

**Quality ID #450 (NQF 1858): Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy**  
– National Quality Strategy Domain: Effective Clinical Care  
– Meaningful Measure Area: Appropriate Use of Healthcare

**2020 COLLECTION TYPE:**  
**MIPS CLINICAL QUALITY MEASURES (CQMS)**

**MEASURE TYPE:**  
Process – High Priority

**DESCRIPTION:**  
Percentage of female patients (aged 18 years and older) with AJCC stage I (T1c) – III, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant chemotherapy who are also receiving Trastuzumab

**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 AJCC stage I (T1c) – III, HER2 positive breast cancer who receive adjuvant chemotherapy

**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  $\geq 6.0$  signals/cell
  - Dual-probe HER2/CEP17 ratio  $\geq 2.0$  with an average HER2 copy number  $\geq 4.0$  signals/cell
  - Dual-probe HER2/CEP17 ratio  $< 2.0$  with an average HER2 copy number  $\geq 6.0$  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  $\geq 4.0$  and  $< 6.0$  signals/cell
    - Dual-probe HER2/CEP17 ratio  $< 2.0$  with an average HER2 copy number  $\geq 4.0$  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  $\leq$  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 aged  $\geq$  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**

**Breast Adjuvant Chemotherapy administered:** G9829

**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 EXCLUSIONS:**

**Patient transfer to practice after initiation of chemotherapy:** G9833

**OR**

**Patient has metastatic disease at diagnosis:** G9834

**NUMERATOR:**

Trastuzumab administered within 12 months of diagnosis

**NUMERATOR NOTE:** Performance may also be met with administration of an FDA-approved biosimilar. If Trastuzumab (or FDA-approved biosimilar) was not administered within 12 months of diagnosis, the presence of the denominator exception should be examined during that same time period.

**Numerator Options:*****Performance Met:***

Trastuzumab administered within 12 months of diagnosis (**G9835**)

**OR**

***Denominator Exception:***

Reason for not administering Trastuzumab documented (e. g. patient declined, patient died, patient transferred, contraindication or other clinical exclusion, neoadjuvant chemotherapy or radiation NOT complete) (**G9836**)

**OR**

***Performance Not Met:***

Trastuzumab not administered within 12 months of diagnosis (**G9837**)

**RATIONALE:**

Approximately 15% of patients with breast cancer have tumors that overexpress the human epidermal growth hormone receptor protein (HER2). The American Society of Clinical Oncology (ASCO) envisions that use of this measure will improve concordance with recommendations for Trastuzumab administration for patients with AJCC stage I(T1c) – III, HER2/neu 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 Trastuzumab significantly improves overall survival in patients with high-risk HER2 positive breast cancer.

**CLINICAL RECOMMENDATION STATEMENTS:**

Cancer Care Ontario guideline on optimal systemic therapy for early breast cancer in women.

Trastuzumab plus chemotherapy is recommended for all patients with her2-positive, node-positive breast cancer and for patients with her2-positive, node-negative breast cancer greater than 1 cm in size. *Key Evidence and Qualifying Statements:* Phase iii clinical studies have demonstrated improved DFS and OS with the addition of trastuzumab to chemotherapy (compared with chemotherapy alone) in her2-positive early breast cancer.

**References:**

1. Eisen, A., K. G, Fletcher, et. al, "Optimal Systemic Therapy for Early Breast Cancer in Women: A Clinical Practice Guideline." Curr Onc 22. 0 (2014): Available at: [Optimal Systemic Therapy for Early Breast Cancer in Women: A Clinical Practice Guideline](#)
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.

