- TO: Consensus Standards Approval Committee (CSAC)
- FR: Angela Franklin and Lindsey Tighe
- RE: Voting Results for National Voluntary Consensus Standards for Cancer Endorsement Maintenance Phase 1

DA: July 2, 2012

The CSAC will review the recommendations from the project *Cancer Endorsement Maintenance Phase 1* at the July 11-12, 2012, in-person meeting. This memo includes a summary of the project, overarching measure issues, the nature of public and member comments, and member voting results. Individual measure evaluation summary tables from the draft report are included in Appendix A. The complete voting draft report and detailed measure information are available on the <u>project webpage</u>.

CSAC ACTION REQUIRED

Pursuant to the Consensus Development Process (CDP), the CSAC may consider approval of 22 candidate consensus standards as specified in the voting draft of the Cancer report.

BACKGROUND

Cancer refers to a group of more than 100 diseases characterized by uncontrolled cellular growth, proliferation, and spread. This group of diseases has an enormous impact on health in the US. As the second leading cause of death, cancer was responsible for an estimated 569,490 deaths among adults and children in 2010. Measuring the quality of care for the many patients diagnosed with any of these diseases is important to ensure safe, cost-effective care consistent with the current evidence. The recommended measures include those endorsed prior to 2009 that are undergoing maintenance. The majority of measures considered in Phase 1 focus on melanoma, hematology, general oncology, prostate, lung, and palliative and end-of-life care.

A 21-member Steering Committee representing a range of stakeholder perspectives was appointed to review a total of 26 candidate and endorsement maintenance standards for quality performance in melanoma, hematology, general oncology, prostate, lung, and palliative and end-of-life care in this phase. The Steering Committee is recommending 22 measures, 2 of which are being recommended for time-limited endorsement.

The draft report details the work of the first phase of this project.

PROCESS

This project followed NQF's version 1.9 of the CDP. The Steering Committee met by conference call in late February 2012, and then in person on March 13-14, 2012, to evaluate the measures. The Committee met again via conference call on June 6, 2012, to address the comments received during the NQF member and public comment period.

Cancer Endorsement Maintenance Phase 1 Measure Summary

	MAINTENANCE	NEW	TOTAL
Measures under consideration	23	4*	27
Withdrawn from consideration	1	0	1
Recommended	18	4	22
Not recommended	4	0	4
Reasons for Not Recommending	Importance - 3	N/A	
	Scientific Acceptability - 1		

*Includes two untested measures eligible for time-limited endorsement.

Overarching Issues

The measures were evaluated against the <u>2011 Measure Evaluation Criteria</u>. During the Steering Committee's discussion of the measures, several overarching issues emerged that were factored into their ratings and recommendations. These issues are discussed in detail in the following sections.

Palliative Measures

The Steering Committee noted that several of the events covered by the palliative care measures including receipt of chemotherapy (#0210), having more than one emergency room visit (#0211) and admission to the ICU in the last days of life (#0213) can and should happen in some cases. The Committee agreed that the measures would be useful for detecting patterns in practice, variation in performance and identifying outliers when comparing similar practices with similar patient populations; addressing patient preference and overtreatment at the end of life; and, reflecting disparities in access to care and the capacity of the local healthcare system to treat patients appropriately at the end of life. The Committee also noted that two measures related to admission to hospice and hospice length of stay were important as they could indicate a need for more hospice facilities or a need for greater physician and patient education around using this resource, leading to improved patient-centered quality of care. The Committee also noted that the area of palliative care and the concept of hospice and the settings in which hospice care is given are evolving and that future measures should consider that palliative care may be provided in the home, special facility, or in a hospital.

