NQF #0385 Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients

NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the <u>submitting standards web page</u>.

NQF #: 0385 NQF Project: Cancer Project

(for Endorsement Maintenance Review)

Original Endorsement Date: Jul 31, 2008 Most Recent Endorsement Date: Jul 31, 2008

BRIEF MEASURE INFORMATION

De.1 Measure Title: Oncology: Chemotherapy for Stage IIIA through IIIC Colon Cancer Patients

Co.1.1 Measure Steward: American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)

De.2 Brief Description of Measure: Percentage of patients aged 18 years and older with Stage IIIA through IIIC colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy or have previously received adjuvant chemotherapy within the 12 month reporting period

2a1.1 Numerator Statement: Patients who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy* within the 12 month reporting period

Definition: Adjuvant Chemotherapy: *According to current NCCN guidelines, the following therapies are recommended: 5-FU/LV/oxaliplatin (mFOLFOX6) as the standard of care (Category 1); bolus 5-FU/LV/oxaliplatin (FLOX, Category 1), capecitabine/oxaliplatin (CapeOx, Category 1); or single agent capecitabine (Category 2A) or 5-FU/LV (Category 2A) in patients felt to be inappropriate for oxaliplatin therapy. Due to the leucovorin shortage in the United States, levo-leucovorin used in its place may also satisfy the measure.

Prescribed – may include prescription ordered for the patient for adjuvant chemotherapy at one or more visits in the 12-month period OR patient already receiving adjuvant chemotherapy as documented in the current medication list

2a1.4 Denominator Statement: All patients aged 18 years and older with Stage IIIA through IIIC colon cancer

2a1.8 Denominator Exclusions: Documentation of medical reason(s) for not referring for or prescribing adjuvant chemotherapy (eg, medical comorbidities, patient over the age of 80, diagnosis date more than 5 years prior to the current visit date, diagnosis date is within 120 days of the end of the 12 month reporting period, patient's cancer has metastasized, medical contraindication/allergy, poor performance status)

Documentation of patient reason(s) for not referring for or prescribing adjuvant chemotherapy (eg, patient refusal)

Documentation of system reason(s) for not referring for or prescribing adjuvant chemotherapy (eg, patient is currently enrolled in a clinical trial that precludes prescription of chemotherapy)

1.1 Measure Type: Process 2a1. 25-26 Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records 2a1.33 Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

1.2-1.4 Is this measure paired with another measure? No

De.3 If included in a composite, please identify the composite measure (title and NQF number if endorsed):

STAFF NOTES (issues or questions regarding any criteria)						
Comments on Conditions for Consideration:						
Is the measure untested? Yes No If untested, explain how it meets criteria for consideration for time-limited endorsement:						
1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (<i>check De.5</i>): 5. Similar/related <u>endorsed</u> or submitted measures (<i>check 5.1</i>): Other Criteria:						
Staff Reviewer Name(s):						
1. IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT						
Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See <u>guidance on evidence</u> . <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria</i> . (evaluation criteria)						
1a. High Impact: H M L I Image: Constraint of the second secon						
De.4 Subject/Topic Areas (Check all the areas that apply): Cancer, Cancer : Colorectal De.5 Cross Cutting Areas (Check all the areas that apply):						
1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, A leading cause of morbidity/mortality, Patient/societal consequences of poor quality, Severity of illness						
1a.2 If "Other," please describe:						
1a.3 Summary of Evidence of High Impact (<i>Provide epidemiologic or resource use data</i>): An estimated 101,340 cases of colon and 39,870 cases of rectal cancer are expected to occur in 2011. Colorectal cancer is the third most common cancer in both men and women.(1) On January 1, 2008, in the United States there were approximately 1,110,077 men and women alive who had a history of cancer of the colon and rectum 542,127 men and 567,950 women, [including both persons with active disease and those who are cured of their disease.](2) An estimated 49,380 deaths from colorectal cancer are expected to occur in 2011, accounting for about 9% of all cancer deaths. (1) The 1 and 5 year relative survival rates for persons with colorectal cancer are 83% and 65%, respectively. Survival continues to decline beyond 5 years to 58% at 10 years after diagnosis. (1) Based on rates from 2006-2008, 5.08% of men and women born today will be diagnosed with cancer of the colon and rectum at some time during their lifetime.(2)						
1a.4 Citations for Evidence of High Impact cited in 1a.3: Quoted verbatim from the following sources:						
(1) American Cancer Society. Cancer Facts & Figures 2011. Atlanta, GA: American Cancer Society; 2011. (2) Howlader N, Noone AM, Krapcho M, Neyman N, Aminou R, Waldron W, Altekruse SF, Kosary CL, Ruhl J, Tatalovich Z, Cho H, Mariotto A, Eisner MP, Lewis DR, Chen HS, Feuer EJ, Cronin KA, Edwards BK (eds). SEER Cancer Statistics Review, 1975-2008, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2008/, based on November 2010 SEER data submission, posted to the SEER web site, 2011.						
1b. Opportunity for Improvement: H M L I . (<i>There is a demonstrated performance gap - variability or overall less than optimal performance</i>)						
1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure: This measure is aimed at increasing the rates of Stage III colon cancer patients receiving adjuvant chemotherapy given its well documented efficacy and effect on survival.						
1b.2 Summary of Data Demonstrating Performance Gap (Variation or overall less than optimal performance across providers):						

[For <u>Maintenance</u> – Descriptive statistics for performance results <u>for this measure</u> - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]

ASCO's Quality Oncology Practice Initiative (QOPI®) includes a slight adaptation of this measure assessing the receipt of adjuvant chemotherapy within 4 months of diagnosis for patients with AJCC stage III colon cancer. Among 212 self-selected participating practices, an average performance rate of 94.52% was found for this measure with variation among practices ranging from 70% to 100% (N charts=1187). QOPI is a physician-led, voluntary, practice-based, quality-improvement program using performance measurement and benchmarking among oncology practices across the United States. (1)

The measure has been in use in CMS' Physician Quality Reporting System (PQRS) program since 2007. The mean performance rate for 2009 was reported as 98.83%. Unfortunately, data regarding the variability in performance rates across reporting eligible professionals for PQRS 2009 is not available at this time.(2)

The following data represent performance rates from PQRS 2008, the only year for which distribution by quartile/decile is available:(3)

Mean performance rate= 77.76%

10th percentile: 0.00% 25th percentile: 0.00% 50th percentile: 20.29% 75th percentile: 50.00% 90th percentile: 75.00%

A recent analysis of the quality of nonmetastatic colorectal cancer care in the Department of Veterans Affairs found that approximately 73.5% of Stage III colorectal cancer patients received adjuvant fluorouracil-based chemotherapy. (4)

1b.3 Citations for Data on Performance Gap: [For <u>Maintenance</u> – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included] (1) American Society of Clinical Oncology. Quality Oncology Practice Initiative. Unpublished data, fall 2011.

