** Quantitative non-HER2 IHC evaluation (eg, testing for estrogen or progesterone receptors, [ER/PR]) performed

OR

Quantitative Evaluation of HER2 by IHC Performed but did not use the System Recommended in the ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer:
Append a reporting modifier (**8P**) to CPT Category II code **3394F** to report circumstances when the action described in the numerator is not performed and the reason is not otherwise specified.
Performance Not Met: **3394F *with* 8P:** 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

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 3þ positive or (b) ISH positive using either a single-probe ISH or dual-probeISH (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 2þ equivocal or (b) ISH equivocal using single-probe ISH or dual-probe ISH (Table 1; Figs 1 to 3). This assumes that there is no apparent histopathologic discordance observed by the pathologist (Table 2). Note that there are some rare breast cancers (eg, gland-forming tumors, micropapillary carcinomas) that show IHC 1þ 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 1þ 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.

COPYRIGHT:

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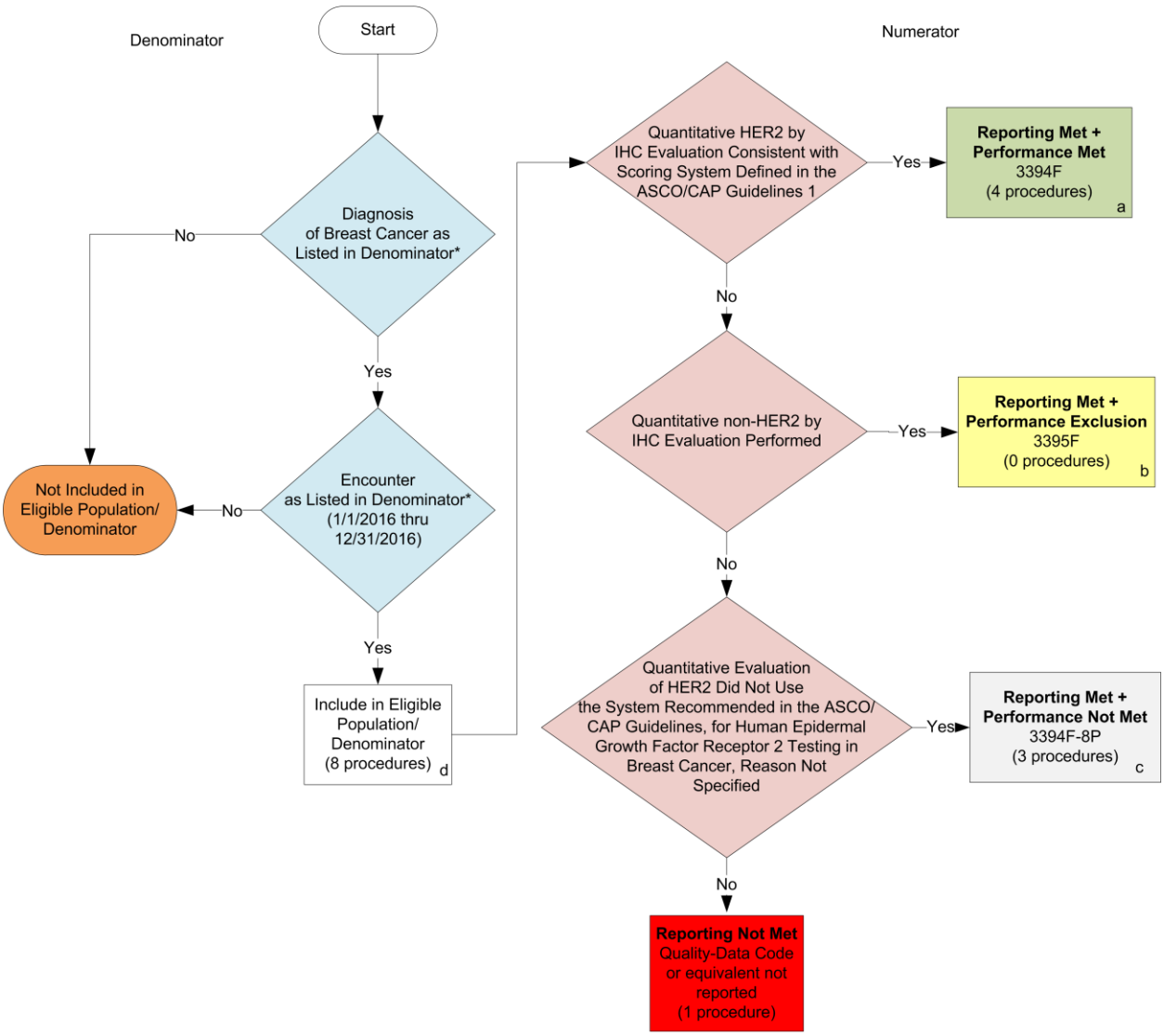


SAMPLE CALCULATIONS:

