MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Purple text represents the responses from measure developers.

Red text denotes developer information that has changed since the last measure evaluation review.

Brief Measure Information

NQF #: 0223

Corresponding Measures:

De.2. Measure Title: Adjuvant chemotherapy is recommended, or administered within 4 months (120 days) of diagnosis for patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer

Co.1.1. Measure Steward: Commission on Cancer, American College of Surgeons

De.3. Brief Description of Measure: Percentage of patients, age = 18 and < 80 at diagnosis, who have their first diagnosis of cancer (epithelial malignancy) that is lymph node positive and at AJCC stage III, whose primary tumor is of the colon and chemotherapy was recommended or administered within 4 months (120 days) of diagnosis

1b.1. Developer Rationale: Improved survival for patients with Stage III lymph node positive colon cancer

S.4. Numerator Statement: Adjuvant chemotherapy is administered within 4 months (120 days) of the date of diagnosis or it is recommended but not administered

S.6. Denominator Statement: Include if all of the following characteristics are identified:

Men or Women
Age = 18 and < 80 at time of diagnosis
Known or assumed to be first or only cancer diagnosis
Epithelial malignancy only
Invasive tumors
Primary tumors of the colon
All or part of 1st course of treatment performed at the reporting facility
Known to be alive within 4 months (120 days) of date of diagnosis
Lymph node positive disease
Surgical procedure of the primary site

S.8. Denominator Exclusions: Exclude, if any of the following characteristics are identified:

Under age 18 or over age 80 at time of diagnosis
Second or subsequent cancer diagnosis
Tumor not originating in the colon
Non-epithelial malignancies
Non-invasive tumors
Stage 0, in situ tumor

Stage IV, metastatic tumor
None of 1st course therapy performed at reporting facility
Died within 4 months (120 days) of diagnosis
Not lymph node positive disease
Patient enrolled in a clinical trial that directly impacts delivery of the standard of care
No surgical procedure of the primary site

De.1. Measure Type: Process

S.17. Data Source: Registry Data

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Mar 01, 2007 **Most Recent Endorsement Date:** Oct 26, 2016

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? Not Applicable

Preliminary Analysis: Maintenance of Endorsement

To maintain NQF endorsement endorsed measures are evaluated periodically to ensure that the measures still meets the NQF endorsement criteria ("maintenance"). The emphasis for maintaining endorsement is focused on how effective the measure is for promoting improvements in quality. Endorsed measures should have some experience from the field to inform the evaluation. The emphasis for maintaining endorsement is noted for each criterion.

Criteria 1: Importance to Measure and Report

1a. Evidence

Maintenance measures – less emphasis on evidence unless there is new information or change in evidence U**since the prior evaluation.**

1a. Evidence. The evidence requirements for a _structure, process or intermediate outcome_ measure is that it is based on a systematic review (SR) and grading of the body of empirical evidence where the specific focus of the evidence matches what is being measured. For measures derived from patient report, evidence also should demonstrate that the target population values the measured process or structure and finds it meaningful.

The developer provides the following evidence for this measure:

- **Systematic Review of the evidence specific to this measure?** ☐ Yes ☒ No
- **Quality, Quantity and Consistency of evidence provided?** ☐ Yes ☒ No
- **Evidence graded?** ☒ Yes ☐ No

Evidence Summary or **Summary of prior review in 2016**

Summary of prior review in 2016 summarized earlier 2012 review:

- National Comprehensive Cancer Network (NCCN)Practice Guideline:

- Pathologic Stage T1-3, N1-2, M0 or T4, N1-2, M0: FOLFOX or CapeOx (both category 1 and preferred). Other options include: FLOX (category 1) or Capecitabine or 5-FU/Leucovorin. **Level of evidence: Category 1** (defined as: based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate)
- Additional evidence included a systematic review of the body of evidence including multiple randomized clinical demonstrating approxate 25% reduction in risk of death.

Changes to evidence from last review

☒ **The developer attests that there have been no changes in the evidence since the measure was last evaluated.**

☐ **The developer provided updated evidence for this measure:**

Updates:

Questions for the Committee:

○ *The developer attests the underlying evidence for the measure has not changed since the last NQF endorsement review. Does the Committee agree the evidence basis for the measure has not changed and there is no need for repeat discussion and vote on Evidence?*

- For structure, process, and intermediate outcome measures:
  ○ What is the relationship of this measure to patient outcomes?
  ○ How strong is the evidence for this relationship?
  ○ Is the evidence directly applicable to the process of care being measured?
- For possible exception to the evidence criterion:
  ○ Are there, or could there be, performance measures of a related health outcome, OR evidence-based intermediate clinical outcomes, intervention/treatment?
  ○ Is there evidence of a systematic assessment of expert opinion beyond those involved in developing the measure?
  ○ Does the SC agree that it is acceptable (or beneficial) to hold providers accountable without empirical evidence?

Guidance from the Evidence Algorithm

Process measure/systematic review (Box 3) → Specific information on QQC not presented (Box 4) → evidence graded as high-level evidence (Box 6) → Moderate (highest eligible rating is MODERATE)

Preliminary rating for evidence: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Rationale:
Developer states that body of evidence consists of "multiple randomized clinical trials with high level evidence" but does not indicate the quantity or consistency of evidence used in systematic review. Developer guidelines state that "a summary of the quantity, quality, and concsistency of the body of evidence from a systematic review be provided in the submission form."

In addition, evidence grading system can be inferred as I-III (strongest to weakest) but is not defined as such.

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

Maintenance measures – increased emphasis on gap and variation

1b. Performance Gap. The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- The developer provided the following national trend data from the National Cancer Data Base (NCDB):

	2008	2015
# of facilities	1,449	1,299
# of cases	11,057	10,613
Mean Performance Rate	83.1% (SD=0.4)	88.7% (SD=0.3)
IQR	75.0%-100.0%	84.6%-100.0%
Range	0.0%-100%	0.0%-100%

- The developer stated that more recent performance data was not provided because all adjuvant therapy information are likely incomplete for the most recent year until programs have had time to collect this information.

Disparities
Race/ethnicity

2015	Non-Hispanic white	Other/ Unknown	Asian/Hawaiian/ Pacific Islander (P.I.)	Non-Hispanic Black	Hispanic
# of cases	7,404	429	427	1,564	789
Mean performance rate	90.2%	87.2%	86.2%	85.7%	82.5%

2008	Non-Hispanic white	Other/ Unknown	Asian/Hawaiian/ Pacific Islander (P.I.)	Non-Hispanic Black	Hispanic
# of cases	7,593	991	326	1,494	653
Mean performance rate	84.7%	80.4%	81.6%	80.3%	75.7%

Age at Diagnosis

2015	Age 18-49	Age 50-59	Age 60-69	Age 70-79
# of cases	1,671	2,639	3,421	2,882
Mean performance rates	91.6%	89.0%%	88.2%	87.2%

2008	Age 18-49	Age 50-59	Age 60-69	Age 70-79
# of cases	1,699	2,718	3,299	3,341

Mean performance rates	87.3%	85.0%	82.9%	79.6%

- The developer provided [additional disparities data](#) on insurance status, income, facility type, and sex.

Questions for the Committee:

- Is their sufficient room for improvement in this measure based on the demonstrated gap in care?

Preliminary rating for opportunity for improvement: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

Committee Pre-evaluation Comments:
Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

1a. Evidence to Support Measure Focus: For all measures (structure, process, outcome, patient-reported structure/process), empirical data are required. How does the evidence relate to the specific structure, process, or outcome being measured? Does it apply directly or is it tangential? How does the structure, process, or outcome relate to desired outcomes? For maintenance measures –are you aware of any new studies/information that changes the evidence base for this measure that has not been cited in the submission? For measures derived from a patient report: Measures derived from a patient report must demonstrate that the target population values the measured outcome, process, or structure."

- Previous evidence is still relevant

- age should be greater than, not equal to 18. high level evidence that adjuvant tx improves survival.

- Evidence for using chemotherapy is based off of landmark randomized controlled studies that will not be repeated. there is no need to revisit the evidence unless countervailing studies are published

- Patients with stage III colon cancer, target population of this measure, achieve benefit from adjuvant chemotherapy. Several chemotherapies are acceptable and adopted as stated in the analysis. There is no major change to the recommendation of start of chemotherapy, however, new evidence supports shorter duration for select patients (IDEA Collaboration). Although this measure is intended to assess the provider recommendation for adjuvant chemotherapy, the measurement timeline from diagnosis to start of adjuvant therapy can be affected by structure of care (insurance, hospital policies, ...). Therefore it would be of value to assess the performance of this measure by insurance (presented in this analysis) and hold insurance accountable for this measure.

- This measure should be supported, though typically chemotherapy treatments within 60 to 90 days of diagnosis

- Evidence does exist and was in the initial submission, no additional recent evidence appears to have been added. I am not aware of any new literature.

- Moderate level of evidence but without full and clear explanation of grading of evidence

- yes

- I am not aware of any new studies that change the basis for the measure and it appears the basis for the measure has not changed.

- Evidence suggests that adjuvant therapy for Stage III lymph node positive colon cancer (rectal excluded) is associated with improved survival (25% reduction in the risk of death.) The evidence for adjuvant therapy has not changed since the last review. NCCN recommends this therapy in its guidelines. Most of the evidence is high level (level 1).   There remains an ongoing gap in receiving therapy within 120 days for older patients, certain ethnic minorities, older patients, uninsured or poorly insured patients, site of care, etc. There has been an improvement in performance in all groups since last report but gaps remain. This measure remains important to measure.

1b. Performance Gap: Was current performance data on the measure provided? How does it demonstrate a gap in care (variability or overall less than optimal performance) to warrant a national performance measure? Disparities: Was data on the measure by population subgroups provided? How does it demonstrate disparities in the care?

- Still a gap

- mean performance has increased from 75-85%. still room for improvement. racial and age disparities have improved but still exists.

- while the disparity has decreased, it still exists.

- Most recent data presented is from 2015. The data presented suggests disparities, however, performance on minority population is improving in parallel to whites.

- There is room for improvement in the disparities, while it's marked moderate it should be marked high, especially as we enter 2020

- There is a performance gap and measure has room for improvement. Data was run to look at multiple disparities data and showed some potentially meaningful differences.

- Some gap still noted allowing additional improvement for performance (gaps in race/ethnicity and age of diagnosis)

- yes

- I would think there is room for improvement based on gap in care.

- Performance data was presented for 2014 and 2015. There was an overall improvement in aggregate scores since the last review however variablity in performance continues based on data presented from multiple subgroups. Differences were seen in multiple areas including age, race, insurance status, etc., to name a few.

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing

2b. Validity: Testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability; Missing Data

2c. For composite measures: empirical analysis support composite approach

Reliability

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

2a2. Reliability testing demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

Validity

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Composite measures only:

2d. Empirical analysis to support composite construction. Empirical analysis should demonstrate that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct.

Complex measure evaluated by Scientific Methods Panel? ☐ Yes ☒ No

Evaluators: NQF Staff

Questions for the Committee regarding reliability:

- Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?
- The [staff] or [Scientific Methods Panel] is satisfied with the reliability testing for the measure. Does the Committee think there is a need to discuss and/or vote on reliability?

Questions for the Committee regarding validity:

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- The [staff] or [Scientific Methods Panel] is satisfied with the validity analyses for the measure. Does the Committee think there is a need to discuss and/or vote on validity?