Harmonization of Related Measures

The Steering Committee recommended that the developer harmonize the description language of measure #0384 with currently endorsed measures #1628 and #1634, which are also related to pain assessment and pain treatment. The measures differ in the following ways:

	1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits (RAND)	Pain Screening (UNC-Chapel Hill)	0384 Oncology: Pain Intensity Quantified – Medical Oncology and Radiation Oncology (paired with 0383) (AMA-PCPI)
Data Source	Registry, paper records.	EHR, structured medical record abstraction tool.	Administrative claims, EHR, registry paper records.
Level of Analysis	Facility, health plan, integrated delivery system	Group practice, facility	Group practice, facility, individual clinician, team
Numerator Statement	Outpatient visits from the denominator in which the patient was screened for pain	1 1 1	Patient visits in which pain intensity is quantified* *Pain intensity should be quantified

	1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits (RAND)	1634 Hospice and Palliative Care Pain Screening (UNC-Chapel Hill)	0384 Oncology: Pain Intensity Quantified – Medical Oncology and Radiation Oncology (paired with 0383) (AMA-PCPI)
	(and if present, severity noted) with a quatitative standardized tool.	a standardized quantitative tool during the admission evaluation for hospice / initial encounter for palliative care.	using a standard instrument, such as a 0-10 numerical rating scale, a categorical scale, or the pictoral scale.
Patient Population	more after diagnosis and who	Patients enrolled in hospice for 7 or more days OR patients receiving hospital-based palliative care for 1 or more days. The Pain Screening quality measure is intended for patients with serious illness who are enrolled in hospice care OR receive palliative care in an acute hospital setting. Conditions may include, but are not limited to: cancer, heart disease, pulmonary disease, dementia and other progressive neurodegenerative diseases, stroke, HIV/AIDS, and advanced renal or hepatic failure. [NOTE: Measure should be paired with the Pain Assessment quality measure to ensure that all patients who report pain are clinically assessed.]	All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy, within a 12 month period. [NOTE: Measure is paired with #0383 Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology]
Exclusions	None, other than patients who did not survive at least 30 days after cancer diagnosis.	Patients with length of stay < 7 days in hospice, or < 1 day in palliative care. Calculation of length of stay; discharge date - date of initial encounter.	None

The Committee noted the burden on providers but agreed that there is a preference for a standardized quantitative pain tool that could be used across measures. It was also suggested that in the future, the developer of measures #0383 Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology and #0384 Oncology: Pain Intensity Quantified – Medical Oncology and Radiation Oncology eliminate specifications for documenting a care plan for patients with mild pain, in order to focus on patients who most need an intervention (patients with moderate to severe pain), and further define what constitutes a plan of care to clarify the measures. The Committee suggested that care plans for pain should be broadly specified to include all patients regardless of the type of modality of treatment but also be more precise as to what may be included as an acceptable plan of care as additional data collection methods become more common, including registry reporting and Electronic Health Record reporting.

Electronic Health Record Specifications

One measure recommended for endorsement in this phase was submitted with additional electronic specifications: <u>#0389 Prostate Cancer: Avoidance of Overuse Measure - Bone Scan for Staging Low Risk Patients</u> (AMA-PCPI). This was one of the measures retooled in 2010 and updated in 2011. The submitted e-specifications were reviewed by NQF Health IT staff for accuracy.

COMMENTS AND REVISED REPORT

NQF received 109 comments from 14 member organizations, representing a variety of stakeholders.

A table of complete comments submitted during the comment period, with the responses to each comment and the actions taken by the Steering Committee and measure developers, is posted to the <u>Cancer Endorsement Maintenance project page</u> under the Public and Member Comment – Phase 1 section.

The revised draft document, *National Voluntary Consensus Standards: Cancer Endorsement Maintenance Phase 1*, is posted on the <u>Cancer Endorsement Maintenance project page</u> on the NQF website along with the following additional information:

- Measure submission forms
- <u>Meeting and call transcripts and recordings</u> from the Steering Committee's discussions.

COMMENTS AND THEIR DISPOSITON

The Steering Committee reviewed the comments and focused its discussion on specific measures or topic areas with the most significant and recurring issues that arose from the comments. Comments about specific measure specifications were forwarded to the measure developers, who were invited to respond.

During the review of all comments, the Steering Committee had the benefit of developer responses, and focused their discussion on recurring concerns, specific measures and topic areas that were most controversial or that questioned positions the Committee had taken. The Committee made no changes to its measure recommendations.