Reporting Rate=

Performance Met (a=4 procedures) + Performance Exclusion (b=0 procedures) + Performance Not Met (c=3 procedures) = 7 procedures = **87.50%**

Eligible Population / Denominator (d=8 procedures) = 8 procedures

Performance Rate=

Performance Met (a=4 procedures) = 4 procedures = **57.14%**

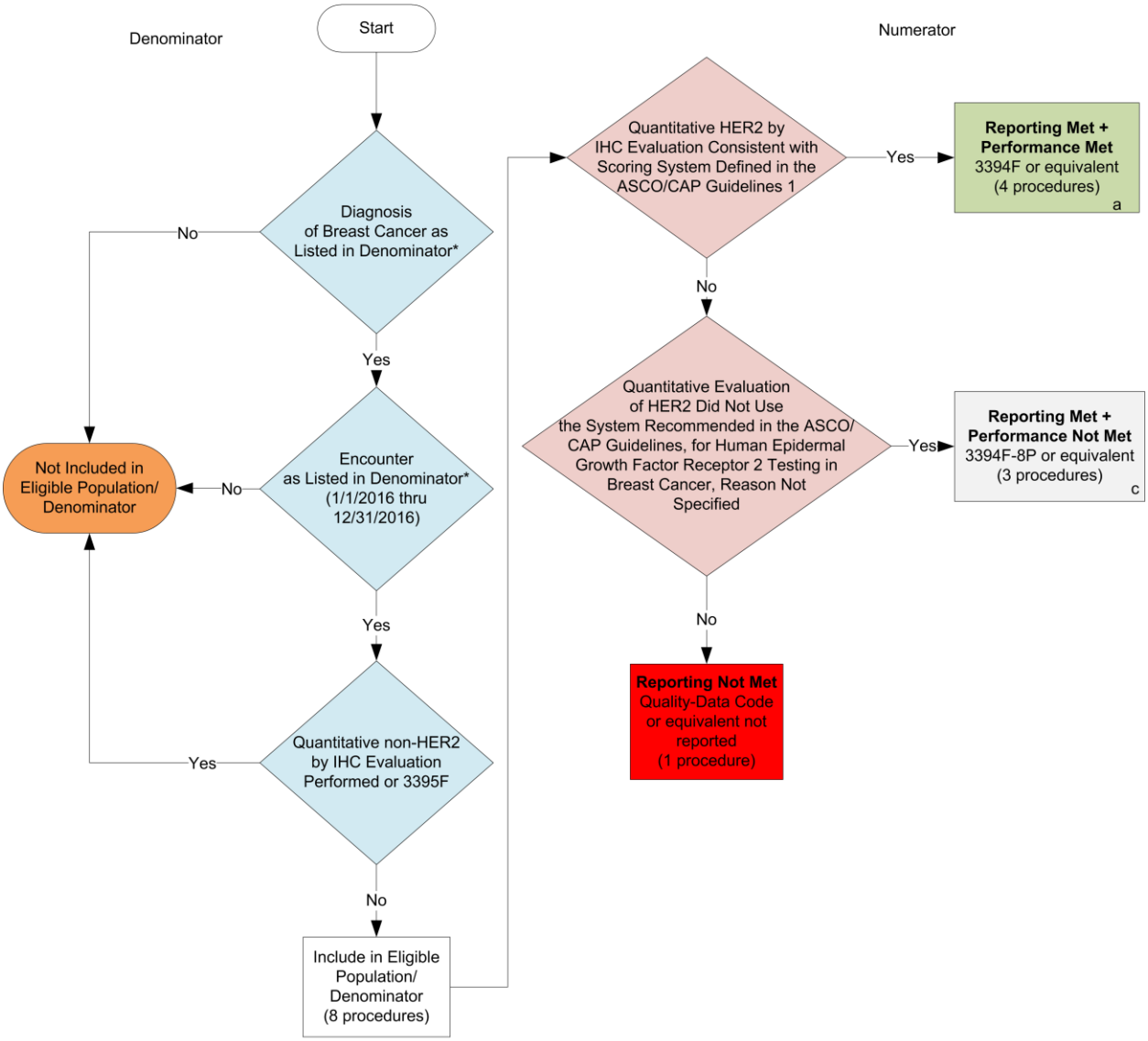
Reporting Numerator (7 procedures) - Performance Exclusion (b=0 procedures) = 7 procedures

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

NOTE: Reporting Frequency: Procedure

v2

2016 Registry Individual Measure Flow
PQRS #251 NQF #1855: Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients



SAMPLE CALCULATIONS:

Reporting Rate=

Performance Met (a=4 procedures) + Performance Not Met (c=3 procedures) = 7 procedures = **87.50%**
Eligible Population / Denominator (d=8 procedures) = 8 procedures

Performance Rate=

Performance Met (a=4 procedures) = 4 procedures = **57.14%**
Reporting Numerator (7 procedures) = 7 procedures

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

NOTE: Reporting Frequency: Procedure

v2

2016 Claims Individual Measure Flow
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Please refer to the specific section of the Measure Specification to identify the denominator and numerator information for use in reporting this Individual Measure.

