Quality ID #450 (NQF 1858): Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer

2023 COLLECTION TYPE:
MIPS CLINICAL QUALITY MEASURES (CQMS)

MEASURE TYPE:
Process – High Priority

DESCRIPTION:
Percentage of female patients aged 18 to 70 with stage I (T1c) – III HER2 positive breast cancer for whom appropriate treatment is initiated.

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:
All female breast cancer patients aged 18 to 70 with stage I (T1c) – III HER2 positive breast cancer

Definitions:
Use the 2018 ASCO/CAP guideline definitions to determine HER2 status-
HER2 Positive:

- If result is IHC 3+ based on circumferential membrane staining that is complete, intense and in >10% of the invasive tumor cells
- If result is 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 = 6.0 signals/cell

HER2 Equivocal:

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

HER2 Negative:

- If result is IHC 1+ based on incomplete membrane staining that is faint/barely perceptible and in > 10% of the invasive tumor cells
- If result is IHC 0 based on no staining observed or membrane staining that is incomplete and is faint/barely perceptible and in ≤ 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

HER2 Indeterminate:

Report HER2 test result as 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.

Denominator Criteria (Eligible Cases):

Female Patients age 18-70 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

At least two patient encounters during performance period (CPT): 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215

WITHOUT

Telehealth Modifier (including but not limited to): GQ, GT, 95, POS 02

AND

HER-2/neu positive: G9830

AND

AJCC stage at breast cancer diagnosis = II or III: G9831

OR

AJCC stage at breast cancer diagnosis = I (IA or IB) and T-Stage at breast cancer diagnosis does NOT equal = T1, T1a, T1b: G9832

AND NOT

DENOMINATOR EXCLUSION:

Patients with pregnancy during adjuvant treatment course: G2205

NUMERATOR:

Patients whose adjuvant treatment course includes both chemotherapy and HER2-targeted therapy

NUMERATOR NOTE: *The quality action of this measure is the appropriateness of treatment rather than timeliness of treatment. The timing of administration of HER2-targeted therapies is expected to vary depending on the cytotoxic agents used. The numerator statement is intended to capture an adjuvant treatment course that includes both chemotherapy and HER2-targeted therapy, independent of possible administration sequences. Adjuvant chemotherapy is defined as a chemotherapy regimen initiated within six months of cancer diagnosis. An FDA-approved trastuzumab biosimilar is an appropriate substitute for trastuzumab.*

Numerator Options:

Performance Met: Patient received adjuvant treatment course

		including both chemotherapy and HER2-targeted therapy **(G2206)**
OR		
	Denominator Exception:	Reason for not administering adjuvant treatment course including both chemotherapy and HER2-targeted therapy (e.g. poor performance status (ECOG 3-4; Karnofsky ≤50), cardiac contraindications, insufficient renal function, insufficient hepatic function, other active or secondary cancer diagnoses, other medical contraindications, patients who died during initial treatment course or transferred during or after initial treatment course) **(G2207)**
OR		
	Performance Not Met:	Patient did not receive adjuvant treatment course including both chemotherapy and HER2-targeted therapy **(G2208)**

RATIONALE:

Approximately 15% of patients with breast cancer have tumors that overexpress the human epidermal growth hormone receptor protein (HER2). All of the adjuvant trials of trastuzumab have demonstrated clinically significant improvements in DFS. The benefits of trastuzumab are independent of estrogen receptor (ER)status. The American Society of Clinical Oncology (ASCO) envisions that use of this measure will improve concordance with recommendations for the use of HER2-targeted therapy with chemotherapy for patients with stage I (T1c) – III, HER2 positive breast cancer. We recognize the importance of ensuring that the appropriate patient population receives guideline concordant treatment as studies have shown that the administration of HER2-targeted therapies significantly improves overall survival in patients with high-risk HER2 positive breast cancer (NCCN 2022).

CLINICAL RECOMMENDATION STATEMENTS:

NCCN Recommendation for Adjuvant HER2-Targeted Therapy

The panel recommends HER2-targeted therapy in patients with HER2-positive tumors. Trastuzumab is a humanized monoclonal antibody with specificity for the extracellular domain of HER2. The panel has designated use of trastuzumab with chemotherapy as a category 1 recommendation in patients with HER2-positive tumors greater than 1 cm (NCCN 2022).

