Measure #449 (NQF 1857): HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies – National Quality Strategy Domain: Efficiency and Cost Reduction

2017 OPTIONS FOR INDIVIDUAL MEASURES:
REGISTRY ONLY

MEASURE TYPE:
Process

DESCRIPTION:
Proportion of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2)/neu negative who are not administered HER2-targeted therapies

INSTRUCTIONS:
This measure is to be reported a minimum of once per performance period for patients with breast cancer seen during the performance period. This measure may be reported by eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

Measure Reporting:
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-based submissions; however, these codes may be submitted for those registries that utilize claims data.

DENOMINATOR:
Adult women with breast cancer that are HER2 negative or HER2 undocumented

Definitions:
Use the following definitions to determine HER-2/neu status-
Positive:
IHC 3+ based on circumferential membrane staining that is complete, intense
ISH positive based on:

- Single-probe average HER2 copy number =6.0 signals/cell
- Dual-probe HER2/CEP17 ratio =2.0 with an average HER2 copy number =4.0 signals/cell
- Dual-probe HER2/CEP17 ratio =2.0 with an average HER2 copy number <4.0 signals/cell
- Dual-probe HER2/CEP17 ratio < 2.0 with an average HER2 copy number =6.0 signals/cell

Equivocal:

- IHC 2+ based on circumferential membrane staining that is incomplete and/or weak/moderate and within > 10% of the invasive tumor cells or complete and circumferential membrane staining that is intense and within = 10% of the invasive tumor cells

ISH equivocal based on:

- Single-probe ISH average HER2 copy number = 4.0 and < 6.0 signals/cell
- Dual-probe HER2/CEP17 ratio < 2.0 with an average HER2 copy number = 4.0 and < 6.0 signals/cell

Negative:
IHC 1+ as defined by incomplete membrane staining that is faint/barely perceptible and within > 10% of the invasive tumor cells or IHC 0 as defined by no staining observed or membrane staining that is incomplete and is faint/barely perceptible and within = 10% of the invasive tumor cells
ISH negative based on:

- Single-probe average HER2 copy number < 4.0 signals/cell
- Dual-probe HER2/CEP17 ratio < 2.0 with an average HER2 copy number < 4.0 signals/cell

Indeterminate:
Indeterminate if technical issues prevent one or both tests (IHC and ISH) from being reported as positive, negative, or equivocal.
Conditions may include:

- Inadequate specimen handling,
- Artifacts (crush or edge artifacts) that make interpretation difficult
- Analytic testing failure

Transferred to Practice:
Patients who have transferred to the reporting practice after the initiation of HER2 targeted therapy at another practice. This prevents practices from being held accountable for another practices' treatment decisions. The clinician submitting the measure should have initiated the treatment for the denominator eligible patient.

Denominator Criteria (Eligible Cases):
Female Patients aged ≥ 18 years on date of encounter
AND
Diagnosis of Breast Cancer (ICD-10-CM): C50.011, C50.012, C50.019, C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.311, C50.312, C50.319, C50.411, C50.412, C50.419, C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, C50.812, C50.819, C50.911, C50.912, C50.919
AND
Patient encounter during performance period (CPT): 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215
AND
Two or more encounters at the reporting site
AND
HER-2/neu Negative or Undocumented/Unknown: G9825
AND NOT
DENOMINATOR EXCLUSION:
Patient transferred to practice after initiation of chemotherapy: G9826

NUMERATOR:
HER2-targeted therapies not administered during the initial course of treatment

Numerator Options:

Performance Met:	HER2-targeted therapies not administered during the initial course of treatment (G9827)
OR	
Performance Not Met:	HER2-targeted therapies administered during the initial course of treatment (G9828)

RATIONALE:
Human epidermal growth factor receptor (HER2) gene is amplified and/or overexpressed in approximately 15% to 20% of primary breast cancers. The American Society of Clinical Oncology (ASCO) recognizes the importance of ensuring that the appropriate patient population receives guideline concordant treatment as studies have shown that the administration of HER2-targeted therapies such as Pertuzumab offer no clinical benefit to patients diagnosed with HER2 negative metastatic disease. Additionally, the contraindicated administration of HER2-targeted therapies to patients with HER2 negative breast cancer can propagate potentially toxic, costly and adverse effects and ultimately have a negative impact on the patient's quality of life. This measure aims to deter oncology providers from providing treatment (specifically HER-2 targeted therapies) to patients where this treatment may be contraindicated. Additionally, this measure will allow providers to assess their performance and serve as a basis for employing quality improvement initiatives as needed within practices.

