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

**Measure Number** (*if previously endorsed*)**:** 386

**Measure Title**: Oncology: Cancer Stage Documented

**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**: 4/16/2018

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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: Click here to name what is being measured

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.



Any standardized system may be used to stage the cancer patient. Alternatively, there may be

documentation in the medical record that the cancer is metastatic. Cancer stage or documentation of

metastatic cancer should be documented in the medical record within one month of the first office visit.

**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.)

**\*\*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** | * NCCN Clinical Practice Guidelines in Oncology – Breast Cancer * NCCN * March 20, 2018 * <https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf>   NCCN, *Clinical Practice Guidelines in Oncology - Breast Cancer.* 2018. **Version 1.2018**: p. MS-4 |
| 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. | **Breast Cancer**  “All patients with breast cancer should be assigned a clinical stage of disease, and, if appropriate evaluation is available, a pathologic stage of disease. The routine use of staging allows for efficient identification of local treatment options, assists in identifying systemic treatment options, allows the comparison of outcome results across institutions and clinical trials, and provides baseline prognostic information.” (MS-4)  “A central component of the treatment of breast cancer is full knowledge of extent of disease and biologic features. These factors contribute to the determination of the stage of disease, assist in the estimation of the risk that cancer will recur, and provide information that predicts response to therapy (eg, ER, PR, HER2).” (MS-4) |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | Not Applicable |
| Provide all other grades and definitions from the evidence grading system | NCCN Categories of Evidence and Consensus  Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.  Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.  Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.  Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate. |
| Grade assigned to the **recommendation** with definition of the grade | Not Applicable |
| Provide all other grades and definitions from the recommendation grading system | NCCN Categories of Evidence and Consensus  Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.  Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.  Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.  Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate. |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | Not Applicable |
| Estimates of benefit and consistency across studies | Not Applicable |
| What harms were identified? | Not Applicable |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | Not Applicable |

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | * NCCN Clinical Practice Guidelines in Oncology – Colon Cancer * NCCN * March 14, 2018 * <https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf>   NCCN, *Clinical Practice Guidelines in Oncology - Colon Cancer.* 2018.  **Version 2.2018**: p. MS-5 |
| 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. | **Colon Cancer**  “Some of the criteria that should be included in the report of the pathologic evaluation include the following: grade of the cancer; depth of penetration and extension to adjacent structures (T); number of regional lymph nodes evaluated; number of positive regional lymph nodes (N); an assessment of the presence of distant metastases to other organs, the peritoneum or an abdominal structure, or in non-regional lymph nodes (M); the status of proximal, distal, radial, and mesenteric margins; lymphovascular invasion; perineural invasion (PNI); and tumor deposits.” (MS-5) |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | Not Applicable |
| Provide all other grades and definitions from the evidence grading system | NCCN Categories of Evidence and Consensus  Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.  Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.  Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.  Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate. |
| Grade assigned to the **recommendation** with definition of the grade | Not Applicable |
| Provide all other grades and definitions from the recommendation grading system | NCCN Categories of Evidence and Consensus  Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.  Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.  Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.  Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate. |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | Not Applicable |
| Estimates of benefit and consistency across studies | Not Applicable |
| What harms were identified? | Not Applicable |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | Not Applicable |

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | * NCCN Clinical Practice Guidelines in Oncology – Rectal Cancer * NCCN * March 14, 2018 * <https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf>.   NCCN, *Clinical Practice Guidelines in Oncology - Rectal Cancer.* 2018. **Version 1.2018**: p. MS-5 |
| 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. | **Rectal Cancer**  “Some of the information that should be detailed in the report of the pathologic evaluation of rectal cancer includes: 1) gross description of the tumor and specimen; 2) grade of the cancer; 3) depth of penetration and extension to adjacent structures (T); 4) number of regional lymph nodes evaluated; (5) number of positive regional lymph nodes (N); 6) the presence of distant metastases to other organs or sites including non-regional lymph nodes (M); 7) the status of proximal, distal, circumferential (radial), and mesenteric margins; 8) neoadjuvant treatment effect; 9) lymphovascular invasion (LVI); 10) perineural invasion (PNI); and 11) the number of tumor deposits.” (MS-5) |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | Not Applicable |
| Provide all other grades and definitions from the evidence grading system | NCCN Categories of Evidence and Consensus  Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.  Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.  Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.  Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate. |
| Grade assigned to the **recommendation** with definition of the grade | Not Applicable |
| Provide all other grades and definitions from the recommendation grading system | NCCN Categories of Evidence and Consensus  Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.  Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.  Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.  Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate. |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | Not Applicable |
| Estimates of benefit and consistency across studies | Although there is no explicit statement regarding the overall consistency of results across studies in the guidelines supporting the measure, the recommendation received uniform NCCN consensus that the intervention is appropriate. |
| What harms were identified? | Not Applicable |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | Not Applicable |

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | * Primary breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up * Senkus E, et al. * September 2015 * <https://www.ncbi.nlm.nih.gov/pubmed/26314782>   Senkus, E., et al., *Primary breast cancer: ESMO Clinical*  *Practice Guidelines for diagnosis, treatment and*  *follow-up.* Ann Oncol, 2015. **26 Suppl 5**: p. v8-30. |
| 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. | “Final pathological diagnosis should be made according to the World Health Organization (WHO) classiﬁcation [16] and the tumour–node–metastases (TNM) staging system. The pathological report should include the histological type, grade, immunohistochemical (IHC) evaluation of oestrogen receptor (ER) status (using a standardised assessment methodology, e.g. Allred or H-score) and, for invasive cancer, IHC evaluation of progesterone receptor (PgR) and human epidermal growth factor 2 receptor (HER2) gene expression. HER2 gene ampliﬁcation status may be determined directly from all invasive tumours using *in situ* hybridisation (ﬂuorescent, chromogenic or silver), replacing IHC or only for tumours with an ambiguous (2+) IHC score [V, B].” |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | V. Studies without the control group, case reports, experts opinions |
| Provide all other grades and definitions from the evidence grading system | Level of Evidence:  I Evidence from at least one large, randomised, controlled trial of good methodological quality (low potential for bias) or meta-analyses of well- conducted randomised trials without heterogeneity  II Small randomised trials or large randomised trials with a suspicion of bias (lower methodological quality) or meta-analyses of such trials or of trials with demonstrated heterogeneity  III Prospective cohort studies  IV Retrospective cohort studies or case–control studies  V Studies without control group, case reports, experts opinions |
| Grade assigned to the **recommendation** with definition of the grade | B |
| Provide all other grades and definitions from the recommendation grading system | Grades of recommendation:  A Strong evidence for efficacy with a substantial clinical benefit, strongly recommended  B Strong or moderate evidence for efficacy but with a limited clinical benefit, generally recommended  C Insufficient evidence for efficacy or benefit does not outweigh the risk or the disadvantages (adverse events, costs, ...), optional  D Moderate evidence against efficacy or for adverse outcome, generally not recommended  E Strong evidence against efficacy or for adverse outcome, never Recommended |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | The ESMO guideline does not summarize the quality of different randomized clinical trials nor the systematic reviews. |
| Estimates of benefit and consistency across studies | Not Available |
| What harms were identified? | Not Applicable |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | Not Applicable |

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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.*

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

Cancer stage is a critical component in determining treatment options for patients with cancer. Despite its importance, cancer stage is often not documented in the medical record. Additionally, documentation of cancer stage in the medical record facilitates communication and care coordination among providers for a disease that is often treated by a multidisciplinary care team (e.g. medical oncology, surgery, and radiation oncology).

**Importance**

Recently updated NCCN and ECMO guidelines on breast, colon, and rectal cancer offer the following

guidance on staging:

Breast:

“All patients with breast cancer should be assigned a clinical stage of disease, and, if appropriate evaluation is available, a pathologic stage of disease. The routine use of staging allows for efficient identification of local treatment options, assists in identifying systemic treatment options, allows the comparison of outcome results across institutions and clinical trials, and provides baseline prognostic information1.”

“A central component of the treatment of breast cancer is full knowledge of extent of disease and biologic features. These factors contribute to the determination of the stage of disease, assist in the estimation of the risk that cancer will recur, and provide information that predicts response to therapy (eg, ER, PR, HER2)1.”

““Final pathological diagnosis should be made according to the World Health Organization (WHO) classiﬁcation [16] and the tumour–node–metastases (TNM) staging system. The pathological report should include the histological type, grade, immunohistochemical (IHC) evaluation of oestrogen receptor (ER) status (using a standardised assessment methodology, e.g. Allred or H-score) and, for invasive cancer, IHC evaluation of progesterone receptor (PgR) and human epidermal growth factor 2 receptor (HER2) gene expression. HER2 gene ampliﬁcation status may be determined directly from all invasive tumours using *in situ* hybridisation (ﬂuorescent, chromogenic or silver), replacing IHC or only for tumours with an ambiguous (2+) IHC score [V, B]2.”

Colon:

“Some of the criteria that should be included in the report of the pathologic evaluation include the following: grade of the cancer; depth of penetration and extension to adjacent structures (T); number of regional lymph nodes evaluated; number of positive regional lymph nodes (N); an assessment of the presence of distant metastases to other organs, the peritoneum or an abdominal structure, or in non-regional lymph nodes (M); the status of proximal, distal, radial, and mesenteric margins; lymphovascular invasion; perineural invasion (PNI); and tumor deposits3.”

Rectal:

“Some of the information that should be detailed in the report of the pathologic evaluation of rectal cancer includes: 1) gross description of the tumor and specimen; 2) grade of the cancer; 3) depth of penetration and extension to adjacent structures (T); 4) number of regional lymph nodes evaluated; (5) number of positive regional lymph nodes (N); 6) the presence of distant metastases to other organs or sites including non-regional lymph nodes (M); 7) the status of proximal, distal, circumferential (radial), and mesenteric margins; 8) neoadjuvant treatment effect; 9) lymphovascular invasion (LVI); 10) perineural invasion (PNI); and 11) the number of tumor deposits4.”

**Performance Gap**

Despite its importance, cancer stage is often not documented in the medical record. For example, colon

cancer is the third most common cancer in the United States5, and Abernethy et al.

demonstrated in a retrospective review of 499 colorectal cancer patients that only 38 percent of patient

records provided TNM stage (which improved to 73 percent when any clinical notation of stage was

accepted). Accordingly, Abernethy et al. concluded that assessment of care quality is impeded by the

absence of data elements vital to the calculation of performance6.

In 2015, the Surveillance, Epidemiology, and End Results (SEER) program implemented a field study to determine how often T, N, and M were not available in a total of 280 medical records (56 each for breast, prostate, colon, lung, and ovarian cancer). The authors determined that Pathologic T and N were only available for roughly two-thirds of the medical records examined and concluded that the data elements for TNM staging and stage group were often missing from the medical records7.

A more recent 2017 study examined how often physician-assigned staging components were

documented in the medical records of 282 routine cases at five cancer sites selected from the

SEER registries. Noone et al. concluded that the physician-assigned TNM components and stage groups

were often not found in the medical record, with pathologic T and N found most frequently at 65

percent and 64 percent, respectively8.

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

A targeted literature search was conducted to identify support for first clinical principles and the important of cancer staging, as well as variation in rates of cancer staging found in medical records.

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

1. NCCN, *Clinical Practice Guidelines in Oncology - Breast Cancer.* 2018. **Version 1.2018**: p. MS-4.

2. Senkus, E., et al., *Primary breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up.* Ann Oncol, 2015. **26 Suppl 5**: p. v8-30.

3. NCCN, *Clinical Practice Guidelines in Oncology - Colon Cancer.* 2018. **Version 2.2018**: p. MS-5.

4. NCCN, *Clinical Practice Guidelines in Oncology - Rectal Cancer.* 2018. **Version 1.2018**: p. MS-5.

5. Haggar, F.A. and R.P. Boushey, *Colorectal cancer epidemiology: incidence, mortality, survival, and risk factors.* Clin Colon Rectal Surg, 2009. **22**(4): p. 191-7.

6. Abernethy, A.P., et al., *Poor documentation prevents adequate assessment of quality metrics in colorectal cancer.* J Oncol Pract, 2009. **5**(4): p. 167-74.

7. Noone, A.M., et al., *Availability of TNM Staging Data Elements in the Medical Record and Training Needs Assessment: Results from the 2014 SEER Training Needs Assessment for TNM Study.* J Registry Manag, 2015. **42**(2): p. 40-7.

8. Noone, A.M., et al., *Medical Record-Documented TNM Categories and Stage Group: Feasibility of Use for Cancer Surveillance.* J Registry Manag, 2017. **44**(2): p. 46-53.