(2) CMS. 2009 Reporting Experience Including Trends (2007 – 2010): Physician Quality Reporting System and Electronic Prescribing (eRx) Incentive Program

4/4/2011. Available at: https://www.cms.gov/PQRS. Accessed 1/10/2012.

(3)Confidential CMS PQRI 2008 Performance Information by Measure. Jan-Sept TAP file.

(4) Jackson GL, Melton LD, Abbott DH, Zullig LL, Ordin DL, Grambow SC, Hamilton NS, Zafar SY, Gellad ZF, Kelley MJ, Provenzale D. Quality of nonmetastatic colorectal cancer care in the Department of Veterans Affairs. J Clin Oncol. 2010 Jul 1;28(19):3176-81. Epub 2010 Jun 1.

1b.4 Summary of Data on Disparities by Population Group: [*For <u>Maintenance</u> – Descriptive statistics for performance results <u>for this measure</u> by population group]*

Racial and ethnic disparities in the use of adjuvant chemotherapy have been well documented and persisted over time. (1-4) For example, one study found that 52.1% of black patients receive adjuvant chemotherapy for stage III colon cancer compared with 64.1% of white patients. (4)

1b.5 Citations for Data on Disparities Cited in 1b.4: [*For <u>Maintenance</u> – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]

(1) Schrag D,Cramer LD,Bach PB, et al. Age and adjuvant chemotherapy use after surgery for stage III colon cancer. J Natl Cancer Inst. 2001; 93: 850–857.

(2) Ayanian JZ,Zaslavsky AM,Fuchs CS, et al. Use of adjuvant chemotherapy and radiation therapy for colorectal cancer in a population-based cohort. J Clin Oncol. 2003; 21: 1293–1300.

(3) Demissie K,Oluwole OO,Balasubramanian BA, et al. Racial differences in the treatment of colorectal cancer: a comparison of surgical and radiation therapy between whites and blacks. Ann Epidemiol. 2004; 14: 215–221.

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 (4) Baldwin LM, Dobie SA, Billingsley K, et al. Explaining black-white differences in receipt of recommended colon cancer treatment. J Natl Cancer Inst. 2005;97:1211–1220. (5) Gross CP, Smith BD, Wolf E, et al. Racial disparities in cancer therapy: did the gap narrow between 1992 and 2002? Cancer. 2008;112:900–908. 							
1c. Evidence (Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.) Is the measure focus a health outcome? Yes No If not a health outcome, rate the body of evidence. Quantity: H M L I							
Quantity	Quality	Consistency	Does the measure pass subcriterion1c?				
M-H	M-H	M-H	Yes				
L	M-H	М	Yes IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No				
M-H	L	M-H	Yes IF potential benefits to patients clearly outweigh potential harms: otherwise No				
L-M-H	L-M-H	L	No 🗌				
Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service				Does the measure pass subcriterion1c? Yes IF rationale supports relationship			
1c.1 Structure-Process-Outcome Relationship (Briefly state the measure focus, e.g., health outcome, intermediate clinical							

1c.1 Structure-Process-Outcome Relationship (Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome):

The measure focuses on the receipt of adjuvant chemotherapy among adult patients with Stage III colon cancer. The receipt of adjuvant chemotherapy in Stage III colon cancer patients following primary surgical treatment is associated with a significant survival benefit.

1c.2-3 Type of Evidence (*Check all that apply*): Clinical Practice Guideline

1c.4 Directness of Evidence to the Specified Measure (State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population): 6 months of adjuvant chemotherapy is recommended for stage III colon cancer patients following primary surgical treatment.

The measure focus is on adult patients with Stage III colon cancer. Although the measure focus is not limited to patients following surgical treatment, the numerator of the measure allows for current OR PREVIOUS receipt of adjuvant chemotherapy as well as a referral for adjuvant chemotherapy.

1c.5 Quantity of Studies in the Body of Evidence (*Total number of studies, not articles*): The description of the evidence supporting the guideline recommendation did not address the overall quantity of studies in the body of evidence. However, 15 articles are cited specific to the relevant recommendation statement.

1c.6 Quality of Body of Evidence (Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events): The quality of the body of evidence supporting the guideline recommendation is summarized according to the NCCN categories of evidence and dependent on the type of pharmacologic agent. The majority of the agents are listed as being based on "high-level evidence". High-level evidence is later described as high-quality evidence from controlled clinical trials or meta-analyses. 2 of the agents (single agent capecitabine or 5-FU/LV) are recommended for patients felt to be inappropriate for oxaliplatin therapy and based on "lower-level evidence." Lower-level evidence is later described as evidence that may include non-randomized trials; case series; or when other data are lacking, the clinical experience of expert physicians.

1c.7 Consistency of Results across Studies (Summarize the consistency of the magnitude and direction of the effect): Although there is no explicit statement regarding the overall consistency of results across studies in the guidelines supporting the measure, the recommendation received uniform NCCN consensus that the intervention is appropriate.

1c.8 Net Benefit (Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms):

The use of adjuvant chemotherapy following resection has been demonstrated to improve both disease-free and overall survival in patients with stage III colon cancer. Although the benefit far outweighs the harm in most cases, toxicities associated with the use of these agents varies with diarrhea and dehydration being reported for several of them.