Preliminary rating for reliability: ☐ High ☒ Moderate ☐ Low ☐ Insufficient
Preliminary rating for validity: ☐ High ☐ Moderate ☐ Low ☒ Insufficient

Scientific Acceptability: Preliminary Analysis Form

Measure Number: 0223

Measure Title: Adjuvant chemotherapy is recommended, or administered within 4 months (120 days) of diagnosis for patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer

Type of measure:

☒ Process ☐ Process: Appropriate Use ☐ Structure ☐ Efficiency ☐ Cost/Resource Use

☐ Outcome ☐ Outcome: PRO-PM ☐ Outcome: Intermediate Clinical Outcome ☐ Composite

Data Source:

☐ Claims ☐ Electronic Health Data ☐ Electronic Health Records ☐ Management Data
☐ Assessment Data ☐ Paper Medical Records ☐ Instrument-Based Data ☒ Registry Data
☐ Enrollment Data ☐ Other

Level of Analysis:

☐ Clinician: Group/Practice ☐ Clinician: Individual ☒ Facility ☐ Health Plan
☐ Population: Community, County or City ☐ Population: Regional and State
☐ Integrated Delivery System ☐ Other

Measure is:

☐ **New** ☒ **Previously endorsed (**NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

RELIABILITY: SPECIFICATIONS

1. **Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented?** ☒ **Yes**   ☐ **No**

   Submission document: "MIF_xxxx" document, items S.1-S.22

   NOTE*: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.*

2. **Briefly summarize any concerns about the measure specifications.**

RELIABILITY: TESTING

Submission document: "MIF_xxxx" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

3. **Reliability testing level**   ☒ **Measure score**   ☐ **Data element**   ☐ **Neither**

4. **Reliability testing was conducted with the data source and level of analysis indicated for this measure**
   ☒ **Yes**   ☐ **No**

5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical <u>VALIDITY</u> testing** of <u>patient-level data</u> conducted?

   ☐ **Yes**   ☐ **No**

6. **Assess the method(s) used for reliability testing**

   Submission document: Testing attachment, section 2a2.2

   Reliability of the computed measure score was measured as the ratio of signal to noise and testing was modeled from 2-level hierarchical logistic regression models using Bayesian shrinkage adjustments that control for random error for both patients and hospitals.

7. **Assess the results of reliability testing**

   Submission document: Testing attachment, section 2a2.3

   The unadjusted reliability mean coefficients of 0.40 and 0.52 for measure #0223 are regarded as moderate, achieved respectively from diagnosis year 2014 and 2014-2015. The unadjusted reliability coefficient of 0.38 is regarded as low reliability calculated from 2015.

   There is a strong impact of case volume on reliability after excluding small volume hospitals described as <u><</u>5 cases per hospital for each year cohort. Reliability estimates increased to moderate reliability (2015 unadjusted: 0.48) after controlling for volume.

8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate.

   Submission document: Testing attachment, section 2a2.2

   ☒ **Yes**

   ☐ **No**

   ☐ **Not applicable** (score-level testing was not performed)

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

   Submission document: Testing attachment, section 2a2.2

   ☒ **Yes**

   ☐ **No**

   ☐ **Not applicable** (data element testing was not performed)

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and <u>all</u> testing results):

☐ **High** (NOTE: Can be HIGH <u>only if</u> score-level testing has been conducted)

☒ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has <u>not</u> been conducted)

☐ **Low** (NOTE: Should rate <u>LOW</u> if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

☐ **Insufficient** (NOTE: Should rate <u>INSUFFICIENT</u> if you believe you do not have the information you need to make a rating decision)

11. **Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.**

Precise specifications (Box 1) →empirical testing as specified (Box 2) → empirical reliability tested as specified (Box 4)→performance measure scores computed (Box 5)→ Reliability testing demonstrates moderate confidence in score reliability (Box 6b.)→Moderate

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

12. **Please describe any concerns you have with measure exclusions.**

Submission document: Testing attachment, section 2b2.

No exclusions listed but denominator lists the numerous exclusions.

- In 2011, the Committee noted that the overall poor performance on this measure is concerning, given the very strong level 1 evidence of the impact on patient outcomes. A Committee member questioned whether Stage 2b colon cancers should be included in the measure. The developer explained the ability to identify that subset of Stage 2 colon cancers is not yet routinely possible due to the way the staging systems were designed until 2010, and stated the evidence is not settled regarding the appropriateness of adjuvant chemotherapy for Stage 2b disease.

13. **Please describe any concerns you have regarding the ability to identify meaningful differences in performance.**

Submission document: Testing attachment, section 2b4.

14. **Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.**
Submission document: Testing attachment, section 2b5.
Not applicable

15. **Please describe any concerns you have regarding missing data.**

Submission document: Testing attachment, section 2b6.

Not applicable

16. **Risk Adjustment**

16a. **Risk-adjustment method**   ☒ **None**   ☐ **Statistical model**   ☐ **Stratification**

16b. **If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?**

☐ Yes   ☐ No   ☒ Not applicable

16c. **Social risk adjustment:**

16c.1 Are social risk factors included in risk model?   ☐ Yes   ☐ No ☒ Not applicable

16c.2 Conceptual rationale for social risk factors included? ☐ Yes   ☐ No

16c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? ☐ Yes ☐ No

16d. **Risk adjustment summary:**

16d.1 All of the risk-adjustment variables present at the start of care? ☐ Yes ☐ No

16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ☐ Yes ☐ No

16d.3 Is the risk adjustment approach appropriately developed and assessed? ☐ Yes ☐ No

16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration) ☐ Yes ☐ No

16d.5. Appropriate risk-adjustment strategy included in the measure? ☐ Yes ☐ No

16e. **Assess the risk-adjustment approach**

VALIDITY: TESTING

17. **Validity testing level:** ☐ **Measure score** ☒ **Data element** ☐ **Both**

18. **Method of establishing validity of the measure score:**

☐ **Face validity**

☐ **Empirical validity testing of the measure score**

☒ **N/A (score-level testing not conducted)**

19. **Assess the method(s) for establishing validity**

Submission document: Testing attachment, section 2b2.2

Developer did not run statistical test to assess data quality. Instead, CoC performs annual caseload reviews and cases are reviewed for coding accuracy. This data is submitted annually to maintain hospital accreditation.

20. **Assess the results(s) for establishing validity**

Submission document: Testing attachment, section 2b2.3

The scope of the evaluation is 10% of the analytic caseload for each program or a maximum of 300 cases annually. Given the moderate-to-low reliability rating and the number of small-volume hospitals included, 10% of annual caseload seems low.

Additional validity testing of critical data elements was not performed, though required.

21. **Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?**

Submission document: Testing attachment, section 2b1.

☐ **Yes**

☐ **No**

☒ **Not applicable** (score-level testing was not performed)

22. **Was the method described and appropriate for assessing the accuracy of ALL critical data elements?**

NOTE that data element validation from the literature is acceptable.

Submission document: *Testing attachment, section 2b1.*

☐ **Yes**

☒ **No**

☐ **Not applicable** (data element testing was not performed)

23. **OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.**

    ☐ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

    ☐ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been conducted)

    ☐ **Low** (NOTE: Should rate LOW if you believe that there <u>are</u> threats to validity and/or relevant threats to validity were <u>not assessed OR</u> if testing methods/results are not adequate)

    ☒ **Insufficient** (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level <u>is required</u>; if not conducted, should rate as INSUFFICIENT.)

24. **Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.**

Developer did not empirically assess all threats to validity or all critical data elements.

ADDITIONAL RECOMMENDATIONS

25. **If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.**

Committee Pre-evaluation Comments:
Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

2a1. Reliability-Specifications: Which data elements, if any, are not clearly defined? Which codes with descriptors, if any, are not provided? Which steps, if any, in the logic or calculation algorithm or other specifications (e.g., risk/case-mix adjustment, survey/sampling instructions) are not clear? What concerns do you have about the likelihood that this measure can be consistently implemented?

- Specifications are adequate
- no concerns
- none
- I don't see any issues with reliability. However, this measure is only applicable to CoC centers and the number of CoC centers is trending down, I am curious to know how this affects the reliability testing. I believe increasing the pool of minorities is important and thus greater focus should be placed on racial/ethnic minorities.
- No concerns, I think think this measure can consistently be implemented.
- Most of the data elements are clearly defined. The only concern would be the pitfalls of manually abstracted measurement which could introduce different data intepretations.
- No concerns
- Yes
- I would think the measure could continue to be consistently implemented.
- All data elements appear to be completely defined. All relevant codes are provided. Updates in codes and data elements based on changing staging standards were described. All steps in the calculation algorithm are clear. This measure is likely to be consistently implemented.

2a2. Reliability - Testing: Do you have any concerns about the reliability of the measure?

The reliability testing doesn't give one great confidence that the score is a reliable indicator of quality

- no
- no
- The reliability testing for year 2015 (last year of measure) is poor (coefficient of 0.38). The reliability seems to be an issue for lower volume hospitals. This creates a threat to the observed results.
- No concerns - rated as moderately
- No
- No concerns
- No
- No concerns
- The testing was at the measure level. The data was presented in aggregate for years 2014 and 2015 and then separately for each year to demonstrate performance variation. The data was presented for all sites and again after excluding low volume sites (less than 5 cases per year.) The statistical measures were adequately described. The data presented appears to be consistent and reliable.

2b1. Validity -Testing: Do you have any concerns with the testing results?

- Not enough information available to assess
- no
- no
- No.
- No concerns - since this directly invovles stage III
- Yes
- Preliminary analysis noted as insufficient?
- no - the NCDB data has been used extensively, I'm unclear what the staff concerns are.
- I think it might be worth discussing the concerns expressed in 2011; however, I do not have anything to add on the issue.
- No. Validity testing was done at the critical data element level. The measure developer did not run statistical tests to assess data quality. Instead, CoC performs annual caseload reviews and cases are reviewed for coding accuracy. Reviews of each site are conducted annually and 10% of the cases are reviewed. I feel that this is sufficient to assure the validity of data.

2b4-7. Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data)2b4. Meaningful Differences: How do analyses indicate this measure identifies meaningful differences about quality? 2b5. Comparability of performance scores: If multiple sets of specifications: Do analyses indicate they produce comparable results? 2b6. Missing data/no response: Does missing data constitute a threat to the validity of this measure?

- As the number of cases decreases, the validity of this measure drops
- no concerns
- these are meaningful differences
- Presented data suggests only a minority of hospitals are performing worse than average. Are we sure the hospital performing better than average are truly doing so?
- No threat to the validity of this measure
- N/A
- Developer did not assess all threats to validity or all critical data elements
- no
- No concerns

- Ninety-five percent confidence intervals were calculated at the hospital level to determine statistical significance. Each site is compared to the aggregate to determine significant variation and identify meaningful differences. The developers presented multiple comparisons of the data to demonstrate that results were comparable and consistent. The missing data was presented and appears to be low, consistent, and unlikely to represent a threat to validity.

2b2-3. Other Threats to Validity (Exclusions, Risk Adjustment)2b2. Exclusions: Are the exclusions consistent with the evidence? Are any patients or patient groups inappropriately excluded from the measure?2b3. Risk Adjustment: If outcome (intermediate, health, or PRO-based) or resource use performance measure: Is there a conceptual relationship between potential social risk factor variables and the measure focus? How well do social risk factor variables that were available and analyzed align with the conceptual description provided? Are all of the risk-adjustment variables present at the start of care (if not, do you agree with the rationale provided)? Was the risk adjustment (case-mix adjustment) appropriately developed and tested? Do analyses indicate acceptable results? Is an appropriate risk-adjustment strategy included in the measure?

- None
- none
- yes; there is no risk-adjustment, nor is one really needed for this definition
- Why age more than 80 is excluded? Most providers believe that age more than 75 should be an exclusion criteria and consideration should be given to comorbidities.
- No threats or concerns
- Patient preferences are not taken into account in the exclusions
- No Concerns
- No threats I see.
- No concerns
- The denominator exclusions are listed, descriptive and consistent with clinical standards. No groups appear to be excluded inappropriately. The measure itself is not risk adjusted. The data is adjusted to present the aggregate data and to present data after excluding low volume sites (less than 5 cases.) This appears to improve the reliability of the data.

Criterion 3. Feasibility

Maintenance measures – no change in emphasis – implementation issues may be more prominent

3. Feasibility is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- Required data elements are routinely generated and used during care delivery.
- Data elements are abstracted from a record by someone other than person obtaining original information.
- Some data is in defined fields in electronic sources.
- Most data is available in electronic health records or other electronic sources. If they are not, a credible, near-term path to electronic colletion is specified.

Questions for the Committee:

- Are the required data elements routinely generated and used during care delivery?
- Are the required data elements available in electronic form, e.g., EHR or other electronic sources?

- Is the data collection strategy ready to be put into operational use?

Preliminary rating for feasibility: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

RATIONALE:

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Committee Pre-evaluation Comments:
Criteria 3: Feasibility

3. Feasibility: Which of the required data elements are not routinely generated and used during care delivery? Which of the required data elements are not available in electronic form (e.g., EHR or other electronic sources)? What are your concerns about how the data collection strategy can be put into operational use?

