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

2019 COLLECTION TYPE:
MIPS CLINICAL QUALITY MEASURES (CQMS)

MEASURE TYPE:
Process – High Priority

DESCRIPTION:
Percentage 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 submitted a minimum of **once per performance period** for patients with breast cancer seen during the performance period. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

Measure Submission Type:
Measure data may be submitted by individual MIPS eligible clinicians, groups, or third party intermediaries. The listed denominator criteria are used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions as allowed by the measure. The quality-data codes listed do not need to be submitted by MIPS eligible clinicians, groups, or third party intermediaries that utilize this modality for submissions; however, these codes may be submitted for those third party intermediaries that utilize Medicare Part B claims data. For more information regarding Application Programming Interface (API), please refer to the Quality Payment Program (QPP) website.

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' prior treatment decisions. The MIPS eligible 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 NOTE: *HER-2 targeted therapies are defined as Trastuzumab, Pertuzumab and TDM1.*

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).

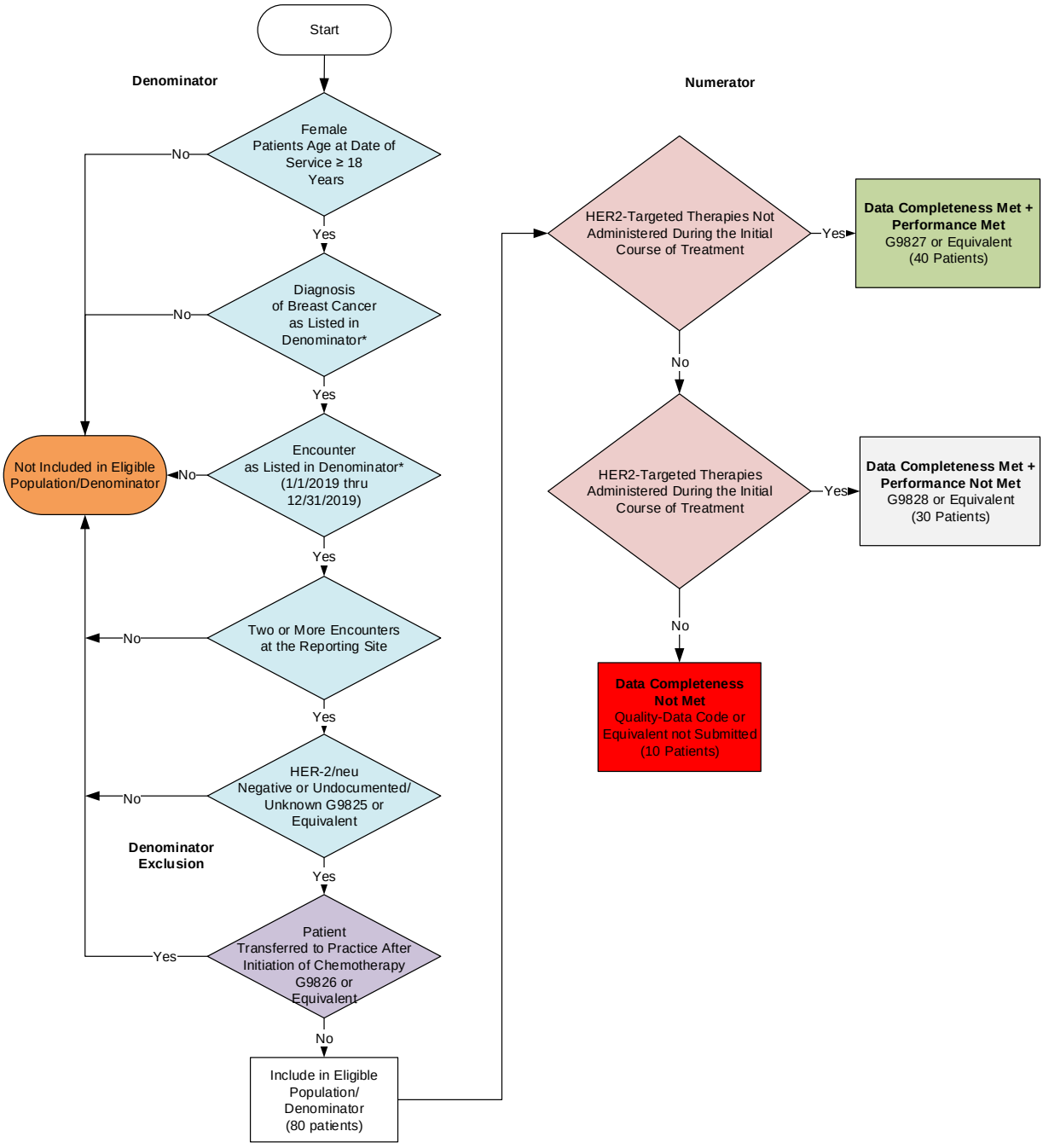
Giordano, S. H., Temin, S., et. al., "Systemic Therapy for Patients with Advanced Human Epidermal Growth Factor Receptor 2- Positive Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline." J Clin Onc 32. 19 (2014): 2078-099. Available at: Systemic Therapy for Patients with 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

COPYRIGHT:

2019 Clinical Quality Measure Flow for Quality ID #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 submit this measure.

NOTE: Submission Frequency – Patient intermediate

v3

2019 Clinical Quality Measure Flow for Quality ID #449 NQF #1857: HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies

SAMPLE CALCULATIONS:

Data Completeness=

Performance Met (a = 40 patients) + Performance Not Met (c = 30 patients) = 70 patients = **87.50%**
Eligible Population / Denominator (d = 80 patients) = 80 patients

Performance Rate=

Performance Met (a = 40 patients) = 40 patients = **57.14%**
Data Completeness Numerator (70 patients) = 70 patients

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

2019 Clinical Quality Measure Flow Narrative for Quality ID #449 NQF #1857: HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2 – Targeted Therapies

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

1. Start with Denominator
2. Check Female Patient Age:
    a. If Female Patient Age is greater than or equal to 18 Years equals No, do not include in Eligible Population. Stop Processing.
    b. If Female Patient Age is greater than or equal to 18 Years equals Yes, proceed to check Patient Diagnosis.
3. Check Patient Diagnosis:
    a. If Diagnosis of Breast Cancer as Listed in the Denominator equals No, do not include in Eligible 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 as Listed in the Denominator equals No, do not include in Eligible Population. Stop Processing.
    b. If Encounter as Listed in the Denominator equals Yes, proceed to check Two or more Encounters at the Reporting Site.
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 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 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 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 80 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 40 patients in the Sample Calculation.

    c. If HER2-Targeted Therapies Not Administered During the Initial Course of Treatment equals No, proceed to check 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 30 patients in the Sample Calculation.

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

12. Check Data Completeness Not Met:

    a. If Data Completeness Not Met, the Quality Data Code or equivalent was not submitted. 10 patients have been subtracted from the Data Completeness Numerator in the Sample Calculation.

SAMPLE CALCULATIONS:

Data Completeness=

Performance Met (a =40 patients) + Performance Not Met (c=30 patients) / Eligible Population / Denominator (d=80 patients) = 70 patients / 80 patients = **87.50%**

Performance Rate=

Performance Met (a = 40 patients) / Data Completeness Numerator (70 patients) = 40 patients / 70 patients = **57.14%**