Many of the comments were supportive of the work by NQF and the Steering Committee around the Cancer Endorsement Maintenance measures. Several themes emerged in the comments including:

- Concern regarding the clarity and burden of measures #0383 and #0384
- Request for reconsideration of measure #0562
- Concern regarding the understandability and usability of the Palliative Measures (#0210-#0216)
- Request for reconsideration of measure #0212

Concern regarding the clarity and burden of measures #0383 and #0384

Commenters stated that measure #0383: Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (paired with #0384) and measure #0384: Oncology: Pain Intensity Quantified – Medical Oncology and Radiation Oncology (paired with #0383) need to be harmonized with other pain measures that do not require an intervention for reports of mild pain. Commenters noted that by focusing on interventions and care plans for mild pain, the providers may be burdened and the impact of this measure for patients experiencing severe pain may be diluted.

Steering Committee Response: The Steering Committee agreed with the commenter that patients with mild pain likely do not require documented care plans for addressing the pain. The Steering

Committee stated that documentation of a care plan for patients with mild pain in this patient population may very well present a substantial burden to the provider, as many patients being actively treated with chemotherapy or radiation therapy for cancer have mild pain. However, upon confirming that similar measures in the NQF portfolio do not target the entirety of the patient population addressed by this measure – patients with cancer being treated at an outpatient facility, the Steering Committee agreed to move this measure forward with a recommendation for endorsement. The Steering Committee also made several recommendations for future iterations of the measure:

- Remove specifications for documenting a care plan for patients with mild pain, in order to focus on patients who most need an intervention (patients with moderate to severe pain).
- Further define what constitutes a plan of care, to remove ambiguity about what "counts" for the measure. This will move the measure away from being a "check the box" measure and further assist in defining the measure as we move toward integration into electronic health records.

Request for reconsideration of Measure #0562: Overutilization of Imaging Studies in Melanoma (AMA-PCPI)

The Steering Committee did not recommend measure #0562 for endorsement following the initial review of the measure at the in-person meeting. The American Academy of Dermatology (AAD), the American Medical Association (AMA) convened Physician Consortium for Performance Improvement® (PCPI), and the National Committee for Quality Assurance (NCQA) requested reconsideration of the measure. As the measure did not pass importance, specifically the evidence subcriteria, the developers provided additional evidence demonstrating that the measure was based on evidence-based guidelines from the National Comprehensive Cancer Network (NCCN) and the AAD.

New information on the Scientific Acceptability of the measure testing results was also provided, including the agreement data on exceptions to the measure.

Lastly, with respect to Steering Committee concerns that patients with recurrent disease would not be restaged at the time of recurrence and thus may not receive appropriate care, including potential imaging, the developers noted that this measure focuses on localized melanoma patients only. The measure is specified to capture patients "without signs or symptoms suggesting systemic spread."

Steering Committee Response: Steering Committee members stated that there is limited evidence of overuse of imaging in this patient population, as no study has been undertaken. The developers noted that the measure is supported by evidence-based guidelines (AAD and NCCN) that recommend that both newly diagnosed patients with stage 0-IIC melanoma without signs or symptoms suggesting systemic spread and patients with a history of melanoma at any stage without signs or symptoms suggesting systemic spread should not receive unnecessary imaging. The developers emphasized that patients with signs or symptoms suggesting systemic spread would not be counted in the denominator and thus would be eligible for imaging, allowing providers to exercise clinical judgment when signs and/or symptoms are present.

Steering Committee members raised concerns that the measure would restrict imaging of patients with recurrence of melanoma, not taking into account patients who are seen many years out for follow up who present with symptoms or signs of illness. Steering Committee members noted that these patients receive imaging, in accordance with NCCN guidelines. The developers noted that the measure provides explicit denominator exceptions for patients with signs or symptoms of systemic spread to be

evaluated using imaging (see denominator exclusion details, section 2a1.9 of the measure submission form). Patients with a history of melanoma who present with signs or symptoms of systemic spread would not be included in the denominator and would be eligible for imaging.