- No concern
- no concerns
- this is routinely generated
- Data for this measure is abstracted by cancer registrar. Data is abstracted from EHR and some elements are subject to interpretation and completeness (including comorbidities). This measure had been operationalized, however, has some flaws.
- No concerns
- This metric continues to be feasible because it is mandated registry values, however there will continue to be data lags.
- Moderate, some elements defined in EHRs, others abstracted from medical records
- yes
- No concerns
- All of the data elements are routinely generated and used during care delivery. Not all data is routinely available in an electronic format including pathology reports, staging data, reasons for not delivering adjuvant therapy, etc. Cancer registries have been collecting and reporting this data routinely for many years and I have no concerns about the ability to collect the data as described in the measure.

</div>

Criterion 4: [Usability and Use](#)

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure

Publicly reported?   ☒ **Yes** ☐   **No**

Current use in an accountability program? ☐ **Yes** ☐ **No** ☒ **UNCLEAR**

OR

Planned use in an accountability program? ☒ **Yes** ☐ **No**

Accountability program details

- Public Reporting by the Pennsylvania Health Care Quality Alliance (PHCQA)
- Quality Improvement with Benchmarking by the Commission on Cancer, National Cancer Database
- Regulatory and Accreditation, Commission on Cancer (CoC) Standards

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others [vetting]

Developer states that facilities have fostered the development of the CP3R, commenting on the design of the feedback to facilitate utilization of the tools. The RQRS was developed and based on survey results from alpha and beta testers.

CP3R/CQIP: Registrars and physicians review the measures through phone calls and e-mails.

RQRS: The responses have been positive. For example, a hospital administrator has stated that he had better physician recruiting with the implementation of this clinical data support system that alerts providers of adjuvant therapy for their patients.

Additional Feedback: [feedback loops]

The Pennsylvania Health Care Alliance (PHCQA) approached the CoC to support voluntary hospital reporting of clinical measures on their website (http://www.phcqa.org/) and has of to date yielded positive feedback in that the relationship still exists. The CoC provides the means for data collection through the annual call for data. Calculations are made and sent to the hospitals, who have stated that they wish to participate in this voluntary reporting of their performance on the measure. Upon agreement by these hospitals, the NCDB sends the Performance Rates to the PHCA for posting on the website.

Questions for the Committee:

- How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?
- How has the measure been vetted in real-world settings by those being measured or others?

Preliminary rating for Use: ☒ **Pass** ☐ **No Pass**

RATIONALE: Commission on Cancer (CoC) accredited cancer programs in Pennsylvania may elect to voluntarily report their estimated performance rates through the Pennsylvania Health Care Quality Alliance (PHCQA). Currently 60 of 73 (82.19%) CoC Pennsylvania programs are participating.

4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results [Impact/trends over time/improvement]

Between 2008 and 2015, aggregate compliance with the colon adjuvant chemotherapy measure increased from 83.1% to 88.7%. Within race and ethnicity, compliance rates for black (80.3% to 85.7%) and Hispanic (75.7% to 82.5%) patients have improved. For the uninsured/Medicaid patient cohort, the compliance rates moved upward from 78.3% (2008) to 86.2% (2015). By Census region, the West with the lowest aggregate compliance rate improved from 77.9% (2008) to 89.5% (2015).

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

None reported.

Potential harms

No harms identified.

Additional Feedback:

Questions for the Committee:

- How can the performance results be used to further the goal of high-quality, efficient healthcare?
- Do the benefits of the measure outweigh any potential unintended consequences?

Preliminary rating for Usability and use: ☐ **High** ☒ **Moderate** ☐ **Low** ☐ **Insufficient**

RATIONALE:

Committee Pre-evaluation Comments:
Criteria 4: Usability and Use

4a1. Use - Accountability and Transparency: How is the measure being publicly reported? Are the performance results disclosed and available outside of the organizations or practices whose performance is measured? For maintenance measures - which accountability applications is the measure being used for? For new measures - if not in use at the time of initial endorsement, is a credible plan for implementation provided? 4a2. Use - Feedback on the measure: Have those being measured been given performance results or data, as well as assistance with interpreting the measure results and data? Have those being measured or other users been given an opportunity to provide feedback on the measure performance or implementation? Has this feedback has been considered when changes are incorporated into the measure?

- In use
- planned for use and currently pubically reported
- selectively reported, used as part of CoC standards
- The performance on this measure is included in aggregate measures for Pennsylvania. Some hospitals are required to publicly report their performance. each CoC center can compare itself to other hospitals. Although this is a process measure, the impact of payer and practice policies of the group can affect the performance eo the measure. None of these factors can be used in comparison to other CoC sites and thus hard to use for QI.
- Yes
- Measure is being used as part of internal quality reporting, and Commission on Cancer reporting.
- Public reporting by PHCQA, QI benchmarking with CoC and CoC Accreditation Standards
- No problem

- It appears the measure results are disclosed and available; and can be used for improvement efforts.
- Multiple initiatives include the measure in public reporting. The developers describe these initiatives. These results are available outside of the organizations/practices. These are used for accountable care payment models including oncology medical home models, the CoC, and others. ASCO also uses a similar measure for its QOPI reporting. The RQRS reporting system has increased usefulness and reporting based on this measure.

4b1. Usability – Improvement: How can the performance results be used to further the goal of high-quality, efficient healthcare? If not in use for performance improvement at the time of initial endorsement, is a credible rationale provided that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations?4b2. Usability – Benefits vs. harms: Describe any actual unintended consequences and note how you think the benefits of the measure outweigh them.

- No unintended consequences foreseen
- no perceived harms
- performance will help streamline care
- I don't see any harm except for the time of registrar. Given that adjuvant chemotherapy improves cure rate this would be considered a time well spent.
- Access to patient clinical follow-up may be limited or unavailable
- More timely data would be needed to be able to use the metric for more ongoing performance improvement.
- Improvements noted between 2008 and 2015 but moderate capacity for continued improvements remain.
- Useful
- No concerns
- There are unlikely to be any unintended consequences related to the uses of this measure as it focuses on a process that is associated with performance improvement in the delivery of adjuvant therapy to high risk patients with Stage III colon cancer.

Criterion 5: Related and Competing Measures

Related or competing measures

0385e: Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients

Harmonization

The measure specifications were not harmonized. The measures assess different levels of data analysis, 0385 assesses clinical group practice while 0223 assesses facility level performance. The data sources are also different for the two measures increasing the burden of collection for harmonization.

Committee Pre-evaluation Comments: Criterion 5:
Related and Competing Measures

5. Related and Competing: Are there any related and competing measures? If so, are any specifications that are not harmonized? Are there any additional steps needed for the measures to be harmonized?

- They aren't harmonized. It does seem like there is some room for harmonization, though.

- 0385e measures at level of clinical group practice and current measure at facility level. unclear why both are needed.
- no
- 0385e: Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients. The two measures have different sources for data. 0385e is independent of CoC and can be adopted a broader population.
- No additional steps at this time.
- No
- Compteting measures documented 0385e Colon Cancer chemotherapy for AJCC Stage III colon cancer patients
- Not that I know of
- This measure does not appear to compete with any other measure; e.g. measure 0385.
- There appears to be one competing measure which has not been harmonized. (0385e)

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: 02/14/2020

- No comments received

ADDITIONAL RECOMMENDATIONS

26. **If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.**

Developer Submission

Additional evaluations and submission materials attachments…

NQF #: 0223

Corresponding Measures:

De.2. Measure Title: Adjuvant chemotherapy is recommended, or administered within 4 months (120 days) of diagnosis for patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer

Co.1.1. Measure Steward: Commission on Cancer, American College of Surgeons

De.3. Brief Description of Measure: Percentage of patients, age = 18 and < 80 at diagnosis, who have their first diagnosis of cancer (epithelial malignancy) that is lymph node positive and at AJCC stage III, whose primary tumor is of the colon and chemotherapy was recommended or administered within 4 months (120 days) of diagnosis

1b.1. Developer Rationale: Improved survival for patients with Stage III lymph node positive colon cancer

S.4. Numerator Statement: Adjuvant chemotherapy is administered within 4 months (120 days) of the date of diagnosis or it is recommended but not administered

S.6. Denominator Statement: Include if all of the following characteristics are identified:

Men or Women
Age = 18 and < 80 at time of diagnosis
Known or assumed to be first or only cancer diagnosis
Epithelial malignancy only
Invasive tumors
Primary tumors of the colon
All or part of 1st course of treatment performed at the reporting facility
Known to be alive within 4 months (120 days) of date of diagnosis
Lymph node positive disease
Surgical procedure of the primary site

S.8. Denominator Exclusions: Exclude, if any of the following characteristics are identified:

Under age 18 or over age 80 at time of diagnosis
Second or subsequent cancer diagnosis
Tumor not originating in the colon
Non-epithelial malignancies
Non-invasive tumors
Stage 0, in situ tumor
Stage IV, metastatic tumor
None of 1st course therapy performed at reporting facility
Died within 4 months (120 days) of diagnosis
Not lymph node positive disease
Patient enrolled in a clinical trial that directly impacts delivery of the standard of care
No surgical procedure of the primary site

De.1. Measure Type: Process

S.17. Data Source: Registry Data

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Mar 01, 2007 **Most Recent Endorsement Date:** Oct 26, 2016

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? Not Applicable

1. Evidence and Performance Gap – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. *Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.*

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

ACT_evidence-637069930027797874.docx

1a.1 <u>For Maintenance of Endorsement:</u> Is there new evidence about the measure since the last update/submission?
Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

No

1a. Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*)**:** 0223

Measure Title: Adjuvant chemotherapy is recommended, or administered within 4 months (120 days) of diagnosis for patients under the age of 80 with AJCC Stage III (lymph node positive) colon 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: <u>11/1/2019</u>

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 chemotherapy is recommended, or administered within 4 months (120 days) of diagnosis for patients under the age of 80 with AJCC Stage III (lymph node positive) colon 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.
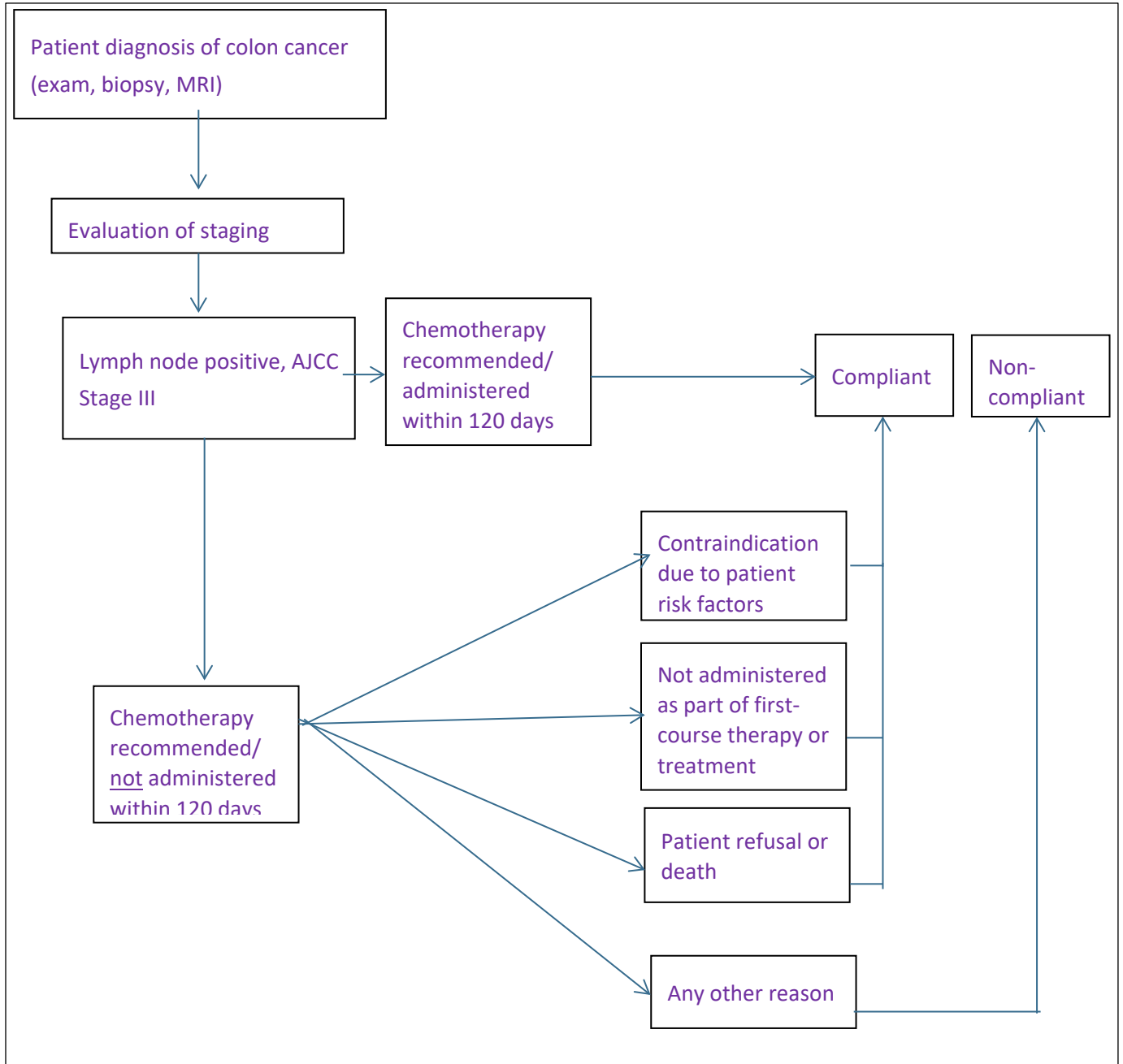
Identify Problem:	The standard of care states that adjuvant chemotherapy is recommended for AJCC Stage III colon cancer patients under the age of 80, however there continues to be patient populations not receiving this care
Goal:	To ensure all AJCC Stage III colon cancer patients under the age of 80, where applicable, undergo chemotherapy within 120 days of diagnosis