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? Yes

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: A panel of experts with members from each of the NCCN Member Institutions develops the NCCN Guidelines. Specialties that must be included on a particular panel are identified before that panel is convened but also evolve as the standard of care changes over time. This multidisciplinary representation varies from panel to panel. The NCCN Guidelines Panel Chairs are charged with ensuring that representatives of all treatment strategies are included. Many of the panels also include a patient representative, especially when issues of long-term care and patient preference are paramount in the panel's considerations.

The following individuals were listed as panel members for the 2012 NCCN colon cancer guidelines cited in this submission: J. Pablo Arnoletti, MD; Tanios Bekaii-Saab, MD; Al B. Benson III, MD, FACP; Emily Chan, MD, PhD; Yi-Jen Chen, MD, PhD; Michael A. Choti, MD, MBA; Harry S. Cooper, MD; Paul F. Engstrom, MD, FACP; Peter C. Enzinger, MD; Marwan G Fakih, MD; Deborah Freedman-Cass, PhD; Charles S. Fuchs, MD, MPH; Lauren Gallagher, RPh, PhD; Kristina M. Gregory, RN, MSN, OCN; Jean L. Grem, MD; Steven Hunt, MD; Lucille A. Leong, MD; Edward Lin, MD; Kilian Salerno May, MD; Joan S. McClure, MS; Mary F. Mulcahy, MD; Kate Murphy, BA; Eric Rohren, MD, PhD; David P. Ryan, MD; Leonard Saltz, MD; Sunil Sharma, MD; David Shibata, MD; John M. Skibber, MD; William Small, MD; Constantinos T. Sofocleous, MD, PhD, FSIR; Alan P. Venook, MD; Christopher G. Willett, MD

NCCN publishes individual disclosures of potential conflicts of interest for panel members, NCCN Guidelines staff, and NCCN senior management. Relationships disclosed include research funding, participation in advisory groups, participation in speakers' bureaus, employment, and equity or patent ownership. Beginning in 2010, the NCCN Board of Directors has directed that panel members compensation from external sources be less than published thresholds. These thresholds are <= \$20,000 from a single entity and <= \$50,000 in aggregate from any source.

1c.11 System Used for Grading the Body of Evidence: Other

1c.12 If other, identify and describe the grading scale with definitions: NCCN Categories of Evidence and Consensus Panel members identify the level of evidence supporting each recommendation. These categories are:

Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

1c.13 Grade Assigned to the Body of Evidence: Category 1; Category 2A

1c.14 Summary of Controversy/Contradictory Evidence: While there is no controversy or contradictory evidence reported, it is important to note that there is currently a shortage of leucovorin (LV) in the United States. The NCCN guideline provides the following guidance: "There are no specific data to guide management under these circumstances, and all proposed strategies are empiric. The panel recommends several possible options to help alleviate the problems associated with this shortage. One is the use of levo-leucovorin, which is commonly used in Europe. A dose of 200 mg/m2 of levo–leucovorin is equivalent to 400 mg/m2 of standard leucovorin. Another option is for practices or institutions to use lower doses of leucovorin for all doses in all patients, since

the panel feels that lower doses are likely to be as efficacious as higher doses, based on several studies...Finally, if none of the above options are available, treatment without leucovorin would be reasonable."

1c.15 Citations for Evidence other than Guidelines (Guidelines addressed below):

1c.16 Quote verbatim, <u>the specific guideline recommendation</u> (Including guideline # and/or page #): For stage III patients (T1-4, N1-2, M0), the panel recommends 6 months of adjuvant chemotherapy following primary surgical treatment. The treatment options are: 5-FU/LV/oxaliplatin (mFOLFOX6) as the standard of care (Category 1); bolus 5-

FU/LV/oxaliplatin (FLOX, Category 1), capecitabine/oxaliplatin (CapeOx, Category 1); or single agent capecitabine (Category 2A) or 5-FU/LV (Category 2A) in patients felt to be inappropriate for oxaliplatin therapy. (1)

1c.17 Clinical Practice Guideline Citation: (1) National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Colon Cancer. Version 2, 2012. Available at: http://www.nccn.org.

1c.18 National Guideline Clearinghouse or other URL: www.nccn.org

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: Same as above in 1.c.10.

1c.21 System Used for Grading the Strength of Guideline Recommendation: Other

1c.22 If other, identify and describe the grading scale with definitions: NCCN Categories of Evidence and Consensus Panel members identify the level of evidence supporting each recommendation. These categories are:

Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

1c.23 Grade Assigned to the Recommendation: Category 1; Category 2A

1c.24 **Rationale for Using this Guideline Over Others:** It is the PCPI policy to use guidelines, which are evidence-based, applicable to physicians and other health-care providers, and developed by a national specialty organization or government agency. In addition, the PCPI has now expanded what is acceptable as the evidence base for measures to include documented quality improvement (QI) initiatives or implementation projects that have demonstrated improvement in quality of care.

Based on the NQF descriptions for rating the evidence, what was the <u>developer's assessment</u> of the quantity, quality, and consistency of the body of evidence?

1c.25 Quantity: Moderate 1c.26 Quality: High1c.27 Consistency: High

Was the threshold criterion, *Importance to Measure and Report*, met? (*1a & 1b must be rated moderate or high and 1c yes*) Yes No Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP. For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & 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. (evaluation criteria)

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See <u>guidance on measure testing</u>.

S.1 Measure Web Page (In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained). Do you have a web page where current detailed specifications for this measure can be obtained? Yes

S.2 If yes, provide web page URL: www.physicianconsortium.org

2a. RELIABILITY. Precise Specifications and Reliability Testing: H M L I

2a1. Precise Measure Specifications. (The measure specifications precise and unambiguous.)