Steering Committee members questioned whether providers might be able to manipulate the measure and create exceptions in order to justify ordering imaging tests. The developers noted that there have been several studies on exception methodology, with very high concordance between what is documented and what are considered acceptable exceptions as defined by a group of experts. With respect to this measure, for patients with newly diagnosed melanoma, the exception agreement was 100%. For patients with existing diagnoses of melanoma, the exception agreement was 74.59%. The developer cautioned that this was calculated using a small sample size.

Steering Committee members agreed to reconsider the measure in light of the information presented by the developers. The Steering Committee voted to recommend measure #0562 for endorsement. Full voting results and the details of the Steering Committee discussion can be found in the <u>measure</u> evaluation of measure #0562.

Concern regarding the understandability and usability of the Palliative Care Measures #0210-#0216)

Commenters noted that while overtreatment of terminally ill patients is an important area for study and measurement, there are concerns that the measures imply that patients receiving such treatments as chemotherapy in the last 14 days of life, or patients with more than one emergency room visit in the last days of life, are receiving poor care. The commenters expressed concern that by grouping all patient populations together in these measures, patients appropriately receiving the indicated treatments would be counted in the numerator, and the reporting facility penalized. Further, commenters indicated that prognostication of death is limited, and in addition to being unable to determine accurately in advance a patient's expected death, the measures do not distinguish between patients who were terminally ill and those who died suddenly.

Steering Committee Response: These issues were discussed extensively during the Cancer Steering Committee in-person meeting. In that discussion, the measure developer noted that at times the interventions can and should occur for many patients. The measures are intended to compare similar providers who have similar patient mixes and identify outlying patterns of care. Consequently, relative incidence of the situations should be similar. For example, grouping patients receiving palliative chemotherapies at the end of life with those receiving curative chemotherapies should not result in markedly different measure score performance between two facilities with a similar case mix. This reasoning may also be applied to grouping patients who are terminally ill and those who died suddenly.

Further, the Steering Committee respectfully disagreed with the statement that prognostication of death is limited, and believed that taking this stance would severely limit measures of this type, which are very important quality indicators for patient preference and the availability of resources at the end of life.

The Steering Committee also noted that though there are a limited number of studies, it has been demonstrated that patients who receive palliative care earlier have lower rates of chemotherapy at the end of life, lending credence to the importance of palliative interventions in reducing overtreatment.

Request for reconsideration of Measure #0212: Proportion with more than one hospitalization in the last 30 days of life (American Society of Clinical Oncology), to be paired with Measures #0211 and #0213

The Steering Committee did not recommend measure #0212 for endorsement. Commenters urged endorsement of the measure as complementary to measures #0211 and #0213. Commenters indicated that given the variation in the use of emergency department or direct hospital admissions for patients in advanced stages of illness, as well as variation in the intensity of care provided in diverse health care settings, it would not be possible to understand variations in emergency department and intensive care unit (ICU) use at the end of life without including the hospital admissions piece represented by measure #0212. Commenters suggested excluding patients in inpatient hospice and palliative care units to strengthen the measure.

Steering Committee Response: Steering Committee members noted that emergency department and ICU utilization varies regionally and often by facility, with some facilities utilizing ICUs in circumstances where other facilities would simply admit a patient to the hospital. However, the Committee members stated concerns that without a way to distinguish palliative care units, many patients who were receiving appropriate and necessary care via hospitalization would be counted in this measure. The data source for the measure is Medicare claims data, which does not currently distinguish between palliative care units and other hospitalizations. Because of this the Steering Committee agreed the measure would not present a valid depiction of the quality of care provided within a facility. Consequently, the Committee did not re-vote on measure #0212 and maintains its recommendation that the measure not be endorsed.

NQF MEMBER VOTING

The 15-day voting period for the Cancer Endorsement Maintenance project concluded on June 26, 2012. All twenty-two measures were approved, with total approval ranging from 78 to 100 percent.