Standard of Care:	Adjuvant chemotherapy is recommended, or administered within 4 months (120 days) of diagnosis for patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer
Inputs	• Patient • Clinicians: oncologist, surgeon • Nurses • Chemotherapy • Commission on Cancer (CoC) Accredited Cancer Program • Registrars • National Cancer Database (NCDB) • Rapid Quality Reporting System (RQRS)

Processes	1. Clinician diagnoses patient with AJCC Stage III colon cancer
	    1a. Patient Characteristics:
	        • 18 – 79 years old
	        • Male or female
	        • Alive within 120 days of diagnosis
	        • Lymph node positive
	    1b. Patient's Tumor Characteristics:
	        • First or only diagnosis of malignant neoplasm
	        • Epithelial
	        • Invasive
	2. Clinician recommends chemotherapy as part of first course of treatment to the patient
	3. Patient undergoes surgery of the colon performed by a clinician
	4. Chemotherapy is administered to the patient within 120 days of diagnosis OR chemotherapy is not administered to the patient
	5. Registrar abstracts and submits the patient's treatment to the CoC's NCDB and RQRS

Outputs	• Chemotherapy is recommended • Chemotherapy is administered within 120 days • Alert are given to programs, within 120 days of diagnosis, notifying them the progress of each patient's adherence to the measure by sending reminders to recommend and/or give patients chemotherapy
Outcomes	• Compliant with the standard of care
Impact	• Address "underuse and wide variation in the use of chemotherapy with Stage III colon cancer" (https://www.facs.org/-/media/files/quality-programs/cancer/ncdb/measure-specs-colon.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 <u>systematic review of the body of evidence</u> 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

Source of Systematic Review: • **Title** • **Author** • **Date** • **Citation, including page number** • **URL**	Title: National Comprehensive Cancer Network (NCCN) Guidelines v2.2019 Date Created: 05/05/2019 Date Accessed: 07/31/2019 URL: https://www.nccn.org/professionals/physician_gls/pdf/colon.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.	Pathologic Stage T1-3, N1-2, M0 or T4, N1-2, M0: FOLFOX (category 1) preferred. Other options include: FLOX (category 1) or CapeOx (Category 1) or Capecitabine or 5-FU/Leucovorin
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 with high level evidence
Estimates of benefit and consistency across studies	Approximate net benefit of 25% reduction in risk of death and high level of consistency
What harms were identified?	
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	

_____

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

1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure *(e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)*

If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

Improved survival for patients with Stage III lymph node positive colon cancer

1b.2. Provide performance scores on the measure as specified (<u>current and over time</u>) at the specified level of analysis. *(<u>This is required for maintenance of endorsement</u>. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

The nationally recognized National Cancer Database (NCDB), jointly sponsored by the American College of Surgeons and the American Cancer Society, is a clinical oncology database sourced from hospital registry data that are collected in about 1,500 Commission on Cancer (CoC)-accredited facilities. NCDB data are used to analyze and track patients with malignant neoplastic diseases, their treatments, and outcomes. Data represent approximately 71 percent of newly diagnosed colon, excluding rectum, cancer cases nationwide and 37 million historical records. This analysis uses NCDB data.

The NCDB collects data from CoC accredited cancer programs on an annual basis; the data we collect is in accordance with standard registry procedures. In January of 2018, 2016 diagnoses were collected. This information was released to accredited cancer programs in the late summer. However, we find information on some of the therapies which take longer to be received are not complete upon initial submission and need time to document receipt of adjuvant therapy. Therefore the CoC does not begin surveying or holding programs accountable for their Estimated Performance Rates (EPRs) until the year after it is released to ensure adequate adjuvant therapy information has been documented. We generally see a slight decrease in compliance for the most recent year until programs have had time to collect this information, since we don't feel all adjuvant therapy information are complete at initial submission we did not include the 2016 data in the application for this measure and used the next most recent annual rate of 2015 for this measure.

In 2008, 11,057 cases in 1,449 facilities were in the denominator and the mean estimated performance rate (EPR) was 83.1% (Std.=0.4). IQR=25.0% (75.0%-100.0%), minimum=0.0%, maximum=100.0%. In 2015, 10,613 cases in 1,299 facilities were in the denominator and the mean estimated performance rate (EPR) was 88.7% (Std.=0.3). IQR=15.4% (84.6%-100.0%), minimum=0.0%, maximum=100.0%.

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

Not Applicable

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. *(<u>This is required for maintenance of endorsement</u>. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

The data source is described in 1b.2. Disparities shown in demographic comparisons using EPRs were assessed by sex, race/ethnicity, age at diagnosis, insurance status, income and education at the zip code level, facility type, and census region.

Sex

Sex was defined as male or female. For both males and females, EPRs were higher in 2015 than in 2008. The differences in EPRs from 2008 to 2015 were as follows: 5.7% for males and 5.4% for females. In 2015 the

lowest EPR was males (88.5%, 95% CI: 87.6%-89.3%, n=5,529), and the highest EPR was females (88.8%, 95% CI: 88.0%-89.7%, n=5,084). In 2008 the lowest EPR was males (82.8%, 95% CI: 81.8%-83.8%, n=5,578), and the highest EPR was females (83.4%, 95% CI: 82.4%-84.4%, n=5,479).

Race/Ethnicity

Race/ethnicity was defined as non-Hispanic white, non-Hispanic black, Asian/Hawaiian/Pacific Islander, Hispanic or other/unknown. In all race/ethnicity groups, EPRs were higher in 2015 than in 2008. The differences in EPRs from 2008 to 2015 were as follows: 5.5% for non-Hispanic white, 5.4% for non-Hispanic black, 4.6% for Asian/Hawaiian/Pacific Islander, 6.8% for Hispanic, and 6.8% for other/unknown. In 2015 the lowest EPR was Hispanic (82.5%, 95% CI: 79.9%-85.2%, n=789), followed by non-Hispanic black (85.7%, 95% CI: 83.9%-87.4%, n=1,564), Asian/Hawaiian/Pacific Islander (86.2%, 95% CI: 82.9%-89.5%, n=427), other/unknown (87.2%, 95% CI: 84.0%-90.3%, n=429), and the highest EPR was non-Hispanic whites (90.2%, 95% CI: 89.5%-90.8%, n=7,404). In 2008 the lowest EPR was Hispanic (75.7%, 95% CI: 72.4%-78.9%, n=653), followed by non-Hispanic black (80.3%, 95% CI: 78.3%-82.3%, n=1,494), other/unknown (80.4%, 95% CI: 78.0%-82.9%, n=991), Asian/Hawaiian/Pacific Islander (81.6%, 95% CI: 77.4%-85.8%, n=326), and the highest EPR was non-Hispanic whites (84.7%, 95% CI 83.9%-85.5%, n=7,593).

Age at Diagnosis

Age at diagnosis was defined as 18-49, 50-59, 60-69 or 70-79. In all age groups, EPRs were higher in 2015 than in 2008. The differences in EPRs from 2008 to 2015 were as follows: 4.3% for 18-49, 4.0% for 50-59, 5.3% for 60-69, and 7.6% for 70-79. In 2015 the lowest EPR was 70-79 (87.2%, 95% CI 86.0%-88.4%, n=2,882), followed by 60-69 (88.2%, 95% CI: 87.1%-89.2%, n=3,421), 50-59 (89.0%, 95% CI: 87.8%-90.2%, n=2,639), and the highest EPR was 18-49 (91.6%, 95% CI: 90.3%-93.0%, n=1,671). In 2008 the lowest EPR was 70-79 (79.6%, 95% CI: 78.2%-81.0%, n=3,341), followed by 60-69 (82.9%, 95% CI: 81.7%-84.2%, n=3,299), 50-59 (85.0%, 95% CI: 83.6%-86.3%, n=2,718), and the highest EPR was 18-49 (87.3%, 95% CI 85.7%-88.9%, n=1,699).

Insurance Status

Insurance status was defined as insurance at the time of diagnosis as not insured/Medicaid, private, Medicare, other government and other/unknown. In all insurance status groups, EPRs were higher in 2015 than in 2008. The differences in EPRs from 2008 to 2015 were as follows: 7.9% for not insured/Medicaid, 4.6% for private, 6.8% for Medicare, 5.5% for other government, and 2.5% for other/unknown. In 2015 the lowest EPR was other/unknown (77.3%, 95% CI: 70.7%-83.9%, n=154), followed by other government (85.7%, 95% CI: 79.6%-91.8%, n=126), not insured/Medicaid (86.2%, 95% CI: 84.1%-88.3%, n=1,043), Medicare (87.5%, 95% CI: 86.6%-88.5%, n=4,418), and the highest EPR was private (90.6%, 95% CI: 89.8%-91.5%, n=4,872). In 2008 the lowest EPR was other/unknown (74.8%, 95% CI: 68.1%-81.6%, n=159), followed by not insured/Medicaid (78.3%, 95% CI: 75.3%-81.2%, n=745), other government (80.2%, 95% CI: 72.0%-88.4%, n=91), Medicare (80.7%, 95% CI: 79.6%-81.9%, n=4,616), and the highest EPR was private (86.0%, 95% CI: 85.1%-87.0%, n=5,446).

Median Income Quintile

Median income quintiles was defined as <$36,000, $36,000-$43,999, $44,000-$52,999, $53,000-$68,999, $69,000+ or other/unknown, based on the 2012 American Community Survey at the zip code level. In all median income quintiles, EPRs were higher in 2015 than in 2008. The differences in EPRs from 2008 to 2015 were as follows: 7.1% for <$36,000, 3.6% for $36,000-$43,999, 5.7% for $44,000-$52,999, 4.5% for $53,000-$68,999, 6.6% for $69,000+, and 7.1% for other/unknown. In 2015 the lowest EPR was other/unknown (74.0%, 95% CI: 61.8%-86.2%, n=50), followed by <$36,000 (86.0%, 95% CI: 84.3%-87.7%, n=1,620), $36,000-$43,999 (87.3%, 95% CI: 85.9%-88.8%, n=1,973), $44,000-$52,999 (88.9%, 95% CI: 87.6%-90.3%, n=2,093), $53,000-$68,999 (89.7%, 95% CI: 88.5%-90.9%, n=2,437), and the highest EPR was $69,000+ (90.5%, 95% CI: 89.4%-91.7%, n=2,440). In 2008 the lowest EPR was other/unknown (66.9%, 95% CI: 58.6%-75.3%, n=121), followed by <$36,000 (78.9%, 95% CI: 76.9%-80.8%, n=1,685), $44,000-$52,999 (83.2%, 95% CI: 81.7%-84.8%, n=2,171), $36,000-$43,999 (83.7%, 95% CI: 82.0%-85.3%, n=1,990), $69,000+ (83.9%, 95% CI: 82.5%-85.4%, n=2,529), and the highest EPR was $53,000-$68,999 (85.2%, 95% CI: 83.9%-86.6%, n=2,561).