2a1.1 Numerator Statement (Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome): Patients who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy* within the 12 month reporting period

Definition: Adjuvant Chemotherapy: *According to current NCCN guidelines, the following therapies are recommended: 5-FU/LV/oxaliplatin (mFOLFOX6) as the standard of care (Category 1); bolus 5-FU/LV/oxaliplatin (FLOX, Category 1), capecitabine/oxaliplatin (CapeOx, Category 1); or single agent capecitabine (Category 2A) or 5-FU/LV (Category 2A) in patients felt to be inappropriate for oxaliplatin therapy. Due to the leucovorin shortage in the United States, levo-leucovorin used in its place may also satisfy the measure.

Prescribed – may include prescription ordered for the patient for adjuvant chemotherapy at one or more visits in the 12-month period OR patient already receiving adjuvant chemotherapy as documented in the current medication list

2a1.2 Numerator Time Window (The time period in which the target process, condition, event, or outcome is eligible for inclusion): At least once during the measurement period.

2a1.3 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, codes with descriptors, and/or specific data collection items/responses: For EHR: eMeasure (See attached)

Administrative claims

Report the CPT Category II code: 4180F - Adjuvant chemotherapy referred, prescribed, or previously received for Stage IIIA through IIIC colon cancer

2a1.4 **Denominator Statement** (*Brief, narrative description of the target population being measured*): All patients aged 18 years and older with Stage IIIA through IIIC colon cancer

2a1.5 Target Population Category (Check all the populations for which the measure is specified and tested if any): Adult/Elderly Care

2a1.6 Denominator Time Window (*The time period in which cases are eligible for inclusion*): 12 consecutive months.

2a1.7 Denominator Details (All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses): For EHR: eMeasure (See attached)

Administrative claims data:

AGE: >= 18 years AND Diagnosis: Colon Cancer

ICD-9-CM diagnosis codes: 153.0, 153.1, 153.2, 153.3, 153.4, 153.6, 153.7, 153.8, 153.9 (malignant neoplasm of colon). ICD-10-CM diagnosis codes: C18.0, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C18.9 AND **CPT®** Codes: 99201, 99202, 99203, 99204, 99205 99212, 99213, 99214, 99215 2a1.8 Denominator Exclusions (Brief narrative description of exclusions from the target population): Documentation of medical reason(s) for not referring for or prescribing adjuvant chemotherapy (eq, medical comorbidities, patient over the age of 80, diagnosis date more than 5 years prior to the current visit date, diagnosis date is within 120 days of the end of the 12 month reporting period, patient's cancer has metastasized, medical contraindication/allergy, poor performance status) Documentation of patient reason(s) for not referring for or prescribing adjuvant chemotherapy (eq, patient refusal) Documentation of system reason(s) for not referring for or prescribing adjuvant chemotherapy (eg. patient is currently enrolled in a clinical trial that precludes prescription of chemotherapy) 2a1.9 Denominator Exclusion Details (All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses): The PCPI methodology uses three categories of reasons for which a patient may be excluded from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For this measure, exceptions may include medical reason(s) (eg, medical comorbidities, patient over the age of 80, diagnosis date more than 5 years prior to the current visit date, diagnosis date is within 120 days of the end of the 12 month reporting period, patient's cancer has metastasized, medical contraindication/allergy, poor performance status), patient reason(s) (eq, patient refusal) or system reason(s) for not referring for or prescribing adjuvant chemotherapy (eq, patient is currently enrolled in a clinical trial that precludes prescription of chemotherapy). Where examples of exceptions are included in the measure language, these examples are coded and included in the eSpecifications. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement. For example, it is possible for implementers to calculate the percentage of patients that physicians have identified as meeting the criteria for exception. Additional details by data source are as follows: For EHR: eMeasure (See attached) Administrative claims: **Denominator Exceptions:** Append modifier to CPT Category II code: 4180F-1P

Append modifier to CPT Category II code: 4180F-2P Append modifier to CPT Category II code: 4180F-3P

2a1.10 Stratification Details/Variables (All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses): We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.

2a1.11 Risk Adjustment Type (Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in *2a1.13*): No risk adjustment or risk stratification 2a1.12 If "Other," please describe:

2a1.13 Statistical Risk Model and Variables (Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.): None

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score: Rate/proportion

2a1.19 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

2a1.20 Calculation Algorithm/Measure Logic (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; aggregating data; risk adjustment; etc.):

To calculate performance rates:

1) Find the patients who meet the initial patient population (ie, the general group of patients that the performance measure is designed to address).

2) From the patients within the initial patient population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial patient population and denominator are identical.

3) From the patients within the denominator, find the patients who qualify for the Numerator (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator

4) From the patients who did not meet the numerator criteria, determine if the physician has documented that the patient meets any criteria for denominator exception when exceptions have been specified [for this measure: medical reason(s) (eg, medical comorbidities, patient over the age of 80, diagnosis date more than 5 years prior to the current visit date, diagnosis date is within 120 days of the end of the 12 month reporting period, patient's cancer has metastasized, medical contraindication/allergy, poor performance status), patient reason(s) (eg, patient refusal) or system reason(s)(eg, patient is currently enrolled in a clinical trial that precludes prescription of chemotherapy). If the patient meets any exception criteria, they should be removed from the denominator for performance calculation.

--Although the exception cases are removed from the denominator population for the performance calculation, the number of patients with valid exceptions should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.

If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure.

See calculation algorithm in attachment 2a1.21.

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:

Attachment

Generic Measure Logic-634620633024859689.pdf

2a1.24 **Sampling (Survey) Methodology.** If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate): Not applicable. The measure does not require sampling or a survey.

