**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0220

**Measure Title**: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: 11/1/2019

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Evaluation of staging

Contraindication due to patient risk factors

Non-compliant

Compliant

HT recommended/ administered within 1 year

Patient diagnosis of breast cancer

(exam, mammogram, ultrasound,

biopsy, MRI)

Patient refusal or death

Any other reason

Hormone-receptor

positive, AJCC T1cN0M0

or Stage IB – Stage III

HT recommended/ not administered within 1 year

Not administered as part of first-course therapy or treatment

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| **Identify Problem:** | The standard of care states that hormone therapy is recommended for AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer patients, however there continues to be patient populations not receiving this care |
| **Goal:** | To ensure all AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer patients, where applicable, undergo hormone therapy within 365 days of diagnosis |
| **Standard of Care:** | Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer |
| **Inputs** | * Patient * Clinicians: oncologist, surgeon * Nurses * Hormone therapy * Commission on Cancer (CoC) Accredited Cancer Program * Registrars * National Cancer Database (NCDB) * Rapid Quality Reporting System (RQRS) |
| **Processes** | 1. Clinician diagnoses patient with AJCC T1cN0M0 or Stage IB – Stage III breast cancer    1. Patient Characteristics:       * ≥18 years old       * Female       * Alive within 365 days of diagnosis    2. Patient’s Tumor Characteristics:       * First or only diagnosis of malignant neoplasm       * Epithelial       * Invasive       * Hormone receptor positive 2. Clinician recommends hormone therapy as part of first course of treatment to the patient 3. Patient undergoes surgery of the breast performed by a clinician 4. Hormone therapy is administered to the patient within 365 days of diagnosis OR hormone therapy is not administered to the patient 5. Registrar abstracts and submits the patient’s treatment to the CoC’s NCDB and RQRS |
| **Outputs** | * Hormone therapy is recommended * Hormone therapy is administered within 365 days * Alert are given to programs, within 365 days of diagnosis, notifying them the progress of each patient’s adherence to the measure by sending reminders to recommend and/or give patients hormone therapy |
| **Outcomes** | * Compliant with the standard of care |
| **Impact** | * ”[R]educes the risk of local recurrence, contralateral breast cancer, distant recurrence, and death” (<https://www.facs.org/-/media/files/quality-programs/cancer/ncdb/measure-specs-breast.ashx>) |

**1a.3** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

Not Applicable

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

Not Applicable

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

☐ Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | **Title:** National Comprehensive Cancer Network (NCCN) Guidelines v2.2019  **Date Created:** 07/02/2019  **Date Accessed:** 07/31/2019  **URL:** <https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf> |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | Adjuvant endocrine therapy" [depending on other tumor  characteristics also includes "+/- adjuvant chemotherapy" or +  adjuvant chemotherapy"]    Systemic Adjuvant treatment – hormone receptor positive-  HER2- Positive:  pT1, pT2, or pT3; and pN0 orpN1mi –and pN0 orpN1mi ->Tumor  >1cm -> Adjuvant endocrine therapy +/- adjuvant chemotherapy  with trastzumab (category 1)  Systemic Adjuvant treatment – hormone receptor positive-  HER2- Negative:  pT1, pT2, or pT3; and pN0 orpN1mi –and pN0 orpN1mi ->Tumor  >1cm -> Adjuvant endocrine therapy +/- adjuvant chemotherapy |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | Level: I |
| Provide all other grades and definitions from the evidence grading system | Level: I, IIA, IIB, III |
| Grade assigned to the **recommendation** with definition of the grade | Level: I |
| Provide all other grades and definitions from the recommendation grading system | Level: I, IIA, IIB, III |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | Multiple randomized clinical trials |
| Estimates of benefit and consistency across studies |  |
| What harms were identified? |  |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? |  |

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**1a.4 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

Not Applicable

**1a.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

Not Applicable

**1a.4.2 What process was used to identify the evidence?**

Not Applicable

**1a.4.3.** **Provide the citation(s) for the evidence.**

Not Applicable