Median Education Quartile

Median education quartile was defined as <7.0% with no high school degree, 7.0%-12.9%, 13.0%-20.9%, 21.0%+ or other/unknown, based on the 2012 American Community Survey at the zip code level. In all median education quintiles, EPRs were higher in 2015 than in 2008. The differences in EPRs from 2008 to 2015 were as follows: 4.8% for <7.0%, 5.4% for 7.0%-12.9%, 6.1% for 13.0%-20.9%, 5.7% for 21.0%+, and 11.0% for other/unknown. In 2015 the lowest EPR was other/unknown (75.6%, 95% CI: 63.0%-88.1%, n=45), followed by 21.0%+ (85.1%, 95% CI: 83.6%-86.6%, n=2,119), 13.0%-20.9% (87.2%, 95% CI: 86.0%-88.4%, n=2,847), 7.0%-12.9% (90.3%, 95% CI: 89.3%-91.3%, n=3,365), and the highest EPR was <7.0% (91.7%, 95% CI: 90.6%-92.9%, n=2,237). In 2008 the lowest EPR was other/unknown (64.6%, 95% CI: 55.8%-73.4%, n=113), followed by 21.0%+ (79.4%, 95% CI: 77.7%-81.2%, n=2,125), 13.0%-20.9% (81.1%, 95% CI: 79.7%-82.6%, n=2,912), 7.0%-12.9% (84.9%, 95% CI: 83.7%-86.1%, n=3,452), and the highest EPR was <7.0% (86.9%, 95% CI: 85.6%-88.3%, n=2,455).

Facility Type

Facility type was defined by program's CoC-accreditation status as academic cancer programs, community cancer programs, comprehensive community cancer programs, integrated network cancer programs, NCI & PPS-Exempt cancer programs and other/unknown cancer programs. In all facility types, EPRs were higher in 2015 than in 2008. The differences in EPRs from 2008 to 2015 were as follows: 6.4% for academic cancer programs, 4.0% for community cancer programs, 2.2% for comprehensive community cancer programs, 5.6% for integrated network cancer programs, 12.5% for NCI & PPS-Exempt cancer programs, and 28.6% for other/unknown cancer programs. In 2015 the lowest EPR was academic cancer programs (86.7%, 95% CI: 85.3%-88.1%, n=2,202), followed by community cancer programs (87.9%, 95% CI 86.2%-89.7%, n=1,340), comprehensive community cancer programs (88.8%, 95% CI 87.9%-89.7%, n=4,862), NCI & PPS-Exempt cancer programs (89.1%, 95% CI: 87.2%-91.1%, n=975), integrated network cancer programs (91.8%, 95% CI: 90.2%-93.4%, n=1,156), and the highest EPR was other/unknown cancer programs (97.4%, 95% CI: 93.9%-100.0%, n=78). In 2008 the lowest EPR was other/unknown cancer programs (68.8%, 95% CI: 65.7%-71.9%, n=863) followed by NCI & PPS-Exempt cancer programs (76.6%, 95% CI: 73.5%-79.8%, n=689), academic cancer programs (80.3%, 95% CI 78.6%-82.1%, n=1,998), community cancer programs (83.9%, 95% CI: 81.9%-86.0%, n=1,239), integrated network cancer programs (86.2%, 95% CI: 84.4%-88.0%, n=1,462), and the highest EPR was comprehensive community cancer programs (86.6%, 95% CI: 85.6%-87.5%, n=4,806).

Census Region

Census Region was defined as Northeast, South, Midwest, West, Pacific or missing/out of US. In all census regions, EPRs were higher in 2015 than in 2008. The differences in EPRs from 2008 to 2015 were as follows: 7.5% for Northeast, 5.2% for South, 3.6% for Midwest, 11.6% for West, 5.6% for Pacific, and 29.0% for missing/out of US. In 2015 the lowest EPR was missing/out of US (76.6%, 95% CI: 64.5%-88.7%, n=47), followed by South (87.0%, 95% CI: 86.0%-88.0%, n=4,381), Pacific (87.4%, 95% CI: 85.5%-89.2%, n=1,195), Northeast (88.1%, 95% CI: 86.7%-89.6%, n=1,934), West (89.5%, 95% CI: 86.6%-92.5%, n=420), and the highest EPR was Midwest (92.5%, 95% CI: 91.5%-93.5%, n=2,636). In 2008 the lowest EPR was missing/out of US (47.6%, 95% CI: 26.3%-69.0%, n=21), followed by West (77.9%, 95% CI: 74.4%-81.5%, n=526), Northeast (80.6%, 95% CI: 78.9%-82.3%, n=2,144), South (81.8%, 95% CI: 80.7%-83.0%, n=4,391), Pacific (81.8%, 95% CI: 79.7%-84.0%, n=1,211), and the highest EPR was Midwest (88.9%, 95% CI: 87.7%-90.0%, n=2,764).

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4

Not Applicable

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ***Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.***

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area *(check all the areas that apply):*

Cancer, Cancer : Colorectal

De.6. Non-Condition Specific*(check all the areas that apply):*

Care Coordination, Disparities Sensitive

De.7. Target Population Category *(Check all the populations for which the measure is specified and tested if any):*

Elderly

S.1. Measure-specific Web Page *(Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)*

See pages 3-8:
https://www.facs.org/~/media/files/quality%20programs/cancer/ncdb/measure%20specs%20colon.ashx

S.2a. If this is an eMeasure, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure **Attachment:**

S.2b. Data Dictionary, Code Table, or Value Sets *(and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)*

No data dictionary **Attachment:**

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

No, this is not an instrument-based measure **Attachment:**

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Not an instrument-based measure

S.3.1. For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

Yes

S.3.2. For maintenance of endorsement, please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

The following changes are due to the American Joint Committee on Cancer (AJCC) 8th edition staging manual, the Commission on Cancer's Standards for Oncology Registry Entry (STORE) coding manual and North American Association of Central Cancer Registry (NAACCR) updates and applies to cases diagnosed on and after January 1, 2018:

Stageable epithelial tumors histology [NAACCR Item# 522] = 8010, 8013, 8020, 8041, 8070, 8140, 8213, 8246, 8265, 8480, 8490, 8510, 8560, 8000, 8481

AJCC clinical stage group [NAACCR Item# 1004] ? 0, 4A, 4B, 4C

AJCC pathologic stage group [NAACCR Item# 1014] ? 0, 4A, 4B, 4C

AJCC clinical M [NAACCR Item# 1003] ? cM1, cM1a, cM1b, cM1c, pM1, pM1a, pM1b, pM1c

AJCC pathologic M [NAACCR Item# 1013] ? cM1, cM1a, cM1b, cM1c, pM1, pM1a, pM1b, pM1c

S.4. Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.*

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Adjuvant chemotherapy is administered within 4 months (120 days) of the date of diagnosis or it is recommended but not administered

S.5. Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*

IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Chemotherapy recommended and not received [NAACCR Item# 1390] = 82, 85, 86, 87 (82:not recommended/ administered because it was contraindicated due to patient risk factors, 85:not administered because the patient died prior to planned or recommended therapy, 86:It was recommended by the patient´s physician, but was not administered as part of first-course therapy. No reason was stated in the patient record, 87: it was recommended by the patient´s physician, but this treatment was refused by the patient, the patient´s family member, or the patient´s guardian. The refusal was noted in the patient record)

or

Chemotherapy administered [NAACCR Item# 1390] = 01, 02, 03 AND date chemotherapy started [NAACCR Item# 1220] = 120 days following date of initial diagnosis [NAACCR Item# 390]

S.6. Denominator Statement *(Brief, narrative description of the target population being measured)*

Include if all of the following characteristics are identified:

Men or Women

Age = 18 and < 80 at time of diagnosis

Known or assumed to be first or only cancer diagnosis

Epithelial malignancy only

Invasive tumors

Primary tumors of the colon

All or part of 1st course of treatment performed at the reporting facility

Known to be alive within 4 months (120 days) of date of diagnosis

Lymph node positive disease

Surgical procedure of the primary site

S.7. Denominator Details *(All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection*

items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)

IF an OUTCOME MEASURE, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Sex [NAACCR Item# 220] = 1, 2

Age [NAACCR Item# 230] = 18 and < 80

Known or assumed to be first or only cancer diagnosis [NAACCR Item# 560] = 00, 01

Stageable epithelial tumor ICD-O codes in the AJCC 8th Edition staging manual [NAACCR Item# 522] = 8010, 8013, 8020, 8041, 8070, 8140, 8213, 8246, 8265, 8480, 8490, 8510, 8560, 8000, 8481

Invasive tumor behavior [NAACCR Item# 523] = 3

Primary tumors of the colon [NAACCR Item# 400] = C18.0, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C18.9

AJCC clinical stage group [NAACCR Item# 1004] ? 0, 4A, 4B, 4C

AJCC pathologic stage group [NAACCR Item# 1014] ? 0, 4A, 4B, 4C

AJCC clinical M [NAACCR Item# 1003] ? cM1, cM1a, cM1b, cM1c, pM1, pM1a, pM1b, pM1c

AJCC pathologic M [NAACCR Item# 1013] ? cM1, cM1a, cM1b, cM1c, pM1, pM1a, pM1b, pM1c

All or part of 1st course of treatment performed at the reporting facility [NAACCR Item# 610] = 10-22

Known to be alive within 4 months (120 days) of date of diagnosis: vital status [NAACCR Item# 1760] = 1 AND date of last contact or death [NAACCR Item# 1750] – date of initial diagnosis [NAACCR Item# 390] > 120

Surgical Procedure of the Primary Site [NAACCR Item# 1290] = 30–90

Lymph node positive disease [NAACCR Item# 820] = 1-90, 95, 97

S.8. Denominator Exclusions *(Brief narrative description of exclusions from the target population)*

Exclude, if any of the following characteristics are identified:

Under age 18 or over age 80 at time of diagnosis

Second or subsequent cancer diagnosis

Tumor not originating in the colon

Non-epithelial malignancies

Non-invasive tumors

Stage 0, in situ tumor

Stage IV, metastatic tumor

None of 1st course therapy performed at reporting facility

Died within 4 months (120 days) of diagnosis

Not lymph node positive disease

Patient enrolled in a clinical trial that directly impacts delivery of the standard of care

No surgical procedure of the primary site

S.9. Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

See pages 3-8:
https://www.facs.org/~/media/files/quality%20programs/cancer/ncdb/measure%20specs%20colon.ashx

S.10. Stratification Information (*Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.*)

No stratification applied

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

No risk adjustment or risk stratification

If other:

S.12. Type of score:

Rate/proportion

If other:

S.13. Interpretation of Score (*Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score*)

Better quality = Higher score

S.14. Calculation Algorithm/Measure Logic (*Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.*)

See pages 3-8:
https://www.facs.org/~/media/files/quality%20programs/cancer/ncdb/measure%20specs%20colon.ashx

S.15. Sampling (*If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.*)

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

Not Applicable

S.16. Survey/Patient-reported data (*If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.*)

Specify calculation of response rates to be reported with performance measure results.

Not Applicable

S.17. Data Source (*Check ONLY the sources for which the measure is SPECIFIED AND TESTED*).

If other, please describe in S.18.