CLINICAL RECOMMENDATION STATEMENTS:

HER2 gene is amplified and/or overexpressed in approximately 15% to 20% of primary breast cancers (Giordano, 2014). The ASCO/College of American Pathologists (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. Additionally data have shown that the administration of HER2-targeted therapies such as Pertuzumab offer no clinical benefit in patients with HER2 negative metastatic disease. Additionally, the guideline states HER2-targeted therapy should not be recommended if the HER2 test result is negative and there is no apparent histopathologic discordance with HER2 testing (Wolff, 2013).

The contraindicated administration of HER2-targeted therapy to patients with HER2 negative breast cancer can propagate potentially toxic, costly and adverse effects as well as decrease the patient's overall quality of life (Partridge, 2014).

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: Systemic Therapy for Patients with Advanced Human Epidermal Growth Factor Receptor 2- Positive Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline

Partridge, A.H., Smith, I.E., et. al., "Chemo- and Targeted Therapy for Women with Human Epidermal Growth Factor Receptor 2- Negative (or Unknown) Advanced Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline." J Onc Pr 11.1 (2014): 3307-3329. Available at: Chemo- and Targeted Therapy for Women with Human Epidermal Growth Factor Receptor 2- Negative (or Unknown) Advanced Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline

Wolff, A.C, Hammond, M.E.H, et.al., "Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Update." J Clin Onc 31.31 (2013): 3997-4013. Available at: Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Update

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2017 Registry Individual Measure Flow
#449 NQF #1857: HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies

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

NOTE: Reporting Frequency – Patient intermediate

v1

2017 Registry Individual Measure Flow
#449 NQF #1857: HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies

SAMPLE CALCULATIONS:

Data Completeness=

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

Performance Rate=

Performance Met (a = 4 patients) = 4 patients = **57.14%**
Data Completeness Numerator (7 patients) = 7 patients

*See the posted Measure Specification for specific coding and instructions to report this measure.
NOTE: Reporting Frequency – Patient intermediate

v1

2017 Registry Individual Measure Flow
#449 NQF #1857: HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2 – Targeted Therapies

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 Age:
    a. If Patient age is greater than or equal to 18 years equals No, do not include in Eligible Patient Population. Stop Processing.
    b. If Patient age is greater than or equal to 18 years equals Yes, proceed to check Patient Diagnosis for Colon or Rectal Cancer.
3. 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.
4. Check Encounter Performed:
    a. If Encounter Performed as Listed in the Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
    b. If Encounter Performed as Listed in the Denominator equals Yes, proceed to check Presence of Metastatic Disease Documented.
5. Check Two or more Encounters at the Reporting Site:
    a. If Two or more Encounters at the Reporting Site equals No, do not include in Eligible Patient Population. Stop Processing.
    b. If Two or more Encounters at the Reporting Site equals Yes, proceed to check HER-2/neu Negative or Undocumented/Unknown.
6. Check HER-2/neu Negative or Undocumented/Unknown:
    a. If HER-2/neu Negative or Undocumented/Unknown equals No, do not include in Eligible Patient Population. Stop Processing.
    b. If HER-2/neu Negative or Undocumented/Unknown equals Yes, proceed to check Patient Transfer to Practice after Initiation of Chemotherapy.
7. Check Patient Transfer to Practice after Initiation of Chemotherapy:
    a. If Patient Transfer to Practice after Initiation of Chemotherapy equals Yes, do not include in Eligible Patient Population. Stop Processing.

b. If Patient Transfer to Practice after Initiation of Chemotherapy equals No, include in Eligible population.

8. 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 patients in the sample calculation.

9. Start Numerator

10. Check HER2-Targeted Therapies Not Administered During the Initial Course of Treatment:

    a. If HER2-Targeted Therapies Not Administered During the Initial Course of Treatment 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 4 patients in Sample Calculation.

    c. If HER2-Targeted Therapies Not Administered During the Initial Course of Treatment equals No, proceed to HER2-Targeted Therapies Administered During the Initial Course of Treatment.

11. Check HER2-Targeted Therapies Administered During the Initial Course of Treatment:

    a. If HER2-Targeted Therapies Administered During the Initial Course of Treatment equals Yes, include in Data Completeness Met and Performance Not Met.

    b. 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 3 patients in the Sample Calculation.

    c. If HER2-Targeted Therapies Administered During the Initial Course of Treatment equals No, proceed to Data Completeness Not Met.

12. Check Data Completeness Not Met:

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

SAMPLE CALCULATIONS:

Data Completeness=

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

Performance Rate=

Performance Met (a = 4 patients) = 4 patients = **57.14%**
Data Completeness Numerator (7 patients) = 7 patients