2a1.25 Data Source (Check all the sources for which the measure is specified and tested). If other, please describe: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records					
2a1.26 Data Source/Data Collection Instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.): Not applicable. Zip file for data dictionary/code table to be sent separately (cannot be attached to 2a1.30).					
2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment:					
2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:					
2a1.33 Level of Analysis (<i>Check the levels of analysis for which the measure is specified and tested</i>): Clinician : Group/Practice, Clinician : Individual, Clinician : Team					
2a1.34-35 Care Setting (Check all the settings for which the measure is specified and tested): Ambulatory Care : Clinician Office, Other:Oncology/Outpatient Clinic; Radiation Oncology Dept/Clinic					
2a2. Reliability Testing. (Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.)					
 2a2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included): PCPI Testing Project Five practice sites representing various types, locations and sizes were identified to participate in testing the PCPI/ASCO/ASTRO-developed measures. Site A: hospital, multi-practice sites in urban, rural and suburban settings; 21 physicians; average 9600 oncology/prostate cancer patient visits per month for MD/NP assessment, chemotherapy; submitted PQRS claims for one measure and utilized a full-fledged EHR. Site B: physician owned private practice, suburban setting; 4 physicians; average 48 oncology/prostate cancer patients seen per day; submitted PQRS claims for one measure and utilized paper medical records. Site C: physician owned private practice, urban setting; 41 physicians; average 2500 oncology/prostate cancer patients seen per month; submitted PQRS claims for two measures and utilized a full-fledged EHR. Site D: academic, suburban setting; 9 physicians; average 240 oncology/prostate cancer patients seen per month; submitted PQRS claims for two measures and utilized a full-fledged EHR. Site E: academic, urban setting; 14 physicians; average 240 oncology/prostate cancer patients seen per month; submitted PQRS claims for one measure and EHR. Site E: academic, urban setting; 14 physicians; average 250 oncology/prostate cancer patients seen per month; collected PQRS data on 3 measures and utilized paper and EHR. Site E: academic, urban setting; 14 physicians; average 250 oncology/prostate cancer patients seen per month; collected PQRS data on 3 measures and utilized a full-fledged EHR. The measurement period (data collected from patients seen) was 1/1/2010 through 12/31/2010. Chart abstraction was performed between 8/8/2011 and 11/3/2011. 					
2a2.2 Analytic Method (Describe method of reliability testing & rationale): PCPI Testing Project Data abstracted from patient records were used to calculate inter-rater reliability for the measure. 100 patient records were reviewed.					
 Data analysis included: Percent agreement; and Kappa statistic to adjust for chance agreement. 					
2a2.3 Testing Results (Reliability statistics, assessment of adequacy in the context of norms for the test conducted):					

PCPI Testing Project

N, % Agreement, Kappa (95% Confidence Interval) Overall Reliability: 100, 100.0%, Kappa is noncalculable* Denominator Reliability: 100, 100.0%, Kappa is noncalculable* Numerator Reliability: 100, 100.0%, Kappa is noncalculable* Exception Reliability: 100, 100.0%, Kappa is noncalculable*

This measure demonstrates perfect reliability, as shown in results from the above analysis.

*Kappa Statistics cannot be calculated because of complete agreement. Confidence intervals cannot be calculated because to do so would involve dividing by zero which cannot be done.

2b. VALIDITY. Validity, Testing, including all Threats to Validity: H M L

2b1.1 Describe how the measure specifications (measure focus, target population, and exclusions) are consistent with the evidence cited in support of the measure focus (*criterion 1c*) and identify any differences from the evidence: 6 months of adjuvant chemotherapy is recommended for stage III colon cancer patients following primary surgical treatment.

The measure focus is on adult patients with Stage III colon cancer. Although the measure focus is not limited to patients following surgical treatment, the numerator of the measure allows for current OR PREVIOUS receipt of adjuvant chemotherapy as well as a referral for adjuvant chemotherapy.

2b2. Validity Testing. (Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)

2b2.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

An expert panel was used to assess face validity of the measure. This panel consisted of the following 31 members, with representation from a number of specialties including oncology, radiation oncology, surgical oncology, urology, gastroenterology, hematology, pathology, colon and rectal surgery, otolaryngology, and pain medicine..

The panel members are as follows:

Patricia Ganz, MD (Co-Chair) (Clinical Oncology) Los Angeles, CA James Hayman, MD (Co-Chair) (Radiation Oncology) Ann Arbor MI Joseph Bailes, MD (Clinical Oncology) The Woodlands, TX Nancy Baxter, MD, PhD (Colorectal Surgery) Toronto, Ontario Canada Joel V. Brill, MD (Gastroenterology) Phoenix, AZ Steven B. Clauser, PhD (Outcomes Research) Bethesda, MD Charles Cleeland, PhD (Oncology) Houston, TX J. Thomas Cross, Jr. MD, MPH (Oncology) Colorado Springs, CO Chaitanya R. Divgi, MD (Nuclear Medicine) Philadelphia, PA Stephen B. Edge, MD (Surgical Oncology) Buffalo, NY Patrick L. Fitzgibbons, MD (Oncology) Fullerton, CA Myron Goldsmith, MD (Oncology) Huntington Beach, CA Joel W. Goldwein, MD (Oncology) Merion Station, PA Alecia Hathaway, MD, MPH (Oncology) Fort Worth, TX Kevin P. Hubbard, DO (Oncology) Kansas City, MO Nora Janjan, MD, MPSA (Radiation Oncology) Houston, TX Maria Kelly, MB, BCh (Radiation Oncology) Earlysville, VA Wayne Koch, MD (Head and Neck surgery) Columbia, MD Andre Konski, MD (Radiation Oncology) Philadelphia, PA Len Lichtenfeld, MD (Oncology) Atlanta, GA Norman J. Marcus, MD (Anesthesiology and Psychiatry) New York, NY Catherine Miyamoto, RN, BSN (Oncology) Grand Forks, ND Michael Neuss, MD (Oncology, Hematology) Cincinnati, OH David F. Penson, MD, MPH (Urology) Nashville, TN Louis Potters, MD (Radiation Oncology) New Hyde Park, NY

John M. Rainey, MD (Medical Oncology) Lafayette, LA Christopher M. Rose, MD (Radiation Therapy) Beverly Hills, El Segundo, CA Lee Smith, MD (Oncology) Washington, DC Lawrence A. Solberg, MD, PhD (Oncology) Jacksonville, FL Paul E. Wallner, MD (Radiation Oncology) Willingboro, NJ J. Frank Wilson, MD (Radiation Oncology) Milwaukee, WI

2b2.2 Analytic Method (Describe method of validity testing and rationale; if face validity, describe systematic assessment): All PCPI performance measures are assessed for content validity by a panel of expert work group members during the development process. Additional input on the content validity of draft measures is obtained through a 30-day public comment period and by also soliciting comments from a panel of consumer, purchaser, and patient representatives convened by the PCPI specifically for this purpose. All comments received are reviewed by the expert work group and the measures adjusted as needed. Other external review groups (eg, focus groups) may be convened if there are any remaining concerns related to the content validity of the measures.