Registry Data

S.18. Data Source or Collection Instrument (*Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.*)

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

Hospital cancer registry data, reported to the American College of Surgeons' Commission on Cancer, National Cancer Database

S.19. Data Source or Collection Instrument (*available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1*)

Available at measure-specific web page URL identified in S.1

S.20. Level of Analysis (*Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED*)

S.21. Care Setting *(Check ONLY the settings for which the measure is SPECIFIED AND TESTED)*

Inpatient/Hospital

If other:

S.22. COMPOSITE Performance Measure - Additional Specifications *(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)*

Not Applicable

2. Validity – See attached Measure Testing Submission Form

ACT_testing-637069873924852063.docx

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

No - This measure is not risk-adjusted

Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (*if previously endorsed*)**:** 0223
Measure Title: Adjuvant chemotherapy is recommended, or administered within 4 months (120 days) of diagnosis for patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer

Date of Submission: August 1, 2019

Type of Measure:

☐ **Outcome (***including PRO-PM***)**	☐ **Composite** – *STOP – use composite testing form*
☐ Intermediate Clinical Outcome	☐ Cost/resource
☒ Process *(including Appropriate Use)*	☐ Efficiency
☐ Structure	

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. <u>If there are differences by aspect of testing,</u>(e.g., reliability vs. validity) be sure to indicate the specific differences in question 1.7.

1.1. What type of data was used for testing? (*Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for <u>all</u> the sources of data specified and intended for measure implementation.* ***If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.***)

Measure Specified to Use Data From: (***must be consistent with data sources entered in S.17***)	Measure Tested with Data From:
☐ abstracted from paper record	☐ abstracted from paper record
☐ claims	☐ claims
☒ registry	☒ registry
☐ abstracted from electronic health record	☐ abstracted from electronic health record
☐ eMeasure (HQMF) implemented in EHRs	☐ eMeasure (HQMF) implemented in EHRs
☐ other: Click here to describe	☐ other: Click here to describe

1.2. If an existing dataset was used, identify the specific dataset (*the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry*).

The nationally recognized National Cancer Database (NCDB), jointly sponsored by the American College of Surgeons and the American Cancer Society, is a clinical oncology database sourced from hospital registry data that are collected in approximately 1,500 Commission on Cancer (CoC)-accredited facilities. NCDB data are used to analyze and track patients with malignant neoplastic diseases, their treatments, and outcomes. Data represent approximately 71 percent of newly diagnosed colon, excluding rectum, cancer cases nationwide.

The NCDB collects data from CoC-accredited cancer programs on an annual basis; the data collected is in accordance with standard registry procedures. In January of 2019, 2016 diagnoses were processed and included in the data warehouse. As of this submission, 2017 diagnoses were not yet processed. We find information on some of the therapies which take longer to receive are not complete upon initial submission and need time to document receipt of adjuvant therapy. Therefore the CoC does not begin surveying or holding programs accountable for their performance rates until the year after it is released to ensure adequate adjuvant therapy information has been documented. We generally see a slight decrease in compliance for the most recent data year until programs have had time to submit treatment data and as such 2016 data were not included. Throughout this testing document, there are three patient cohorts presented, which represent combined 2014 and 2015 diagnoses, and 2014 and 2015 separately.

1.3. What are the dates of the data used in testing? Click here to enter date range

January 1, 2014-December 31, 2015

1.4. What levels of analysis were tested? (*testing must be provided for <u>all</u> the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)

Measure Specified to Measure Performance of: (***must be consistent with levels entered in item S.20***)	Measure Tested at Level of:

☐ individual clinician		☐ individual clinician	
☐ group/practice		☐ group/practice	
☒ hospital/facility/agency		☒ hospital/facility/agency	
☐ health plan		☐ health plan	
☐ other: Click here to describe		☐ other: Click here to describe	

1.5. How many and which <u>measured entities</u> were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample*)

Testing for measure #0223 was performed with 1,406 Commission on Cancer- accredited hospitals across the United States from 2014-2015.

Diagnosis Year(s)		2014 – 2015	2014	2015
Hospital N		1,406	1,356	1,299
Range of Cases per Hospital		1 - 193	1 - 107	1 - 86
Hospital Category Type	Academic	189 (13.44%)	185 (13.64%)	187 (14.40%)
	Community	388 (27.60%)	353 (26.03%)	352 (27.10%)
	Comprehensive Community	568 (40.40%)	561 (41.37%)	555 (42.73%)
	Integrated Network	155 (11.02%)	152 (11.21%)	146 (11.24%)
	NCI & PPS-Exempt	45 (3.20%)	45 (3.32%)	44 (3.39%)
	Other	61 (4.34%)	60 (4.42%)	15 (1.15%)

1.6. How many and which <u>patients</u> were included in the testing and analysis (by level of analysis and data source)? (*identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample*)

The 2014-2015 testing data included 21,470 cases, all of which are measure-eligible.

Diagnosis Year(s)		2014 - 2015	2014	2015
Case N		21,470	10,857	10,613
Sex	Male	11,022 (51.34%)	5,493 (50.59%)	5,529 (52.10%)
	Female	10,448 (48.66%)	5,364 (49.41%)	5,084 (47.90%)
Race/ Ethnicity	Non-Hispanic White	15,035 (70.03%)	7,631 (70.29%)	7,404 (69.76%)
	Non-Hispanic Black	3,146 (14.65%)	1,582 (14.57%)	1,564 (14.74%)
	Asian, Hawaiian, Pacific Islander	831 (3.87%)	404 (3.72%)	427 (4.02%)
	Hispanic	1,561 (7.27%)	772 (7.11%)	789 (7.43%)
	Other	897 (4.18%)	468 (4.31%)	429 (4.04%)
	18 - 49	3,364 (15.67%)	1,693 (15.59%)	1,671 (15.74%)

Age at Diagnosis	50 - 59	5,401 (25.16%)	2,762 (25.44%)	2,639 (24.87%)
	60 - 69	6,855 (31.93%)	3,434 (31.63%)	3,421 (32.23%)
	70 - 79	5,850 (27.25%)	2,968 (27.34%)	2,882 (27.16%)
Insurance Status	Not Insured, Medicaid	2,109 (9.82%)	1,066 (9.82%)	1,043 (9.83%)
	Private	9,944 (46.32%)	5,072 (46.72%)	4,872 (45.91%)
	Medicare	8,841 (41.18%)	4,423 (40.74%)	4,418 (41.63%)
	Other Government	243 (1.13%)	117 (1.08%)	126 (1.19%)
	Other/Unknown	333 (1.55%)	179 (1.65%)	154 (1.45%)

1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.

Not Applicable

1.8 What were the social risk factors that were available and analyzed? For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

Not Applicable

_____

2a2. RELIABILITY TESTING

Note: *If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.*

2a2.1. What level of reliability testing was conducted? (*may be one or both levels*)
☐ **Critical data elements used in the measure** (*e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements*)
☒ **Performance measure score** (e.g., *signal-to-noise analysis*)

2a2.2. For each level checked above, describe the method of reliability testing and what it tests (*describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used*)

There are three characteristics that generally inform the reliability of a measure including hospital-level performance, the variability of performance differences across hospitals, and case volume. In an effort to illustrate the impact of performance and volume, reliability is presented in three ways. Three patient cohorts constructed represent combined 2014 and 2015 diagnoses, and 2014 and 2015 separately. Reliability results are shown for each cohort. Within each cohort, data model reliability estimations are shown computed from both unadjusted and risk-adjusted models. Risk-adjustment included patient characteristics of sex, age at diagnosis, race/ethnicity, and insurance status. The impact of case volume on reliability is demonstrated in section 2a2.3. Table 1 depicts reliability for all cases from all hospitals, whereas Table 2 only includes cases from hospitals that have more than 5 measure-eligible cases for each year cohort.

Measure compliance was modeled from 2-level hierarchical logistic regression models using Bayesian shrinkage adjustments that control for random error for both patients and hospitals. Statistical reliability is

determined with a binary-outcome from two types of variability, between hospitals (signal) obtained from the regression model and within hospitals (noise) based on the standard error of the proportion of the hospital random effect. Reliability is presented here on a scale from 0 to 1 from a range indicating measurement error to true differences in hospital performance. Statistical reliability was converted from the log-odds scale to the probability scale through the hierarchical method of calculation as described by Deutsch et al. and referenced in other publications [1][2][3][4][5].

[1]Deutsch A, Smith L, Gage B, et al. Patient-reported outcomes in performance measurement: commissioned paper on PRO-based performance measures for healthcare accountable entities draft no. 1. Prepared for NQF by RTI International and the Brookings Institution. September 4, 2012. Available at: https://www.qualityforum.org/Projects/n-r/Patient-Reported_Outcomes/ Commissioned_Paper_2.aspx. Accessed on September 28, 2017.
[2]Liu JB, Huffman KM, Palis BE, et al. Reliability of the American College of Surgeons Commission on Cancer's quality of care measures for hospital and surgeon profiling. *Journal of the American College of Surgeons*. 2017; 224: 180-190.
[3]Lawson EH, Ko CY, Adams JL, et al. Reliability of evaluating hospital quality by colorectal surgical site infection type. *Annuls of Surgery*. 2013; 258: 994–1000.
[4]Huffman KM, Cohen ME, Ko CY, Hall BL. A comprehensive evaluation of statistical reliability in ACS NSQIP profiling models. *Annuls of Surgery*. 2015; 261:1108–1113.

[5]Cohen ME, Ko CY, Bilimoria KY, et al. Optimizing ACS NSQIP modeling for evaluation of surgical quality and risk: patient risk adjustment, procedure mix adjustment, shrinkage adjustment, and surgical focus. *Journal of the American College of Surgeons.* 2013; 217: 336-346.

2a2.3. For each level of testing checked above, what were the statistical results from reliability testing? (e.*g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis*)

Table 1: All Cases									
Diagnosis Year(s)	Denominator	Numerator	Hospital N	Unadjusted Reliability Mean	Unadjusted Reliability Median	Adjusted Reliability Mean[1]	Adjusted Reliability Median[1]	Mean Cases (per hospital)	Aggregate Compliance Rate
2014 - 2015	21,470	19,062	1,406	0.52	0.54	0.51	0.53	15.27	88.78%
2014	10,857	9,653	1,356	0.40	0.38	0.38	0.36	8.01	88.91%
2015	10,613	9,409	1,299	0.38	0.37	0.37	0.36	8.17	88.66%
[1] Adjusted for sex, age at diagnosis, race/ethnicity and insurance status									

Table 2: Limited to Hospitals with More than 5 Measure-Eligible Cases									
Diagnosis Year(s)	Denominator	Numerator	Hospital N	Unadjusted Reliability Mean	Unadjusted Reliability Median	Adjusted Reliability Mean [1]	Adjusted Reliability Median [1]	Mean Cases (per hospital)	Aggregate Compliance Rate
2014 - 2015	20,578	18,285	1,130	0.58	0.59	0.57	0.56	18.21	88.86%
2014	8,992	7,996	747	0.51	0.48	0.49	0.48	12.04	88.92%
2015	8,806	7,811	720	0.48	0.47	0.47	0.46	12.23	88.70%
* Aggregate compliance rate for the cases treated at programs with 5 or less cases is: 2014-2015 = 87.11%, 2014 = 88.85%, and 2015 = 88.43%									
[1] Adjusted for sex, age at diagnosis, race/ethnicity and insurance status									

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.*e., what do the results mean and what are the norms for the test conducted?*)
The unadjusted reliability mean coefficient of 0.40 and 0.52 for measure #0223 shown in Table 1 are regarded as moderate, achieved respectively from diagnosis year 2014 and 2014-2015. The unadjusted reliability coefficient of 0.38 is regarded as low reliability calculated from 2015.

Table 2 demonstrates the impact of case volume on reliability after excluding small volume hospitals described as < 5 cases per hospital for each year cohort. Reliability estimates increased to moderate reliability (2015 unadjusted: 0.48) after controlling for volume.

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2b1. VALIDITY TESTING

2b1.1. What level of validity testing was conducted? (*may be one or both levels*)

☒ **Critical data elements** (*data element validity must address ALL critical data elements*)

☐ **Performance measure score**

    ☐ **Empirical validity testing**

    ☐ **Systematic assessment of face validity of <u>performance measure score</u> as an indicator** of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

2b1.2. For each level of testing checked above, describe the method of validity testing and what it tests (*describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used*)

Each year, a review of a minimum of 10% of the annual caseload of registry abstracts is performed to verify that abstracted data correctly reflect the information documented in individual patient records, and that the patient's medical condition, care, and participation in treatment decision-making processes are accurate. The abstracted elements reviewed include but are not limited to primary site, staging, first-course treatment, follow-up, and the percentage of data coded as unknown. These procedures are part of the Commission on Cancer's (CoC) Standard 1.6, which is required to maintain accreditation. Each of the following steps must be followed in order to be rated as compliant with this Standard. 1) The cancer committee establishes and implements a quality control plan. 2) The registry quality coordinator works cooperatively with registry staff to maintain a quality control plan. The focus of this plan is to establish data quality benchmarks that include monitoring of abstracting timeliness, accuracy of data, a review of data coded as unknown. 3) The findings are to be reported to the cancer committee annually and 4) the findings are documented in the cancer committee minutes.