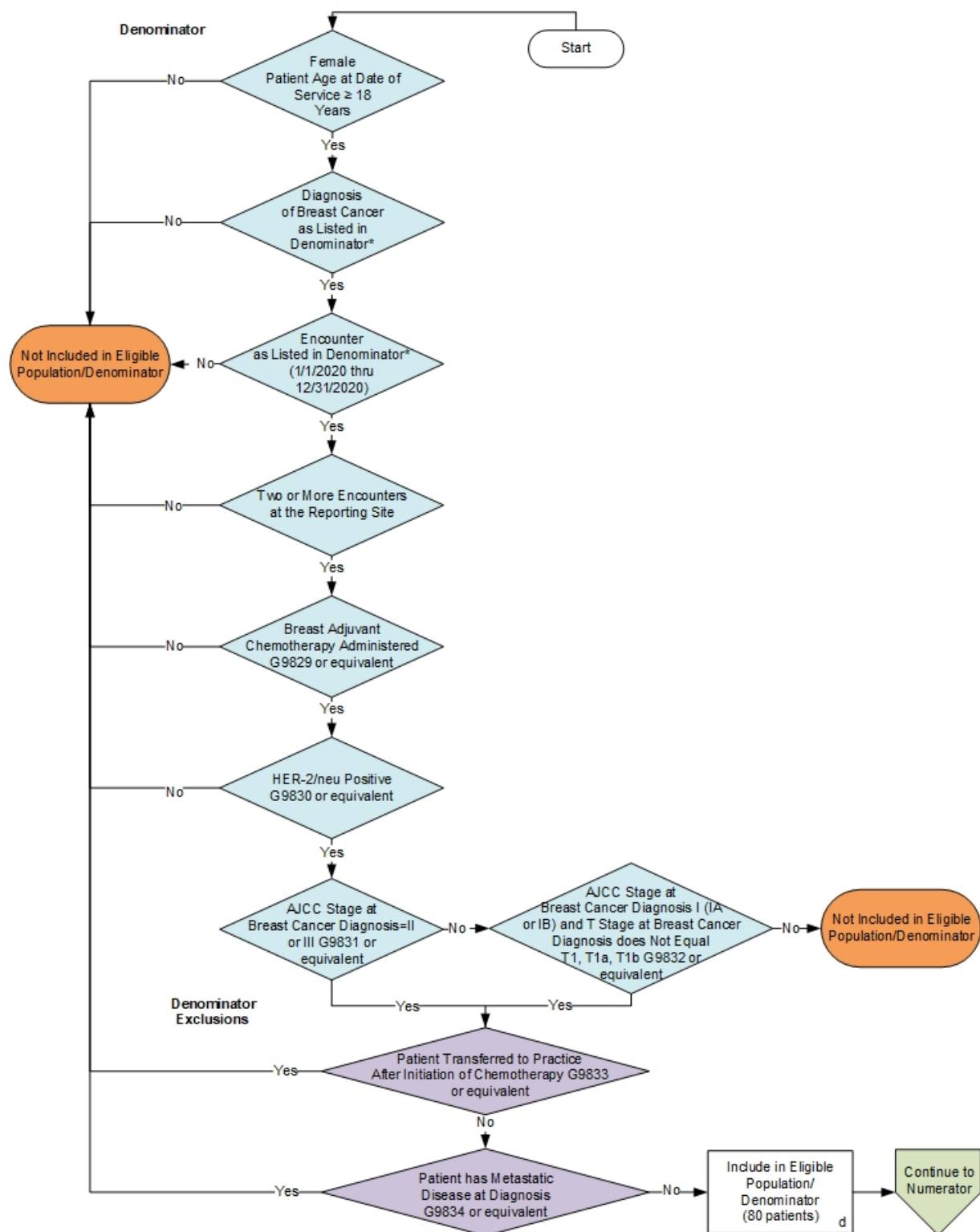
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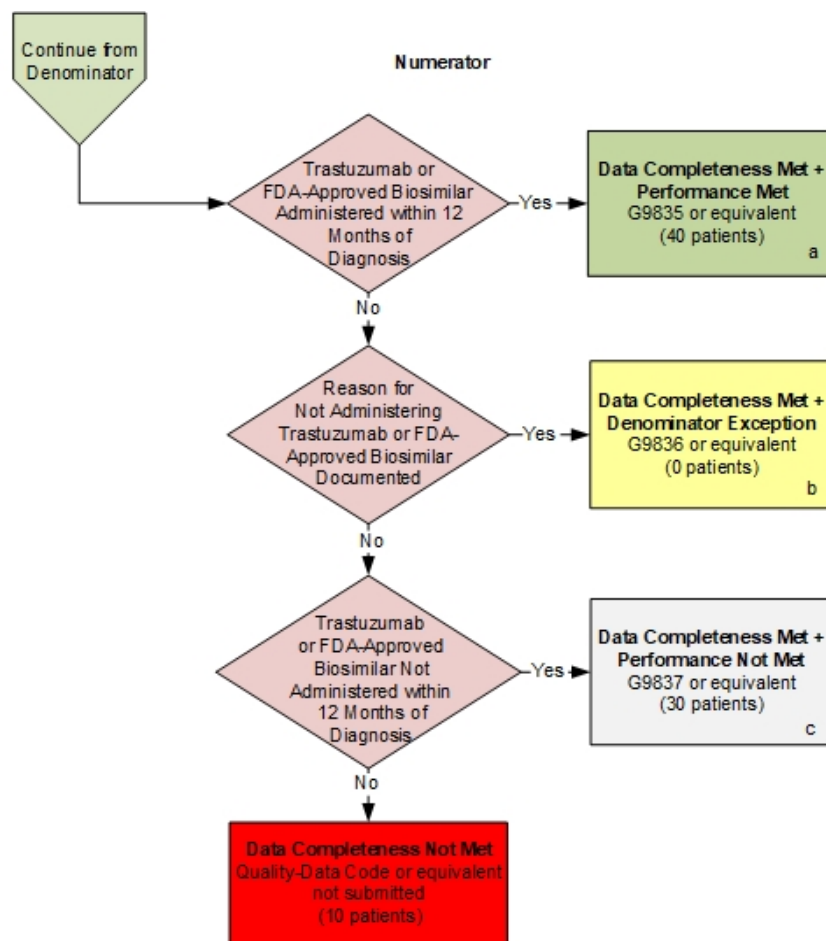
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**2020 Clinical Quality Measure Flow for Quality ID #450 NQF #1858:  
Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer  
Receiving Adjuvant Chemotherapy**

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





#### **SAMPLE CALCULATIONS:**

**Data Completeness=**

$$\frac{\text{Performance Met (a=40 patients)} + \text{Denominator Exception (b=0 patients)} + \text{Performance Not Met (c=30 patients)}}{\text{Eligible Population / Denominator (d=80 patients)}} = \frac{70 \text{ patients}}{80 \text{ patients}} = 87.50\%$$

**Performance Rate=**

$$\frac{\text{Performance Met (a=40 patients)}}{\text{Data Completeness Numerator (70 patients) – Denominator Exception (b=0 patients)}} = \frac{40 \text{ patients}}{70 \text{ patients}} = 57.14\%$$

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

NOTE: Submission Frequency: Patient-Intermediate

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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 specifications.

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**2020 Clinical Quality Measure Flow Narrative for Quality ID #450 NQF #1858:  
Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer  
Receiving Adjuvant Chemotherapy**

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

1. Start with Denominator
2. Check 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 Breast Adjuvant Chemotherapy Administered.
6. Check Breast Adjuvant Chemotherapy Administered:
  - a. If Breast Adjuvant Chemotherapy Administered equals No, do not include in Eligible Population. Stop Processing.
  - b. If Breast Adjuvant Chemotherapy Administered equals Yes, proceed to check HER-2/neu Positive.
7. Check HER-2/neu Positive:
  - a. If HER-2/neu Positive equals No, do not include in Eligible Population. Stop Processing.
  - b. If HER-2/neu Positive equals Yes, proceed to check AJCC Stage at Breast Cancer Diagnosis equals II or III.

8. Check AJCC Stage at Breast Cancer Diagnosis equals II or III:
  - a. If AJCC Stage at Breast Cancer Diagnosis equals 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 equals II or III equals Yes, proceed to check Patient Transferred to Practice After Initiation of Chemotherapy.
9. 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. 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 Patient Transferred to Practice After Initiation of Chemotherapy.
10. Check Patient Transferred to Practice After Initiation of Chemotherapy:
  - a. If Patient Transferred to Practice After Initiation of Chemotherapy equals No, proceed to check Patient has Metastatic Disease at Diagnosis
  - b. If Patient Transferred to Practice After Initiation of Chemotherapy equals Yes, do not include in Eligible Population. Stop Processing.
11. Check Patient has Metastatic Disease at Diagnosis:
  - a. If Patient has Metastatic Disease at Diagnosis equals No, include in Eligible Population
  - b. If Patient has Metastatic Disease at Diagnosis equals Yes, do not include in Eligible Population. Stop Processing.
12. 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.
13. Start Numerator
14. Check Trastuzumab or FDA-Approved Biosimilar Administered within 12 Months of Diagnosis:
  - a. If Trastuzumab or FDA-Approved Biosimilar Administered within 12 Months of Diagnosis 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 Trastuzumab or FDA-Approved Biosimilar Administered within 12 Months of Diagnosis equals No, proceed to check Reason for Not Administering Trastuzumab Documented.

15. Check Reason for Not Administering Trastuzumab or FDA-Approved Biosimilar Documented:
  - a. If Reason for Not Administering Trastuzumab or FDA-Approved Biosimilar Documented equals Yes, include in Data Completeness Met and Denominator Exception.
  - b. 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.
  - c. If Reason for Not Administering Trastuzumab or FDA-Approved Biosimilar Documented equals No, proceed to check Trastuzumab Not Administered within 12 Months of Diagnosis.
16. Check Trastuzumab or FDA-Approved Biosimilar Not Administered within 12 Months of Diagnosis:
  - a. If Trastuzumab or FDA-Approved Biosimilar Not Administered within 12 Months of Diagnosis 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 Trastuzumab or FDA-Approved Biosimilar Not Administered within 12 Months of Diagnosis equals No, proceed to check Data Completeness Not Met.
17. 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=**

$$\frac{\text{Performance Met (a=40 patients)} + \text{Denominator Exception (b=0 patients)} + \text{Performance Not Met (c=30 patients)}}{\text{Eligible Population / Denominator (d=80 patients)}} = \frac{70 \text{ patients}}{80 \text{ patients}} = 87.50\%$$

**Performance Rate=**

$$\frac{\text{Performance Met (a=40 patients)}}{\text{Data Completeness Numerator (70 patients) - Denominator Exception (b=0 patients)}} = \frac{40 \text{ patients}}{70 \text{ patients}} = 57.14\%$$