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 Encour Performed.
3. Check Encounter Performed:
    a. If Encounter as Listed in the Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
    b. If Encounter as Listed in the Denominator equals Yes, include in the Eligible population.
4. 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 8 procedures in the sample calculation.
5. Start Numerator
6. Check Quantitative HER2 by IHC Evaluation Consistent with Scoring System Defined in the ASCO/CAP Guidelines 1:
    a. If Quantitative HER2 by IHC Evaluation Consistent with Scoring System Defined in the ASCO/CAP Guidelines1 equals Yes, include in Reporting Met and Performance Met.
    b. Reporting Met and Performance Met letter is represented in the Reporting Rate and Performance Rate in the Sample Calculation listed at the end of this document. Letter a equals 4 procedures in Sample Calculation.
    c. If Quantitative HER2 by IHC Evaluation Consistent with Scoring System Defined in the ASCO/CAP Guidelines 1 equals No, proceed to Check Quantitative non-HER2 by IHC Evaluation performed.

7. Check Quantitative non-HER2 by IHC Evaluation performed:

    a. If Quantitative non-HER2 by IHC Evaluation performed equals Yes, include in Reporting Met and Performance Exclusion.

    b. If Reporting Met and Performance Exclusion letter is represented in the Reporting Rate and Performance Rate in the Sample Calculation listed at the end of this document. Letter b equals 0 procedures in the Sample Calculation.

    c. If Quantitative non-HER2 by IHC Evaluation performed 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 H:ER2 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 Reporting Met and Performance Not Met.

    b. If Reporting Met and Performance Not Met letter is represented in the Reporting Rate in the Sample Calculation listed at the end of this document. Letter c equals 3 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 Check Reporting Not Met.

9. Check Reporting Not Met

    a. If Reporting Not Met equals No, Quality Data Code or equivalent not reported. 1 procedure has been subtracted from reporting numerator in the sample calculation.

SAMPLE CALCULATIONS:

Reporting Rate=

$$\frac{\text{Performance Met (a=4 procedures) + Performance Exclusion (b=0 procedures) + Performance Not Met (c=3 procedures)}}{\text{Eligible Population / Denominator (d=8 procedures)}} = \frac{\text{7 procedures}}{\text{8 procedures}} = \mathbf{87.50\%}$$

Performance Rate=

$$\frac{\text{Performance Met (a=4 procedures)}}{\text{Reporting Numerator (7 procedures) - Performance Exclusion (b=0 procedures)}} = \frac{\text{4 procedures}}{\text{7 procedures}} = \mathbf{57.14\%}$$

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Please refer to the specific section of the Measure Specification to identify the denominator and numerator information for use in reporting this Individual Measure.

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 Encounter Performed.
3. Check Encounter Performed:
    a. If Encounter as Listed in the Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
    b. If Encounter as Listed in the Denominator equals Yes, proceed to check Quantitative non-HER2 by IHC Evaluation Performed.
4. Check Quantitative non-HER2 by IHC Evaluation Performed:
    a. If Encounter as Listed in the Denominator equals Yes, do not include in Eligible Patient Population. Stop Processing.
    b. If Encounter as Listed in the Denominator 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 8 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 1:
    a. If Quantitative HER2 by IHC Evaluation Consistent with Scoring System Defined in the ASCO/CAP Guidelines1 equals Yes, include in Reporting Met and Performance Met.
    b. Reporting Met and Performance Met letter is represented in the Reporting Rate and Performance Rate in the Sample Calculation listed at the end of this document. Letter a equals 4 procedures in Sample Calculation.
    c. If Quantitative HER2 by IHC Evaluation Consistent with Scoring System Defined in the ASCO/CAP Guidelines 1 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 Reporting Met and Performance Not Met.

    b. If Reporting Met and Performance Not Met letter is represented in the Reporting Rate in the Sample Calculation listed at the end of this document. Letter c equals 3 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 Reporting Not Met.

9. Check Reporting Not Met

    a. If Reporting Not Met equals No, Quality Data Code or equivalent not reported. 1 procedure has been subtracted from reporting numerator in the sample calculation.

SAMPLE CALCULATIONS:

Reporting Rate=

$$\frac{\text{Performance Met (a=4 procedures) + Performance Not Met (c=3 procedures)}}{\text{Eligible Population / Denominator (d=8 procedures)}} = \frac{\text{7 procedures}}{\text{8 procedures}} = \mathbf{87.50\%}$$

Performance Rate=

$$\frac{\text{Performance Met (a=4 procedures)}}{\text{Reporting Numerator (7 procedures)}} = \frac{\text{4 procedures}}{\text{7 procedures}} = \mathbf{57.14\%}$$