These annual caseload reviews inform the data submitted to the National Cancer Database (NCDB) and are subsequently used in the Cancer Program Practice Profile Reports (CP3R) system and Rapid Quality Reporting System (RQRS) measure reporting systems; RQRS shows the performance rates for the five CoC National Quality Forum endorsed measures. Every colon cancer case is submitted from the reporting facility to the NCDB, and is applied to the measure in these reporting systems. In addition to the annual caseload reviews noted above, both reporting systems allow hospitals to review every case for coding accuracy which includes those deemed non-eligible, incomplete, measure denominator eligible, along with numerator compliant and non-compliant cases.

Measure performance is calculated in CP3R and RQRS based on the case-level data submitted by the accredited hospitals.

2b1.3. What were the statistical results from validity testing? (*e.g., correlation; t-test*)

There are no statistical tests run to assess quality of the data. Non-compliance results in any one or more of the four steps listed in 2b1.2 (Standard 1.6) not followed will potentially jeopardize the accreditation status of the program granted by the Commission on Cancer (CoC). The authoritative source for comparison is the patient chart with the goal of this standard to ensure the registry abstract reflects the documented patient experience. The scope of the evaluation is 10% of the analytic caseload for each program or a maximum of 300 cases annually.

The measure reporting system reviews are highly recommended by the CoC to ensure high quality data, which directly impacts the performance rates.

2b1.4. What is your interpretation of the results in terms of demonstrating validity? (i.*e., what do the results mean and what are the norms for the test conducted?*)
Both the annual caseload reviews and the measure reporting system reviews are intended to ensure that reported performance rates are an accurate reflection of the care provided to patients at Commission on Cancer-accredited programs.

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2b2. EXCLUSIONS ANALYSIS

NA ⊠ no exclusions — *skip to section 2b4*
Not Applicable

2b2.1. Describe the method of testing exclusions and what it tests (*describe the steps—do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used*)
 Not Applicable

2b2.2. What were the statistical results from testing exclusions? (*include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores*)
Not Applicable

2b2.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e., the value outweighs the burden of increased data collection and analysis. <u>Note</u>: **If patient preference is an exclusion**, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion*)
Not Applicable

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2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES
If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section 2b5.

2b3.1. What method of controlling for differences in case mix is used?
⊠ **No risk adjustment or stratification**
☐ **Statistical risk model with** Click here to enter number of factors **risk factors**
☐ **Stratification by** Click here to enter number of categories **risk categories**
☐ **Other,** Click here to enter description

2b3.1.1 If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.
Not Applicable

2b3.2. If an outcome or resource use component measure is <u>not risk adjusted or stratified</u>, provide <u>rationale and analyses</u> to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.
Not Applicable

2b3.3a. Describe the conceptual/clinical <u>and</u> statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk (*e.g., potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care*) **Also discuss any "ordering" of risk factor inclusion**; for example, are social risk factors added after all clinical factors?

Not Applicable

2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

☐ **Published literature**

☐ **Internal data analysis**

☒ **Other (please describe)**

Not Applicable

2b3.4a. What were the statistical results of the analyses used to select risk factors?
Not Applicable

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors *(e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.)* **Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.**

Not Applicable

2b3.5. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model <u>or</u> stratification approach (*describe the steps—do not just name a method; what statistical analysis was used*)

Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.
If stratified, skip to [2b3.9](#)

Not Applicable

2b3.6. Statistical Risk Model Discrimination Statistics (*e.g., c-statistic, R-squared*)**:**
Not Applicable

2b3.7. Statistical Risk Model Calibration Statistics (*e.g., Hosmer-Lemeshow statistic*):
Not Applicable

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:
Not Applicable

2b3.9. Results of Risk Stratification Analysis:

Not Applicable

2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.*e., what do the results mean and what are the norms for*

the test conducted)
Not Applicable

2b3.11. Optional Additional Testing for Risk Adjustment (*not required, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed*)
Not Applicable

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2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

2b4.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified (*describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided related to performance gap in 1b)*
Ninety-five percent confidence intervals were calculated at the hospital-level to determine statistical significance. Each hospital's 95% confidence interval was compared to the aggregate EPR to determine significance.

2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (*e.g., number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined*)
 The following table calculates for each set of diagnosis year(s) the aggregate measure compliance and the number of hospitals that were not statistically significant compared to the aggregate measure compliance and the hospitals that were statistically significant (both greater and less than the aggregate measure compliance):

Diagnosis Year(s)	Aggregate Measure Compliance	N Hospitals Statistical Significance Compared to Aggregate Measure Compliance		
		Not Significant	Significantly Greater Than	Significantly Less Than
2014 - 2015	88.78%	695 (49.43%)	613 (43.60%)	98 (6.97%)
2014	88.91%	509 (37.54%)	781 (57.60%)	66 (4.87%)
2015	88.66%	499 (38.41%)	736 (56.66%)	64 (4.93%)

2b4.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities? (i*.e., what do the results mean in terms of statistical and meaningful differences?*)
For the three cohorts of diagnosis years, between a third and half of the programs were not statistically significant compared to aggregate measure compliance; however for those statistically significant programs the majority were statistically greater than the aggregate measure compliance. Overall, only between 4.87% and 6.97% of programs was performing worse when compared to the aggregate.

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2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS
If only one set of specifications, this section can be skipped.

Note*: This item is directed to measures that are risk-adjusted (with or without social risk factors) **OR** to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eMeasures). It does not apply to measures that use more than one source of data in one set of specifications/instructions (e.g., claims data to identify the denominator and medical record abstraction for the numerator).* **Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.**

2b5.1. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications (*describe the steps—do not just name a method; what statistical analysis was used*)
Not Applicable

2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)
Not Applicable

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i.*e., what do the results mean and what are the norms for the test conducted*)
Not Applicable

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2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)
All cancer cases submitted from Commission on Cancer-accredited programs are evaluated for measure eligibility via the Cancer Program Practice Profile Reports system and Rapid Quality Reporting System. Both systems track the completeness of staging and all data fields specifically needed to assess measure #0223 denominator including date completeness. For each hospital, cases with incomplete data were summed and reported as a proportion of all denominator-eligible and incomplete cases.

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (*e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each*)

Diagnosis Year(s)		2014 - 2015	2014	2015
Measure	Aggregate Compliance	88.78%	88.91%	88.66%
	Aggregate Denominator	21,470	10,857	10,613
	Aggregate Hospital N	1,406	1,356	1,299
	Aggregate Incomplete	0.13%	0.10%	0.16%

Incomplete and Complete Data	Aggregate Denominator	21,498	10,868	10,630
	No Incomplete Data for N Hospitals	1,384	1,346	1,286
	Incomplete Data for N Hospitals	23	10	14
	Range of Incomplete Data	1.54% - 100.00%	3.03% - 33.33%	3.45% - 100.00%

2b6.3. What is your interpretation of the results in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias**?** (i*.e., what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis, provide rationale for the selected approach for missing data*)

For 2014-2015 data completeness varied at the hospital-level resulting in a range of 1.54% to 100.00% for the 1.63% of hospitals that had incomplete cases. At the aggregate-level, the proportion of incomplete cases was low, 0.13%, when compared to the number of measure-eligible and incomplete cases. While missing data will always bias compliance rates, we do not believe the proportion to be excessive and therefore not detrimental to the measure. Given that the Commission on Cancer mandates all cancer cases be submitted from a reporting hospital and that all submissions assessed for measure compliance, we expect and allow varying degrees of reporting incompleteness. The measure reporting systems allow hospitals to review case-level data for incomplete cases and are encouraged to make completeness updates.

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (*i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields*) Update this field for **maintenance of endorsement**.

Some data elements are in defined fields in electronic sources

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources. For **maintenance of endorsement**, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

The National Cancer Database (NCDB) captures colon data from 1,406 hospitals across the US with measure-eligible cases from 2014-2015. The availability and usage of electronic health records will vary by hospital. All data elements from accredited institutions are required to be submitted to the NCDB in electronic format following a nationally standardized set of data specifications from the North American Association of Cancer Registries. All accredited hospitals use data abstraction software.

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment:

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. Required for maintenance of endorsement. Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

1) The technical infrastructure to generate and report compliance with this measure has been in place since 2005 for approximately 1,500 Commission on Cancer (CoC) accredited centers performance rates for this measure.   This measure is currently reported to CoC accredited programs through the National Cancer Database (NCDB) using the Cancer Program Practice Profile Report (CP3R) web-based audit and feed-back reporting tool by registrars submitting new and updated cases annually. In addition, this measure is also reported to 1,500 cancer programs participating in its "real clinical time" feedback reporting tool through its Rapid Quality Reporting System (RQRS) reported daily from registrars in regards to new and updated cases. Both of these reporting tools have been utilized in the cancer registry community and do not produce an undue burden on the data collection network. Also when questions arise about coding or the reporting systems they can consult with NCDB staff via email.

2) The data for this measure are key elements already collected in all hospital registries. This measure has been reviewed using cancer registry data. The CoC data demonstrates variation in the measure. The measure is readily implemented.

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified *(e.g., value/code set, risk model, programming code, algorithm).*

The Commission on Cancer charges an annual accreditation fee to each hospital and includes access to the National Cancer Database and the quality measure reporting tools for no additional charge. The accreditation fee covers the resources needed for measure development as well as the infrastructure used to the report the measures.

Above the accreditation fee, hospitals must cover the cost of maintaining a registry, certified tumor registry staff, and abstraction software to submit data to the NCDB. It should be noted that there are State requirements for reporting cancer cases that would already necessitate the costs of maintaining a registry and collecting many of the same data items.

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)
	Public Reporting
	Pennsylvania Health Care Quality Alliance
	http://www.phcqa.org/
	Pennsylvania Health Care Quality Alliance
	http://www.phcqa.org/
	Regulatory and Accreditation Programs
	Commission on Cancer Standards
	https://www.facs.org/quality-programs/cancer/coc/standards
	Quality Improvement (Internal to the specific organization)
	Cancer Program Practice Profile Reports
	https://www.facs.org/quality-programs/cancer/ncdb/qualitytools/cp3r
	Cancer Quality Improvement Program
	https://www.facs.org/quality-programs/cancer/ncdb/qualitytools/cqip
	Rapid Quality Reporting System
	https://www.facs.org/quality-programs/cancer/ncdb/qualitytools/rqrs

4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

d) Public Reporting
Name: Pennsylvania Health Care Quality Alliance (PHCQA)
Purpose: PHCQA is a voluntary group of health care organizations collaboratively working together to improve the quality of health care for the people of Pennsylvania. PHCQA developed a consensus-driven, statewide approach to hospital quality measurement that is supported by quality of care data from a variety of public data sources. It is believed that by sharing aggregated quality performance data openly through public reporting on the Internet, valuable, objective health care quality information can be provided for all consumers. At the same time best practices can be identified and shared to improve the performance of all stakeholders. Commission on Cancer (CoC) accredited cancer programs in Pennsylvania may elect to voluntarily report their estimated performance rates through this program, currently 60 of 73 (82.19%) CoC Pennsylvania programs are participating.
Geographic area: Pennsylvania
Level of measurement and setting: hospital level, Pennsylvania cancer hospitals

f) Quality Improvement with Benchmarking

Name: Commission on Cancer, National Cancer Database

Purpose: The National Cancer Database (NCDB) provides a venue for accredited programs to benchmark their compliance compared to other CoC-accredited cancer programs through the use of the Cancer Program Practice Profile Reports (CP3R), the Rapid Quality Reporting System (RQRS) and the Cancer Quality Improvement Program (CQIP). CP3R, available to about 1,500 CoC-accredited cancer programs, offers local providers comparative information to assess adherence to and consideration of standard of care therapies for major cancer (see more at: https://www.facs.org/quality-programs/cancer/ncdb/qualitytools/cp3r). CQIP reports annual quality and outcomes data to about 1,500 cancer programs accredited by the American College of Surgeons CoC and provides the availability for programs to benchmark their performance on quality measures to other CoC-accredited programs(see more at: https://www.facs.org/quality-programs/cancer/ncdb/qualitytools/cqip). RQRS is a reporting and quality improvement tool which provides real clinical time assessment of hospital level adherence to National Quality Forum (NQF)-endorsed quality of cancer care measures for breast and colorectal cancers (see more at: https://www.facs.org/quality-programs/cancer/ncdb/qualitytools/rqrs).

