# 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

2018 OPTIONS FOR INDIVIDUAL MEASURES:
REGISTRY ONLY

MEASURE TYPE:
Process

DESCRIPTION:
Proportion 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 eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

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

DENOMINATOR:
Adult women with AJCC stage I (T1c) – III, HER2 positive breast cancer who receive adjuvant chemotherapy.

Definitions:
Use the following definitions to determine HER2 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.

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
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: If Trastuzumab 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) |

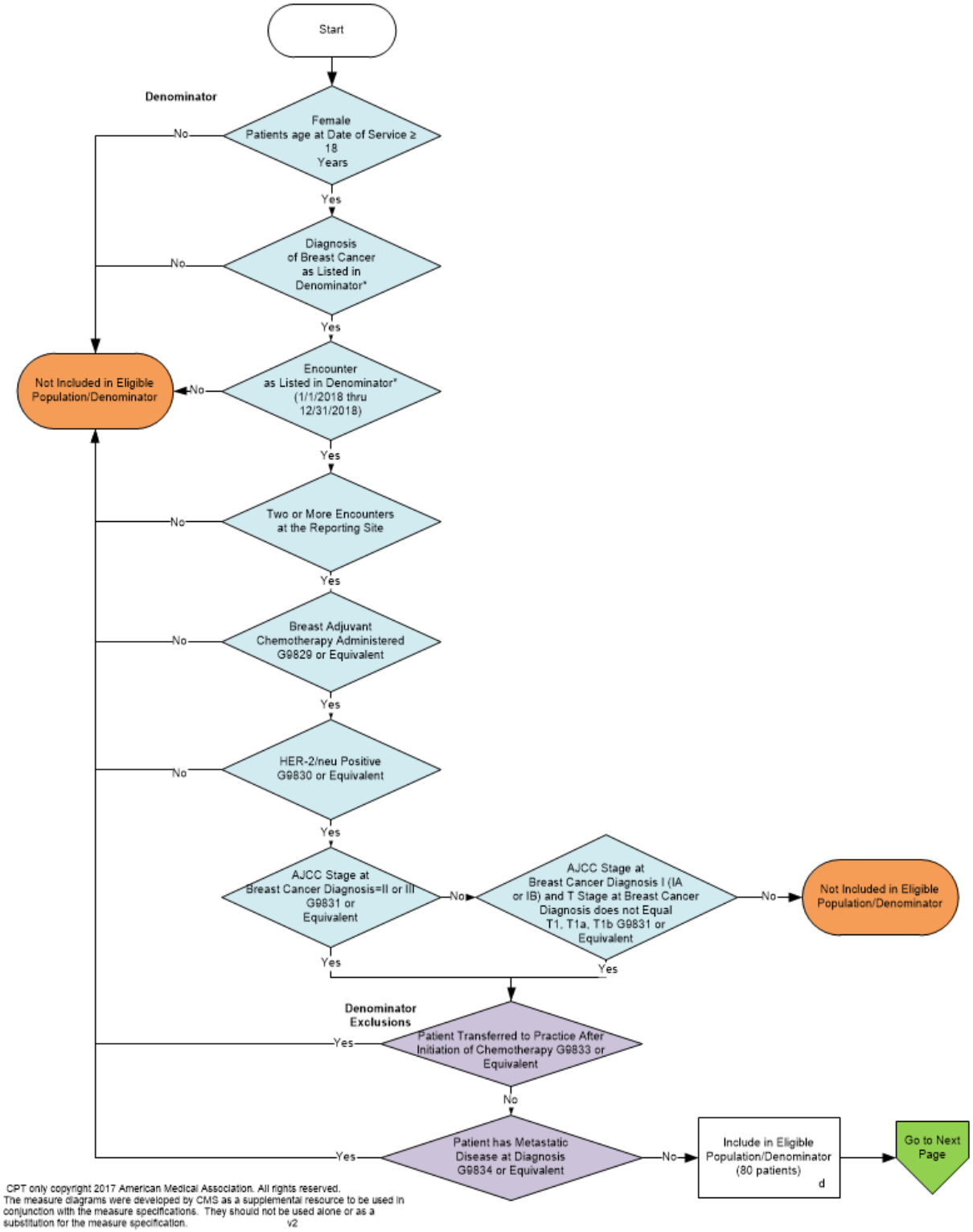
RATIONALE:
Approximately 15% of patients with breast cancer have tumors that overexpress the human epidermal growth hormone receptor protein (HER2). The American Society of Clinical Oncology (ASCO) envisions that use of this measure will improve concordance with recommendations for Trastuzumab administration 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.

Citation: 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

## 2018 Registry 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



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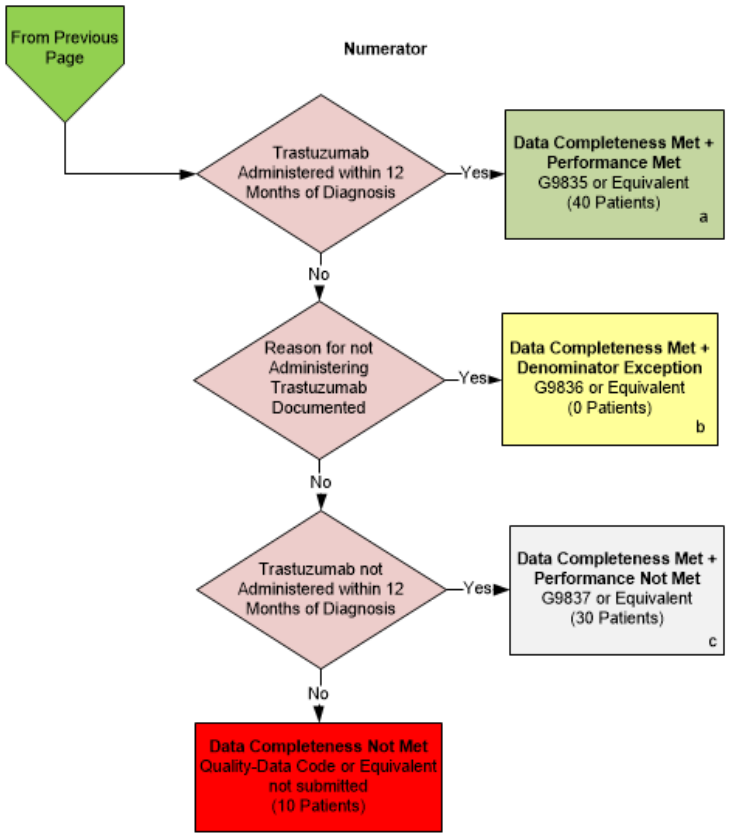


**SAMPLE CALCULATIONS:**

**Data Completion=**

Performance Met (a =40 patients) + Denominator Exception (b = 0 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) – Denominator Exception (b = 0 patients) = 40 patients / 70 patients = **57.14%**

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

NOTE: Submission Frequency: Patient intermediate



v2

# 2018 Registry Flow for Quality ID
# #450 NQF #1859: Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy

Please refer to the specific section of the specification to identify the denominator and numerator information for use in submitting this Individual Specification. This flow is for registry data submission.

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 Breast 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 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 Patient 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 Patient 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 Patient Population. Stop Processing.
    b. If HER-2/neu Positive equals Yes, proceed to check AJCC Stage at Breast Cancer Diagnosis =II or III.

8. 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 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 Patient 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 Patient 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 Patient 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 Administered within 12 Months of Diagnosis:

    a. If Trastuzumab 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 Administered within 12 Months of Diagnosis equals No, proceed to Reason for Not Administering Trastuzumab Documented.

15. Reason for Not Administering Trastuzumab Documented:

a. If Reason for Not Administering Trastuzumab 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 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 Documented equals No, proceed to Trastuzumab Not Administered within 12 Months of Diagnosis.

16. Check Trastuzumab Not Administered within 12 Months of Diagnosis:

    a. If Trastuzumab 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 Not Administered within 12 Months of Diagnosis equals No, proceed to Data Completeness Not Met.

17. Check Data Completeness Not Met:

    a. If Data Completeness Not Met equals No, Quality Data Code or equivalent not submitted. 10 patients have been subtracted from the Data Completeness Numerator in the Sample Calculation.

**SAMPLE CALCULATIONS:**

**Data Completion=**

Performance Met (a =40 patients) + Denominator Exception (b = 0 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) – Denominator Exception (b = 0 patients) = 40 patients / 70 patients = **57.14%**