References:

1. Gradishar WJ, Moran MS,, Abraham J, et al. NCCN Guidelines Panel. NCCN Clinical Practice Guidelines in Oncology – Breast Cancer. Version 2.2022. December 20, 2021. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf

2. Wolff AC, Hammond MEH, Allison KH, Harvey BE, Mangu PB, Bartlett JMS, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. J Clin Oncol. 2018 Jul 10; 36(20):2105-2122.

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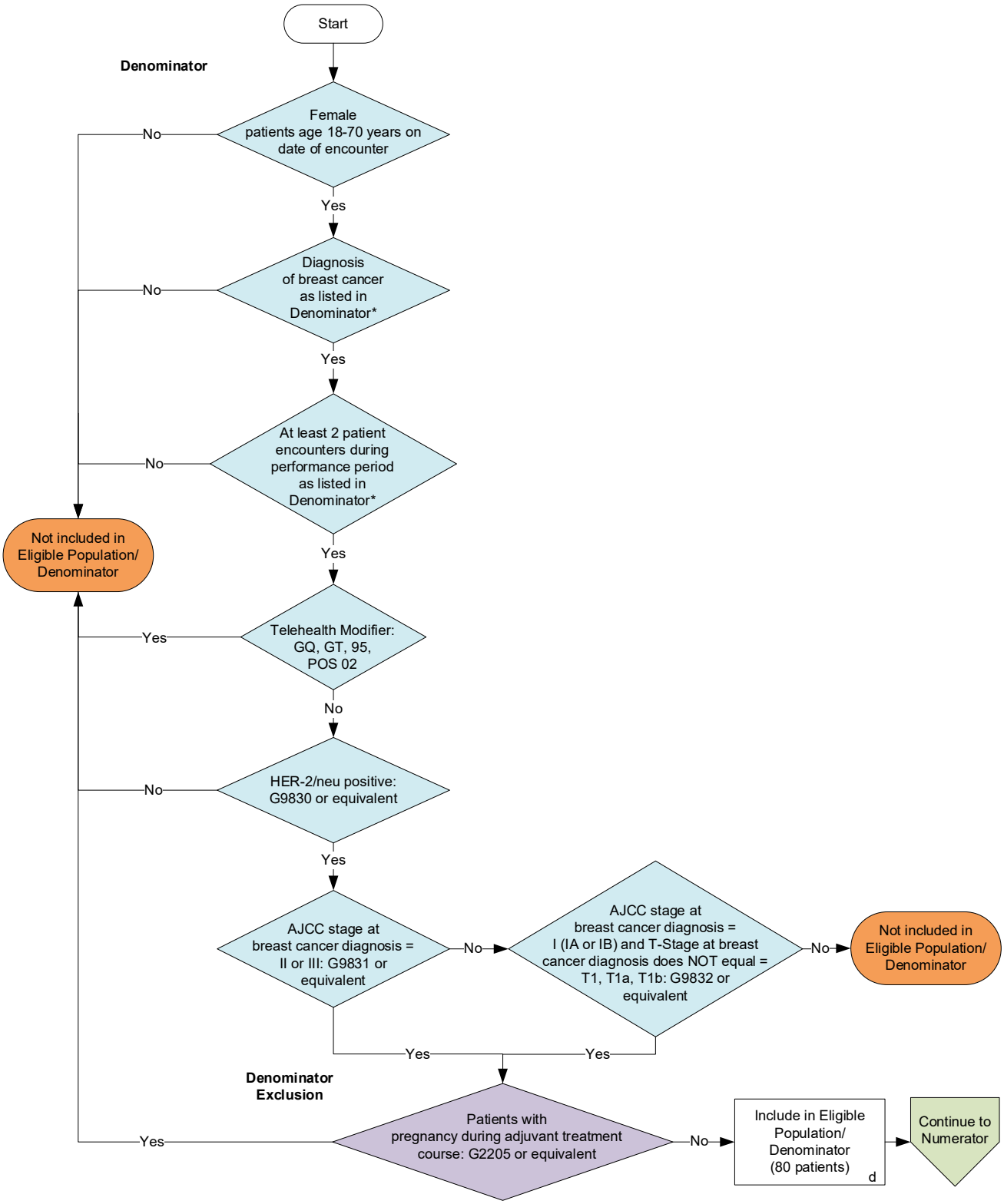
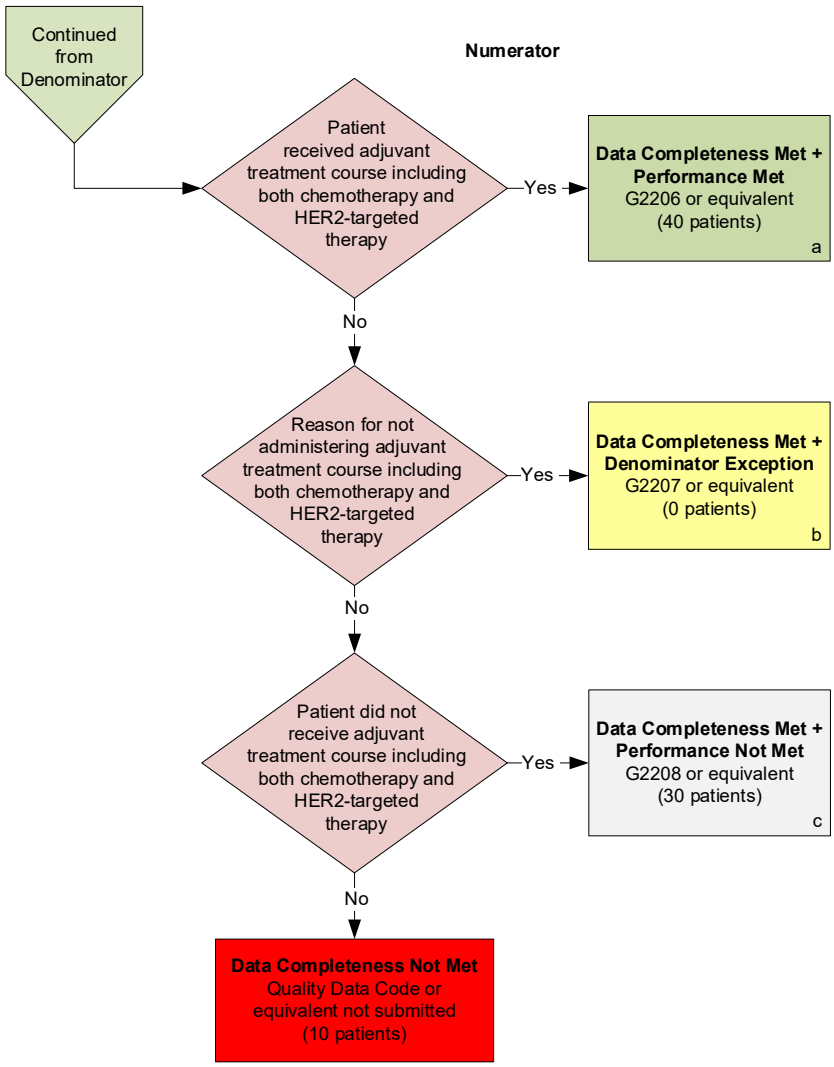
2023 Clinical Quality Measure Flow for Quality ID #450 (NQF 1858): Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer

Disclaimer: *Refer to the measure specification for specific coding and instructions to submit this measure.*





SAMPLE CALCULATIONS

Data Completeness=

Performance Met (a=40 patients) + Denominator Exception (b=0 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) – Denominator Exception (b=0 patients) = 70 patients

*See the posted measure specification for specific coding and instructions to submit this measure.
NOTE: Submission Frequency: Patient-Periodic
NOTE: Telehealth modifiers include **but are not limited to**: GQ, GT, 95, POS 02

v7

2023 Clinical Quality Measure Flow Narrative for Quality ID #450 (NQF 1858): Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer

Disclaimer: *Refer to the measure specification for specific coding and instructions to submit this measure.*

1. Start with Denominator
2. Check *Female patients age 18-70 years on date of encounter*:
    a. If *Female patients age 18-70 years on date of encounter* equals No, do not include in *Eligible Population/Denominator*. Stop processing.
    b. If *Female patients age 18-70 years on date of encounter* equals Yes, proceed to check *Diagnosis of breast cancer as listed in Denominator**.
3. Check *Diagnosis of breast cancer as listed in Denominator**:
    a. If *Diagnosis of breast cancer as listed in Denominator** equals No, do not include in *Eligible Population/Denominator*. Stop processing.
    b. If *Diagnosis of breast cancer as listed in Denominator** equals Yes, proceed to check *At least 2 patient encounters during performance period as listed in Denominator*.*
4. Check *At least 2 patient encounters during performance period as listed in Denominator**:
    a. If *At least 2 patient encounters during performance period as listed in Denominator** equals No, do not include in *Eligible Population/Denominator*. Stop processing.
    b. If *At least 2 patient encounters during performance period as listed in Denominator** equals Yes, proceed to check *Telehealth Modifier*.
5. Check *Telehealth Modifier*:
    a. If *Telehealth Modifier* equals Yes, do not include in *Eligible Population/Denominator*. Stop processing.
    b. If *Telehealth Modifier* equals No, proceed to check *HER-2/neu positive*.
6. Check *HER-2/neu positive*:
    a. If *HER-2/neu positive* equals No, do not include in *Eligible Population/Denominator*. Stop processing.
    b. If *HER-2/neu positive* equals Yes, proceed to check *AJCC stage at breast cancer diagnosis = II or III*.
7. Check *AJCC stage at breast cancer diagnosis = II or III*:
    a. If *AJCC stage at breast cancer diagnosis = II or III* equals No, proceed to check *AJCC stage at breast cancer diagnosis = I (IA or IB) and T-Stage at breast cancer diagnosis does NOT equal = T1, T1a, T1b.*
    b. If *AJCC stage at breast cancer diagnosis = II or III* equals Yes, proceed to check *Patients with pregnancy during adjuvant treatment course*.
8. Check *AJCC stage at breast cancer diagnosis = I (IA or IB) and T-Stage at breast cancer diagnosis does NOT equal = T1, T1a, T1b.*
    a. If *AJCC stage at breast cancer diagnosis = I (IA or IB) and T-Stage at breast cancer diagnosis does*

NOT equal = T1, T1a, T1b equals No, do not include in *Eligible Population/Denominator*. Stop processing.

b. If *AJCC stage at breast cancer diagnosis = I (IA or IB) and T-Stage at breast cancer diagnosis does NOT equal = T1, T1a, T1b* equals Yes, proceed to check *Patients with pregnancy during adjuvant treatment course*.

9. Check *Patients with pregnancy during adjuvant treatment course*:

   a. If *Patients with pregnancy during adjuvant treatment course* equals No, include in *Eligible Population/Denominator.*

   b. If *Patients with pregnancy during adjuvant treatment course* equals Yes, do not include in *Eligible Population/Denominator*. Stop processing.

10. Denominator Population:

    - 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.

11. Start Numerator

12. Check *Patient received adjuvant treatment course including both chemotherapy and HER2-targeted therapy*:

    a. If *Patient received adjuvant treatment course including both chemotherapy and HER2-targeted therapy* equals Yes, include in *Data Completeness Met and Performance Met*.

       - *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.

    b. If *Patient received adjuvant treatment course including both chemotherapy and HER2-targeted therapy* equals No, proceed to check *Reason for not administering adjuvant treatment course including both chemotherapy and HER2-targeted therapy*.

13. Check *Reason for not administering adjuvant treatment course including both chemotherapy and HER2-targeted therapy*:

    a. If *Reason for not administering adjuvant treatment course including both chemotherapy and HER2-targeted therapy* equals Yes, include in *Data Completeness Met and Denominator Exception*.

       - *Data Completeness Met and Denominator Exception* letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter b equals 0 patients in the Sample Calculation.

    b. If *Reason for not administering adjuvant treatment course including both chemotherapy and HER2-targeted therapy* equals No, proceed to check *Patient did not receive adjuvant treatment course including both chemotherapy and HER2-targeted therapy*.

14. Check *Patient did not receive adjuvant treatment course including both chemotherapy and HER2-targeted therapy*:

    a. If *Patient did not receive adjuvant treatment course including both chemotherapy and HER2-targeted therapy* equals Yes, include in *Data Completeness Met and Performance*

Not Met.

- *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.

b. If *Patient did not receive adjuvant treatment course including both chemotherapy and HER2-targeted therapy* equals No, proceed to check *Data Completeness Not Met*.

15. 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 equals Performance Met (a equals 40 patients) plus Denominator Exception (b equals 0 patients) plus Performance Not Met (c equals 30 patients) divided by Eligible Population/Denominator (d equals 80 patients). All equals 70 patients divided by 80 patients. All equals 87.50 percent.

Performance Rate equals Performance Met (a equals 40 patients) divided by Data Completeness Numerator (70 patients) minus Denominator Exception (b equals 0 patients). All equals 40 patients divided by 70 patients. All equals 57.14 percent.

*See the posted measure specification for specific coding and instructions to submit this measure.

NOTE: Submission Frequency: Patient-Periodic

NOTE: Telehealth modifiers include **but are not limited to**: GQ, GT, 95, POS 02

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.