Geographic area: National

Level of measurement and setting: hospital level, CoC cancer programs

g) Regulatory and Accreditation

Name: Commission on Cancer (CoC) Standards

Purpose: The CoC accredits cancer programs and in order to fulfil or maintain accreditation, programs must adhere to requirements called the CoC's Standards. Within these standards there are multiple requirements that incorporate reviewing and maintain performance rates for CoC's quality measures. For instance, Standard 5.2 requires cancer programs to participate in Rapid Quality and Reporting System (RQRS), which allows programs to review real-time clinical care and receives alerts to ensure patients' treatment are compliant with this measures. Additionally, Standards 1.2/4.3 requires each program to have a Cancer Liaison Physician (CLP) and some of the responsibility of a CLP includes reviewing CP3R, RQRS and CQIP four times a year, which includes reviewing this measure, and to discuss the findings with the cancer committee.

Geographic area: National

Level of measurement and setting: hospital level, CoC cancer programs

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (*e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?*)

Not Applicable

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*)

Not Applicable

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

Cancer measures are developed in a multi-disciplinary setting. Clinical leadership panels work with statisticians, business analysts, and registrars to measure developers to ensure the measures are 1) clinically relevant and 2) have adequate NCDB data to support their development. Ongoing maintenance is addressed in 4a2.3. Cancer data collection through registries is uniform throughout North America. Cancer registries utilize the North American Association of Central Cancer Registries (NAACCR). NAACCR develops and promotes uniform data standards for cancer registration and certifies population-based registries among other

important work to reduce the burden of cancer in North America. Data collected through the National Cancer Database (NCDB) utilizes NAACCR standard formats and editing functionality. The CoC-accredited programs file submissions are passed through an edits program to ensure the data meet acceptable quality standards. Cases with errors must be reviewed and resubmitted.

To improve capture of adjuvant therapy reported to the NCDB, the CoC-accredited programs receive individual case information regarding the quality measures supported by the CoC. This notification includes the status of the case (i.e., not eligible, concordant, non-concordant and incomplete) and any potentially missing treatment information needed for calculating the performance rates (PRs). All CoC-accredited facilities receive a report of their performance rates on this measure through the Cancer Program Practice Profile (CP3R) and an estimated performance rate on the Rapid Quality Reporting System (RQRS), a real clinical time decision support system. In 2013, the Commonwealth of Pennsylvania began reporting performance rates on this measure for 72% (52 of 72) of the CoC-accredited hospitals in Pennsylvania. That number of reporting hospitals has risen to 87.5% (63 of 72) of the Commonwealth's hospitals (7/01/2019).

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

The Web-based Cancer Program Practice Profile Report (CP3R) offers local providers comparative information to assess adherence to and consideration of standard of care therapies for this measure, and provides a platform from which to promote continuous practice improvement aimed to improve quality of patient care at the local level. This tool also permits hospitals to compare their care for these patients relative to that of other providers. The aim is to empower clinicians, administrators, and other staff to work cooperatively and collaboratively to identify problems in practice and delivery and to implement best practices that will diminish disparities in care across Commission on Cancer (CoC)-accredited cancer programs. This tool is updated annually. A quality related audit is initiated for any of the accountability measures, which this measure is considered. The CoC CQIP reflects an annual snapshot of the quality measures contained in CP3R. The Rapid Quality Reporting System (RQRS) is a reporting and quality improvement tool for this measure. This tool provides real clinical time assessment of hospital-level adherence to measure and provides alerts for upcoming adjuvant therapy for patients affected by this measure. The RQRS has been available to all Commission on Cancer (CoC)-accredited cancer programs beginning September 2011. As of January 2017, RQRS participation is required for all CoC-accredited programs. RQRS is updated every 24 hours. Additionally, on the CoC's website there are explanations/user documentation for CP3R, RQRS and CQIP.

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

Our facilities have fostered the development of the CP3R, commenting on the design of the feedback to facilitate utilization of the tools. The RQRS was developed and based on survey results from alpha and beta testers. Design issues continue to be addressed as to how best to capture forthcoming adjuvant therapy.

As this measure is distributed, if any questions about the calculation of the measure or inquiry regarding the numerator/denominator are asked, programs will submit questions through the NCDB mailbox. The User Support Specialists monitor this mailbox and answer these questions. Content related questions are sent to the Site Specific Leaders (SSLs), who are renowned clinical experts on colon cancer.

4a2.2.2. Summarize the feedback obtained from those being measured.

CP3R/CQIP: Our registrars and physicians review the measures through phone calls and e-mails. Our surveyors inform the CoC of potential problems that the measure may encounter. As issues are identified, slight modifications will be made; e.g., excluding patients on related clinical trials. The same feedback may be obtained from CQIP, an annual snapshot of the CP3R measures.

RQRS: The responses have been positive. For example, a hospital administrator has stated that he had better physician recruiting with the implementation of this clinical data support system that alerts providers of

adjuvant therapy for their patients. Further, an often heard comment is that RQRS has "prevented patients from slipping through the cracks" as the first course of treatment can last a year.

4a2.2.3. Summarize the feedback obtained from other users

The Pennsylvania Health Care Alliance (PHCQA) approached the CoC to support voluntary hospital reporting of clinical measures on their website (http://www.phcqa.org/) and has of to date yielded positive feedback in that the relationship still exists. The CoC provides the means for data collection through the annual call for data. Calculations are made and sent to the hospitals, who have stated that they wish to participate in this voluntary reporting of their performance on the measure. Upon agreement by these hospitals, the NCDB sends the Performance Rates to the PHCA for posting on the website. In 2013, the Commonwealth of Pennsylvania began reporting performance rates on this measure for 72% (52 of 72) of the CoC-accredited hospitals in Pennsylvania. That number of reporting hospitals has risen to 87.5% (63 or 72) of the Commonwealth's hospitals (7/01/2019).

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

Site-specific leaders, who are expert clinicians in the care of cancer patients, are notified of any potential issues that have been identified in the calculation of this measure. They review the measure for current practice and potential impact of any clinical trials that may impact the measure. Identified issues are communicated to the CoC and changes, if needed, are incorporated into the measure logic. The CoC-accredited hospitals are notified if changes are made and why.

Improvement
Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

Between 2008 and 2015, aggregate compliance with the colon adjuvant chemotherapy measure increased from 83.1% to 88.7%. Within race and ethnicity, compliance rates for black (80.3% to 85.7%) and Hispanic (75.7% to 82.5%) patients have improved. For the uninsured/Medicaid patient cohort, the compliance rates moved upward from 78.3% (2008) to 86.2% (2015). By Census region, the West with the lowest aggregate compliance rate improved from 77.9% (2008) to 89.5% (2015).

4b2. Unintended Consequences
The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

This measure, as specified, is susceptible to under-reporting of the adjuvant chemotherapy component appearing in the measure numerator. Due to referral of services, access to patient clinical follow-up may initially be limited or unavailable. Programs use of the CoC data quality tools has demonstrated through retrospective case and chart reviews that significant additional and accurate information regarding treatment provided to patients can be ascertained, resulting in higher and clinically more accurate reflections of the care

provided or coordinated through their centers. Additionally, the CoC´s Program Standards require direct review and oversight of quality measures be monitored by an attending physician (Cancer Liaison Physician) on staff at the center on a quarterly basis.

4b2.2. Please explain any unexpected benefits from implementation of this measure.

A benefit of implementing this measure in the prospective RQRS reporting environment is that hospitals are sent alerts on anticipated treatment for new diagnoses as they are abstracted, ensuring timeliness of delivery of care. Beginning in January of 2017, participation in RQRS became a requirement to remain accredited by the CoC.

5. Comparison to Related or Competing Measures

If a measure meets the above criteria <u>and</u> there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

Yes

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

0385e: Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

5a. Harmonization of Related Measures
  The measure specifications are harmonized with related measures;
  OR
  The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):
Are the measure specifications harmonized to the extent possible?
No
5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.
The measures assess different levels of data analysis, 0385 assesses clinical group practice while 0223 assesses facility level performance. The data sources are also different for the two measures increasing the burden of collection for harmonization.
5b. Competing Measures
  The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);
  OR
  Multiple measures are justified.
5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):
Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

The target populations of these measures and the level of analysis are sufficiently different to warrant both measures. Measure 0223 assesses adjuvant chemotherapy on surgically treated patients to be reported at the facility level for CoC-accredited cancer programs.

Measure 0223 assesses receipt of chemotherapy based on information captured through cancer registries utilizing coding of the North American Association of Central Cancer Registries (NAACCR) while measure 0385 assesses compliance utilizing CPT codes through clinical practices.

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

No appendix Attachment:

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): Commission on Cancer, American College of Surgeons

Co.2 Point of Contact: Bryan, Palis, bpalis@facs.org, 312-202-5436-

Co.3 Measure Developer if different from Measure Steward: Commission on Cancer, American College of Surgeons

Co.4 Point of Contact: Bryan, Palis, bpalis@facs.org, 302-202-5436-

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

Original developers:

Christopher (Chris) Pezzi, MD, FACS (Abington Memorial Hospital, Abington PA); Lawrence Shulman, MD (Dana Farber Cancer Institute, Boston MA); Stephen Edge, MD, FACS (Roswell Park Cancer Institute, Buffalo NY); Richard Swanson, MD, FACS (Partners Health Care, Boston MA); Peter Enzinger, MD (Dana Farber Cancer Institute, Boston MA); Elin Sigurdson, MD, FACS (Fox Chase Cancer Center, Philadelphia PA); Mitchell Posner, MD, FACS (University of Chicago, Chicago IL); Anthony Robbins, MD, PhD (American Cancer Society)

The current Measure workgroup includes:

Charles Cheng MD, FACS (Fox Valley Surgical Associates, Appleton, WI), Daniel McKellar, MD, FACS (Wayne Healthcare, Greenville, OH), David Jason Bentrem, MD (Northwestern Memorial Hospital, Chicago, IL), Karl Bilimoria, MD, FACS (Northwestern Univ/Feinberg Sch of Med, Chicago, IL), Lawrence Shulman MD (University of Pennsylvania, Philadelphia, PA), Matthew A Facktor, MD FACS (Geisinger Medical Center, Danville, PA), Ted James (University of Vermont, Burlington, VT)

This panel meets at least once annually to review quality measures currently supported and implemented by the ACoS Commission on Caner and to investigate and consider/review development of possible new measures.Christopher (Chris) Pezzi, MD, FACS (Abington Memorial Hospital, Abington PA); Lawrence Shulman,

MD (Dana Farber Cancer Institute, Boston MA); Stephen Edge, MD, FACS (Roswell Park Cancer Institute, Buffalo NY); Richard Swanson, MD, FACS (Partners Health Care, Boston MA); Peter Enzinger, MD (Dana Farber Cancer Institute, Boston MA); Elin Sigurdson, MD, FACS (Fox Chase Cancer Center, Philadelphia PA); Mitchell Posner, MD, FACS (University of Chicago, Chicago IL); Anthony Robbins, MD, PhD (American Cancer Society)

This panel meets at least once a calendar quarter to review quality measures currently supported and implemented by the ACoS Commission on Caner and to invstigate and consider/review development of possible new measures.

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2007

Ad.3 Month and Year of most recent revision: 01, 2019

Ad.4 What is your frequency for review/update of this measure? Annual

Ad.5 When is the next scheduled review/update for this measure? 01, 2020

Ad.6 Copyright statement:

Ad.7 Disclaimers:

Ad.8 Additional Information/Comments: