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

2026 COLLECTION TYPE:
MERIT-BASED INCENTIVE PAYMENT SYSTEM (MIPS) CLINICAL QUALITY MEASURE (CQM)

MEASURE TYPE:
Process – High Priority

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

INSTRUCTIONS:

Reporting Frequency:
This measure is to be submitted a minimum of once per performance period for denominator eligible cases as defined in the denominator criteria.

Intent and Clinician Applicability:
This intent of this measure is to assess patients aged 18 to 70 with pathologic stage I (T1c) – III HER2 positive breast cancer for appropriate treatment initiation. 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 Strata and Performance Rates:
This measure contains one strata defined by a single submission criteria.
This measure produces a single performance rate.

Implementation Considerations:
For the purposes of MIPS implementation, this patient-process measure is submitted a minimum of once per patient during the performance period.

Telehealth:
NOT TELEHEALTH ELIGIBLE: This measure is not appropriate for nor applicable to the telehealth setting. Patient encounters for this measure conducted via telehealth should be removed from the denominator eligible patient population. Therefore, if the patient meets all denominator criteria but the encounter is conducted via telehealth, it would be appropriate to remove them from the denominator eligible patient population. Telehealth eligibility is at the measure level for inclusion within the denominator eligible patient population and based on the measure specification definitions which are independent of changes to coding and/or billing practices.

Measure Submission:
The quality data codes listed do not need to be submitted by MIPS eligible clinicians, groups, or third party intermediaries that utilize this collection type for submissions; however, these codes may be submitted for those third party intermediaries that utilize Medicare Part B claims data. The coding provided to identify the measure criteria: Denominator or Numerator, may be an example of coding that could be used to identify patients that meet the intent of this clinical topic. When implementing this measure, please refer to the 'Reference Coding' section to determine if other codes or code languages that meet the intent of the criteria may also be used within the medical record to identify and/or assess patients. For more information regarding Application Programming Interface (API), please refer to the Quality Payment Program (QPP) website.

DENOMINATOR:
All breast cancer patients aged 18 to 70 with pathologic stage I (T1c) – III HER2 positive breast cancer diagnosed between July 1st of the previous performance period through June 30th of the current performance period.

Definitions:
Use the 2018 ASCO/CAP guideline definitions (re-affirmed in 2023) 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 Instructions:
For the purposes of this measure, only pathologic staging and HER-2 testing performed between July 1st of the previous performance period through June 30th of the current performance period will be included in the denominator of this measure.

DENOMINATOR NOTE:
This measure includes both female and male breast cancers. While treatment recommendations for males have largely been extrapolated from results of clinical trials focused on breast cancer in females, management of breast cancer in males is similar in overall management to breast cancer in females. Consistent with guidance in NCCN guideline recommendations for adjuvant systemic therapy, chemotherapy with/without HER2-targeted therapy should be recommended for males with breast cancer according to guidelines for females with breast cancer.

The patient must have two encounters during the performance period. This is intended to reflect two separate encounters with the same reporting provider/group during this timeframe. There is no specific timeframe for the requirement for the two encounters that occur during the performance period. For example, two encounters with the

same provider/group could occur in the same week. However, two encounters should not be counted if they occur on the same day. For example, the patient has two encounters and one is with a different provider on the same day.

Denominator Criteria (Eligible Cases):
Patients age 18-70 years on date of encounter
AND
Diagnosis of breast cancer between July 1st of the previous performance period through June 30th of the current performance period (ICD-10-CM): C50.A0, C50.A1, C50.A2, C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929
AND
At least two patient encounters during the current performance period (CPT): 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215
WITHOUT
Encounters conducted via telehealth: M1426
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 = T1c: 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. The timeframe to identify the adjuvant treatment course is within six months of breast cancer pathologic staging. To satisfy the numerator, both chemotherapy and HER2-targeted therapy must occur within six months of pathologic staging. 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 10-20 percent of patients with breast cancer have tumors that overexpress the human epidermal growth factor receptor (HER2) protein (Early Breast Cancer Trialists' Collaborative group (EBCTCG), 2021). High levels of the HER2 protein are linked with a higher likelihood of metastasis, increased risk of disease recurrence, and a decrease in patient survival, but are more likely to respond to targeted therapies (Early Breast Cancer Trialists' Collaborative group (EBCTCG), 2021) & (National Cancer Institute, 2018). Numerous adjuvant trials of trastuzumab have demonstrated clinically significant improvements in disease-free survival, with the HERA, NSABP B31, and NCCTGF N9831 trials also demonstrating significant improvement in overall survival with the use of trastuzumab (Gradishar, Moran, Abraham, & al., 2024). The benefits of trastuzumab are independent of estrogen receptor (ER) status (Gradishar, Moran, Abraham, & al., 2024). 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.

CLINICAL RECOMMENDATION STATEMENTS:

NCCN Recommendation for Adjuvant HER2-Targeted Therapy

The panel recommends HER2-targeted therapy in patients with HER2-positive tumors. The panel has designated use of trastuzumab with chemotherapy as a category 1 recommendation for all HER2 positive tumors >1cm (Gradishar, Moran, Abraham, & al., 2024).

REFERENCES:

Early Breast Cancer Trialists' Collaborative group (EBCTCG). (2021). Trastuzumab for early-stage, HER2-positive breast cancer: a meta-analysis of 13 864 women in seven randomised trials. *The Lancet: Oncology, 22*(8), 1139 - 1150. Retrieved from https://doi.org/10.1016/S1470-2045(21)00288-6

Gradishar, W., Moran, M., Abraham, J., & al., e. (2018, April 11). *NCCN Guidelines Panel. NCCN Clinical Practice Guidelines in Oncology – Breast Cancer. Version 6.2024*. Retrieved from national Comprehensive Cancer Network: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf

National Cancer Institute. (2008, April 11). *HER2's Genetic Link to Breast Cancer Spurs Development of New Treatments*. Retrieved from National Cancer Institute at the National Institutes of Health: https://www.cancer.gov/research/progress/discovery/her2

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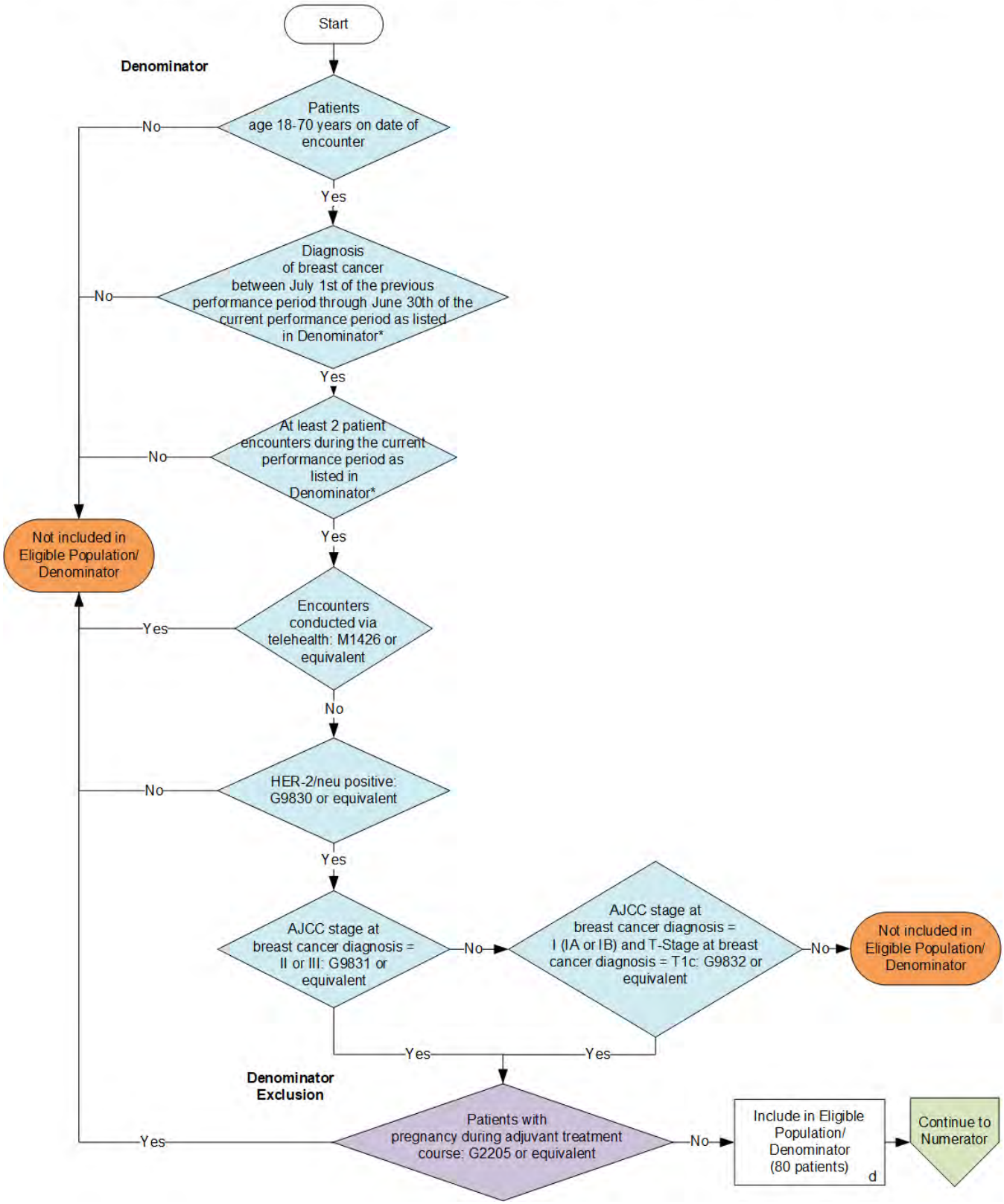
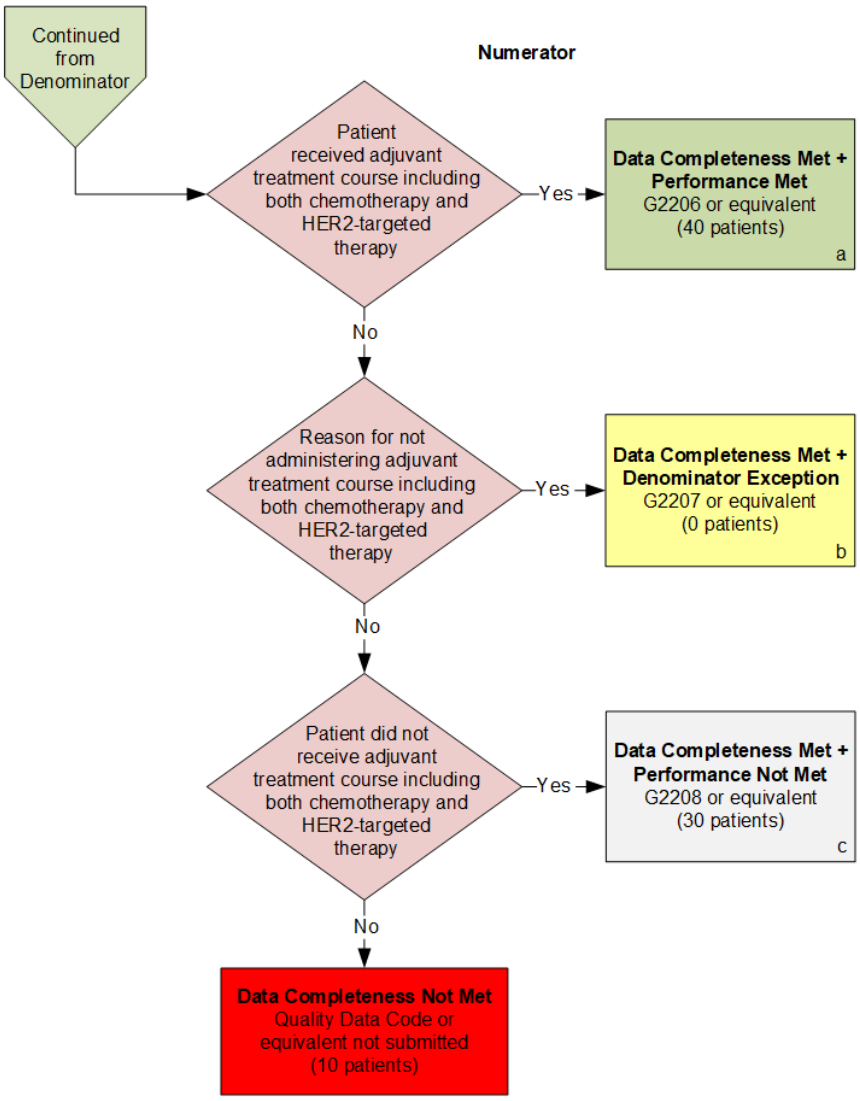
2026 Clinical Quality Measure Flow for Quality ID #450 (CBE 1858): Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer

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) / 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-Process

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2026 Clinical Quality Measure Flow Narrative for Quality ID #450 (CBE 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 *Patients age 18-70 years on date of encounter*:
    a. If *Patients age 18-70 years on date of encounter* equals No, do not include in *Eligible Population/Denominator*. Stop processing.
    b. If *Patients age 18-70 years on date of encounter* equals Yes, proceed to check *Diagnosis of breast cancer between July 1st of the previous performance period through June 30th of the current performance period.*
3. Check *Diagnosis of breast cancer between July 1st of the previous performance period through June 30th of the current performance period as listed in Denominator**:
    a. If *Diagnosis of breast cancer between July 1st of the previous performance period through June 30th of the current performance period as listed in Denominator** equals No, do not include in *Eligible Population/Denominator*. Stop processing.
    b. If *Diagnosis of breast cancer between July 1st of the previous performance period through June 30th of the current performance period 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 the current performance period as listed in Denominator**:
    a. If *At least 2 patient encounters during the current 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 the current performance period as listed in Denominator*** *equals Yes, proceed to check* Encounters conducted via telehealth *as listed in Denominator**.
5. Check *Telehealth Modifier as listed in Denominator**:
    a. If *Encounters conducted via telehealth as listed in Denominator** equals Yes, do not include in *Eligible Population/Denominator*. Stop processing.
    b. If *Encounters conducted via telehealth as listed in Denominator** 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 Yes, proceed to check Patients with pregnancy during adjuvant treatment course.*
    b. 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 equals T1c.

8. Check *AJCC stage at breast cancer diagnosis = I (IA or IB) and T-Stage at breast cancer diagnosis equals T1c.*
    a. If *AJCC stage at breast cancer diagnosis = I (IA or IB) and T-Stage at breast cancer diagnosis equals T1c* 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 equals T1c* 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*:
        - 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-Process

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.