The expert panel was used to assess face validity of the measure. This panel consisted of 31 members, with representation from the following specialties: oncology, radiation oncology, surgical oncology, urology, gastroenterology, hematology, pathology, colon and rectal surgery, otolaryngology, and pain medicine.

The aforementioned panel was asked to rate their agreement with the following statement:

The scores obtained from the measure as specified will accurately differentiate quality across providers.

Scale 1-5, where 1=Strongly Disagree; 3=Neither Disagree nor Agree; 5=Strongly Agree

2b2.3 Testing Results (Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment):

The results of the expert panel rating of the validity statement were as follows: N = 19; Mean rating = 4.26.

Percentage in the top two categories (4 and 5): 73.68%

Frequency Distribution of Ratings

- 1- 0 2- 0 3- 5
- 4- 4
- 5- 10

POTENTIAL THREATS TO VALIDITY. (All potential threats to validity were appropriately tested with adequate results.)

2b3. Measure Exclusions. (Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.)

2b3.1 Data/Sample for analysis of exclusions (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included): PCPI Testing Project

- 100 patient records were reviewed for this measure.
- The measurement period (data collected from patients seen) was 1/1/2010 through 12/31/2010.
- Chart abstraction was performed between 8/8/2011 and 11/3/2011.

2b3.2 Analytic Method (Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference):

Exceptions were analyzed for frequency and variability across providers.

2b3.3 Results (Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):

PCPI Testing Project

N, % Agreement, Kappa (95% Confidence Interval) Exception Reliability: 100, 100.0%, Kappa is noncalculable*

This measure demonstrates perfect reliability, as shown in results from the above analysis.

The exception rate for this measure is 11.0%

*Kappa Statistics cannot be calculated because of complete agreement. Confidence intervals cannot be calculated because to do so would involve dividing by zero which cannot be done.

2b4. Risk Adjustment Strategy. (For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.)

2b4.1 Data/Sample (Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included): This measure is not risk adjusted.

2b4.2 Analytic Method (Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables): This measure is not risk adjusted.

2b4.3 Testing Results (*Statistical risk model*: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. <u>Risk stratification</u>: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata): Not Applicable

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: Not Applicable

2b5. Identification of Meaningful Differences in Performance. (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

2b5.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

PCPI Testing Project

- 100 patient records were reviewed for this measure.
- The measurement period (data collected from patients seen) was 1/1/2010 through 12/31/2010.
- Chart abstraction was performed between 8/8/2011 and 11/3/2011.

CMS Physician Quality Reporting Initiative:

Clinical Condition and Measure: #72

14,042 patients were reported on for the 2008 program, the most recent year for which data are available.

In 2009 the following was reported for this measure:

Eligible Professionals: 68,598

Professionals Reporting >=1 Valid QDC: 1,253

% Professionals Reporting >=1 Valid QDC: 1.83%

Professionals Satisfactorily Reporting: 381

% Professionals Satisfactorily Reporting: 30.41%

2b5.2 Analytic Method (Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance): PCPI Testing Project

Data analysis performed on the measure included:

Average measure performance rate overall and by site, performance rate range by site and overall standard deviation for the measure.

CMS Physician Quality Reporting Initiative:

The inter-quartile range (IQR) was calculated, which provides a measure of the dispersion of performance.

CMS Physician Quality Reporting Initiative:

The inter-quartile range (IQR) was calculated, which provides a measure of the dispersion of performance.

2b5.3 Results (Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance): PCPI Testing Project

Measure rate without exceptions: N= 100 Mean = 89.0% Standard Deviation= 0.3145

The performance rate by site is as follows, where n is the number of performance events by site:

- A 0.0000 n=0
- B 0.9000 n=30
- C 0.9000 n=30
- D 0.8440 n=32
- E 1.0000 n=8

The performance rate range is 0.1560. Although this study captured performance on 100 events, the data were not captured at the physician level, restricting reporting of variation in performance to the organization level only. Additionally, we are unable to present a meaningful calculation of variation in performance across organizations due to the small sample size of sites (n=4) in this study.

2b6. Comparability of Multiple Data Sources/Methods. (If specified for more than one data source, the various approaches result in comparable scores.)

2b6.1 Data/Sample (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

This measure has not been compared across data sources.

2b6.2 Analytic Method (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure):

This measure has not been compared across data sources.

2b6.3 Testing Results (*Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted*):

This measure has not been compared across data sources.

2c. Disparities in Care: H M L I NA (If applicable, the measure specifications allow identification of disparities.)

2c.1 If measure is stratified for disparities, provide stratified results (Scores by stratified categories/cohorts): We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:

The PCPI advocates that performance measure data should, where possible, be stratified by race, ethnicity, and primary language to assess disparities and initiate subsequent quality improvement activities addressing identified disparities, consistent with recent national efforts to standardize the collection of race and ethnicity data. A 2008 NQF report endorsed 45 practices including stratification by the aforementioned variables.(1) A 2009 IOM report "recommends collection of the existing Office of Management and Budget (OMB) race and Hispanic ethnicity categories as well as more fine-grained categories of ethnicity(referred to as granular ethnicity and based on one's ancestry) and language need (a rating of spoken English language proficiency of less than very well and one's preferred language for health-related encounters)."(2)

References:

(1)National Quality Forum Issue Brief (No.10). Closing the Disparities Gap in Healthcare Quality with Performance Measurement and Public Reporting. Washington, DC: NQF, August 2008.

(2)Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. March 2010. AHRQ Publication No. 10-0058-EF. Agency for Healthcare Research and Quality, Rockville, MD. Available at: http://www.ahrq.gov/research/iomracereport. Accessed May 25, 2010.

2.1-2.3 Supplemental Testing Methodology Information:

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met? (*Reliability and Validity must be rated moderate or high*) Yes No Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

C.1 Intended Purpose/ Use (Check all the purposes and/or uses for which the measure is intended): Professional Certification or Recognition Program, Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

3.1 Current Use (Check all that apply; for any that are checked, provide the specific program information in the following *questions*): Public Reporting, Professional Certification or Recognition Program, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H M L I I (*The measure is meaningful, understandable and useful for public reporting.*)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large (*If used in a public reporting program, provide name of program(s), locations, Web page URL(s)*). <u>If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [*For <u>Maintenance</u> – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.*]</u>

This measure was used in the CMS Physician Quality Reporting System (PQRS) program from 2007-2011 and is currently in use in PQRS 2012. Information on the PQRS program can be found at: https://www.cms.gov/PQRS.

The PCPI believes that the reporting of participation information is a beneficial first step on a trajectory toward the public reporting of performance results, which is appropriate since the measure has been tested and the reliability of the performance data has been validated. Continued NQF endorsement will facilitate our ongoing progress toward this public reporting objective.

3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. <u>If usefulness was demonstrated</u> (e.g., focus group, cognitive testing), describe the data, method, and results: The PCPI believes that the reporting of participation information is a beneficial first step on a trajectory toward the public reporting of performance results, which is appropriate since the measure has been tested and the reliability of the performance data has been validated. Continued NQF endorsement will facilitate our ongoing progress toward this public reporting objective.

3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program,

provide name of program(s), locations, Web page URL(s): This measure may be used in a Maintenance of Certification program, including the following current initiatives:

QOPI data can be used to meet the ABIM's practice Performance Improvement Module (PIM) requirement for Maintenance of Certification.

3b. **Usefulness for Quality Improvement:** H M L I (*The measure is meaningful, understandable and useful for quality improvement.*)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s): [*For <u>Maintenance</u> – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement*].

A slight adaptation of this measure is currently being used in ASCO's Quality Oncology Practice Initiative (QOPI®) program. QOPI is a physician-led, voluntary, practice-based, quality-improvement program using performance measurement and benchmarking among oncology practices across the United States. QOPI's goal is to promote excellence in cancer care by helping practices create a culture of self-examination and improvement. The process employed for improving cancer care includes measurement, feedback and improvement tools for hematology-oncology practices.

All PCPI measures are suitable for use in quality improvement initiatives and are made freely available on the PCPI website and through the implementation efforts of medical specialty societies and other PCPI members. The PCPI strongly encourages the use of its measures in QI initiatives and seeks to provide information on such initiatives to PCPI members.

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (*e.g.*, *Ql initiative*), describe the data, method and results:

The PCPI believes that the use of PCPI measures in quality improvement initiatives is a beneficial way to gather scientific data with which to improve physician performance. This is appropriate since the measure has been tested and the reliability of the performance data has been validated. NQF endorsement will facilitate our ongoing progress toward this quality improvement objective.

Overall, to what extent was the criterion, *Usability*, met? H M L I Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

4a. Data Generated as a Byproduct of Care Processes: H M L I

4a.1-2 How are the data elements needed to compute measure scores generated? (*Check all that apply*). Data used in the measure are:

generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition

4b. Electronic Sources: H M L I

4b.1 Are the data elements needed for the measure as specified available electronically (*Elements that are needed to compute measure scores are in defined, computer-readable fields*): ALL data elements in electronic health records (EHRs)

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H M L

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results: We are not aware of any unintended consequences related to this measurement.

4d. Data Collection Strategy/Implementation: H M L I

A.2 Please check if either of the following apply (regarding proprietary measures):

4d.1 Describe what you have learned/modified 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 (*e.g., fees for use of proprietary measures*): This measure was found to be reliable and feasible for implementation.

Overall, to what extent was the criterion, *Feasibility*, met? H M L I Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes No Rationale:

If the Committee votes No, STOP.

If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and 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 before a final recommendation is made.

5.1 If there are related measures *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population)*, list the NQF # and title of all related and/or competing measures: 0223 : Adjuvant chemotherapy is considered or administered within 4 months (120 days) of surgery to patients under the age of 80 with AJCC III (lymph node positive) colon cancer

5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as <u>NQF-endorsed measure(s)</u>: Are the measure specifications completely harmonized? No

5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:

No related measures; See competing measures section below regarding the harmonization of measure specifications.

5b. Competing Measure(s)

5b.1 If this measure has 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*):

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI), 515 N. State Street, Chicago, Illinois, 60654

Co.2 Point of Contact: Mark S., Antman, DDS, MBA, Director, Measure Development Operations Performance Improvement, mark.antman@ama-assn.org, 312-464-5056-

Co.3 Measure Developer if different from Measure Steward: AMA-PCPI, American Society of Clinical Oncology, and National Comprehensive Cancer Network., 515 N. State Street, Chicago, Illinois, 60654

Co.4 Point of Contact: Samantha, Tierney, MPH, samantha.tierney@ama-assn.org, 312-464-5524-

Co.5 Submitter: Mark S., Antman, DDS, MBA, Director, Measure Development Operations Performance Improvement, mark.antman@ama-assn.org, 312-464-5056-, American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)

Co.6 Additional organizations that sponsored/participated in measure development: This measure is jointly copyrighted by the AMA-PCPI, American Society of Clinical Oncology, and National Comprehensive Cancer Network. The measure set was also developed in collaboration with the American Society for Radiation Oncology.

Co.7 Public Contact: Mark S., Antman, DDS, MBA, Director, Measure Development Operations Performance Improvement, mark.antman@ama-assn.org, 312-464-5056-, American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development

Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

Patricia Ganz, MD (Co-Chair) James Hayman, MD (Co-Chair) Joseph Bailes, MD Nancy Baxter, MD, PhD Joel V. Brill, MD Steven B. Clauser, PhD Charles Cleeland, PhD J. Thomas Cross, Jr. MD, MPH Chaitanya R. Divgi, MD Stephen B. Edge, MD Patrick L. Fitzgibbons, MD Myron Goldsmith, MD Joel W. Goldwein, MD Alecia Hathaway, MD, MPH Kevin P. Hubbard, DO Nora Janjan, MD, MPSA Maria Kelly, MB, BCh Wayne Koch, MD Andre Konski, MD Len Lichtenfeld, MD Norman J. Marcus, MD Catherine Miyamoto, RN, BSN Michael Neuss, MD David F. Penson, MD, MPH Louis Potters, MD John M. Rainey, MD Christopher M. Rose, MD Lee Smith, MD Lawrence A. Solberg, MD, PhD Paul E. Wallner, MD J. Frank Wilson, MD Rodger Winn, MD

PCPI measures are developed through cross-specialty, multi-disciplinary work groups. All medical specialties and other health care professional disciplines participating in patient care for the clinical condition or topic under study are invited to participate as equal contributors to the measure development process. In addition, the PCPI strives to include on its work groups individuals representing the perspectives of patients, consumers, private health plans, and employers. This broad-based approach to measure

development ensures buy-in on the measures from all stakeholders and minimizes bias toward any individual specialty or stakeholder group. All work groups have at least two co-chairs who have relevant clinical and/or measure development expertise and who are responsible for ensuring that consensus is achieved and that all perspectives are voiced.

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward:

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: 2007

Ad.4 Month and Year of most recent revision: 12, 2011

Ad.5 What is your frequency for review/update of this measure? Coding/Specifications updates occur annually. See additional information below.

Ad.6 When is the next scheduled review/update for this measure? 2012

Ad.7 Copyright statement: Physician Performance Measures (Measures) and related data specifications, developed by the Physician Consortium for Performance Improvement[®] (the Consortium), are intended to facilitate quality improvement activities by physicians.

These Measures are intended to assist physicians in enhancing quality of care. Measures are designed for use by any physician who manages the care of a patient for a specific condition or for prevention. These performance Measures are not clinical guidelines and do not establish a standard of medical care. The Consortium has not tested its Measures for all potential applications. The Consortium encourages the testing and evaluation of its Measures.

Measures are subject to review and may be revised or rescinded at any time by the Consortium. The Measures may not be altered without the prior written approval of the Consortium. Measures developed by the Consortium, while copyrighted, can be reproduced and distributed, without modification, for noncommercial purposes, e.g., use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of the Measures into a product or service that is sold, licensed or distributed for commercial gain. Commercial uses of the Measures require a license agreement between the user and American Medical Association, on behalf of the Consortium. Neither the Consortium nor its members shall be responsible for any use of these Measures.

THE MEASURES ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND

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Limited proprietary coding is contained in the Measure specifications for convenience. Users of the proprietary code sets should obtain all necessary licenses from the owners of these code sets. The AMA, the Consortium and its members disclaim all liability for use or accuracy of any Current Procedural Terminology (CPT®) or other coding contained in the specifications.

THE SPECIFICATIONS ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND.

CPT® contained in the Measures specifications is copyright 2008 American Medical Association.

Ad.8 Disclaimers: See copyright statement above.

Ad.9 Additional Information/Comments: The PCPI has a formal measurement review process that stipulates regular (usually on a three-year cycle, when feasible) review of the measures. The process can also be activated if there is a major change in scientific evidence, results from testing or other issues are noted that materially affect the integrity of the measure.

Date of Submission (MM/DD/YY): 10/03/2011

Basic Measure Calculation:

= %

= %

(N)

(**D**) – (**E**)

The PCPI strongly recommends that exception rates also be computed and reported alongside performance rates as follows:

Exception Calculation:

(E)

(D)

Exception Types:

E= E1 (Medical Exceptions) + E2 (Patient Exceptions) + E3 (System Exceptions) For patients who have more than one valid exception, only one exception should be be counted when calculating the exception rate

Initial Patient Population (IPP) Definition: The initial patient population identifies the general group of patients that the performance measureis designed to address; usually focused on a specific clinical condition (e.g., coronary artery disease, asthma). For example, a patient aged 18 years and older with a diagnosis of CADwho has at least 2 Visits during the measurement period.	Definition: The denominator defines the specific group of patients for inclusion in a specific performance measure based on specific criteria (e.g., patient's age, diagnosis, prior MI). In some cases, the denominator may be I dentical to the initial patient population.	Numerator (N) Definition: The numerator defines the group of patients in the denominator for whom a process or outcome of care occurs (e.g., flu vaccine received).	Denominator Exceptions (E) This is the prominator exceptions are the valid reasons why patients who are included in the fonominator population did not receive a process or outcome of care (described in the numerator). Patients may have Denominator Exceptions for us they did not receive flu vaccine); patients with dical reasons (e.g., patient has an egg allergy so they did not receive flu vaccine); patient reasons (e.g., patient declined flu vaccine); of yostem reasons (e.g., patient did not receive flu vaccine due to vaccine shortage). These cases are removed from the denominator population for the performance calculation, however the number of patients with valid exceptions should be calculated and reported. This group of patients constitutes the Denominator Exceptions to reporting population – patients for whom the numerator was not achieved and a there is a usid Denominator Exception.
Find the patients who meet the Initial Patient Population criteria (IPP)	Find the patients who qualify for the denominator (D): O From the patients within the Patient Population criteria (IPP) select those people who meet Denominator selection criteria. (In some cases the IPP and D are identical).	 Find the patients who qualify for the Numerator (N): O From the patients within the Denominator (D) criteria, select those people who meet Numerator selection criteria. O Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator 	From the patients who did not meet the Numerator criteria, determine if the patient meets any criteria for the Denominator Exception (E1 + E2+E3). If they meet any criteria, they should be removed from the Denominator for performance calculation. As a point of reference, these cases are removed from the denominator population for the performance calculation, however the number of patients with valid exceptions should be calculated and reported.