Eleven comments pertaining to the measures were submitted by members of the Supplier and Industry Council and the Health Plan Council. These comments are copied verbatim below:

Voting comments on measure #0210: Proportion receiving chemotherapy in the last 14 days of life

- *Submitted by Eisai, Inc.*: Measure #0210 is neither a process measure or an outcomes measure; but rather an imprecise benchmark for identifying outlier patterns of care. The Measure Applications Partnership (MAP) states that there is "the possibility of undesirable consequences from applying certain [hospice and palliative care] measures" (MAP: Performance Measurement Coordination Strategy for Hospice and Palliative Care: Final Report June 2012, page 13). The developer notes that #0210 is not a never event. Yet, there needs to be consideration for the unintended consequence of reducing access to palliative chemotherapy (MAP report, page 17), especially where #0210 is tied to reimbursement through pay-for-performance programs.
- *Submitted by Humana Inc.*: Humana is supportive of the rationale behind this measure. However we feel the measure developer should be able to have exclusions for patients who die from other unexpected causes (e.g. AMI, CVA) or for differentiating palliative chemotherapy versus therapeutic chemotherapy.

Voting comments on measure #0211: Proportion with more than one emergency room visit in the last days of life

• *Submitted by Humana Inc.:* While Humana appreciate the intention of this measure, the developer should consider limiting the rational for the emergency room visit. Further the determination of responsibility may be difficult as it may be physician, hospital or family based. This sounds simple but is really reflective of complex interactions of patients, families and caregivers.

Voting comments on measure #0213: Proportion admitted to the ICU in the last 30 days of life

• *Submitted by Humana Inc.:* The ICU may be a place for critically ill patients for whom high technology resources can be life preserving. However, there are times when the ICU is required for "high touch services" i.e. where the patient's needs for care services exceed what could be provided in a lesser level of care. The measure does not differentiate.

Voting comments on measure #0215: Proportion not admitted to hospice

• *Submitted by Humana Inc.:* While the intention of the measure is excellent, the measure does not respect the values of other cultures that do not accept hospice. This should be resolved by the developer

Voting comments on measure #0216: Proportion admitted to hospice for less than 3 days

• *Submitted by Humana Inc.:* There should be inclusion criteria only for chronic conditions, exceptions made for family refusal or other reasonable exclusion. This is intented to be for patient who was not advised of end of life care options until too late.

Voting comments on measure #0377: Myelodysplastic Syndrome (MDS) and Acute Leukemias – Baseline Cytogenetic Testing Performed on Bone Marrow

• *Submitted by America's Health Insurance Plans:* Due to the specificity of this measurement, only a minimal number of patients will be involved in the reporting. AHIP believes this measure only assesses standard practice that should be routinely occurring for all patients and in the future better measures for quality improvement will need to be developed.

Voting comments on measure #0378: MDS: Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy

• *Submitted by America's Health Insurance Plans:* AHIP believes this measure only assesses standard practice that should be routinely occurring for all patients and in the future better measures for quality improvement will need to be developed.

Voting comments on measure #0380: Multiple Myeloma – Treatment with Bisphosphonates

• *Submitted by America's Health Insurance Plans:* AHIP believes this measure only assesses standard practice that should be routinely occurring for all patients and in the future better measures for quality improvement will need to be developed.

Voting comments on measure # 0383: Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology

• *Submitted by Eisai, Inc.:* Like the current NQF Steering Committee for Cancer Measure Maintenance, the 2008 Steering Committee agreed with commenters that #0383 and #0384 should be broadened to include patients receiving oral chemotherapy. At that time, however, the developer stated that this was not feasible (even though its other measures, like #0385 and #0386, include patients on oral chemotherapy). Consequently, #0383 and #0384 were granted

time-limited endorsement. Since 2008, measures #0383 and #0384 have been designated by CMS for registry reporting only in the Physician Quality Reporting System (PQRS). This year, the developer is establishing an EHR reporting option that includes these measures. Registry and EHR reporting methodologies allow for data on oral chemotherapy to be captured. The time has never been better to revise #0883 and #0384 so that patients on oral chemotherapy can be evaluated for cancer pain. If these paired pain measures are given full NQF endorsement (for 3 years), there would be no reason again for the developer to adopt NQF's recommendation and expand #0384 to include patients on oral chemotherapy.

Voting comments on measure #0384: Oncology: Pain Intensity Quantified – Medical Oncology and Radiation Oncology

• *Submitted by Eisai, Inc.:* Like the current NQF Steering Committee for Cancer Measure Maintenance, the 2008 Steering Committee agreed with commenters that #0383 and #0384 should be broadened to include patients receiving oral chemotherapy. At that time, however, the developer stated that this was not feasible (even though its other measures, like #0385 and #0386, include patients on oral chemotherapy). Consequently, #0383 and #0384 were granted time-limited endorsement. Since 2008, measures #0383 and #0384 have been designated by CMS for registry reporting only in the Physician Quality Reporting System (PQRS). This year, the developer is establishing an EHR reporting option that includes these measures. Registry and EHR reporting methodologies allow for data on oral chemotherapy to be captured. The time has never been better to revise #0883 and #0384 so that patients on oral chemotherapy can be evaluated for cancer pain. If these paired pain measures are given full NQF endorsement (for 3 years), there would be no reason again for the developer to adopt NQF's recommendation and expand #0384 to include patients on oral chemotherapy.

Voting Results

Voting results for the twenty-two candidate consensus standards are provided below. (The full measure summary evaluation tables are in Appendix A.)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	4	0	0	4	100%
Health Professional	5	1	2	8	83%
Provider Organizations	4	2	0	6	67%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	0	1	0	1	0%
All Councils	14	4	2	20	78%
Percentage of councils approving (>50%)					80%
Average council percentage approval					70%

Measure #0210 Proportion receiving chemotherapy in the last 14 days of life

*equation: Yes/ (Total - Abstain)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	4	0	0	4	100%
Health Professional	5	1	2	8	83%
Provider Organizations	3	2	1	6	60%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	0	0	1	1	
All Councils	13	3	4	20	81%
Percentage of councils approving (>50%)					100%
Average council percentage approval					86%

Measure #0211 Proportion with more than one emergency room visit in the last days of life

*equation: Yes/ (Total - Abstain)

Measure #0213 Proportion admitted to the ICU in the last 30 days of life

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	3	1	0	4	75%
Health Professional	5	1	2	8	83%
Provider Organizations	5	0	1	6	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	0	0	1	1	
All Councils	14	2	4	20	88%
Percentage of councils approving (>50%)					100%
Average council percentage approval					90%

*equation: Yes/ (Total - Abstain)

Measure #0215 Proportion not admitted to hospice

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	4	0	0	4	100%
Health Professional	5	1	2	8	83%
Provider Organizations	5	1	0	6	83%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	1	0	0	1	100%
All Councils	16	2	2	20	89%
Percentage of councils approving (>50%)			100%		
Average council percentage approval			93%		

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	4	0	0	4	100%
Health Professional	5	1	2	8	83%
Provider Organizations	5	1	0	6	83%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	1	0	0	1	100%
All Councils	16	2	2	20	89%
Percentage of councils approving (>50%)					100%
Average council percentage approval					93%

Measure #0216 Proportion admitted to hospice for less than 3 days

*equation: Yes/ (Total - Abstain)

Measure #0377 Myelodysplastic Syndrome (MDS) and Acute Leukemias – Baseline Cytogenetic Testing Performed on Bone Marrow

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	4	0	0	4	100%
Health Professional	6	0	2	8	100%
Provider Organizations	6	0	0	6	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	1	0	0	1	100%
All Councils	18	0	2	20	100%
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure #0378 MDS: Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	4	0	0	4	100%
Health Professional	6	0	2	8	100%
Provider Organizations	6	0	0	6	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	1	0	0	1	100%

All Councils	18	0	2	20	100%
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

Measure #0379 Chronic Lymphocytic Leukemia (CLL) – Baseline Flow Cytometry

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	3	1	0	4	75%
Health Professional	6	0	2	8	100%
Provider Organizations	6	0	0	6	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	1	0	0	1	100%
All Councils	17	1	2	20	94%
Percentage of councils approving (>50%)					100%
Average council percentage approval					95%

*equation: Yes/ (Total - Abstain)

Measure #0380 Multiple Myeloma – Treatment with Bisphosphonates

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	4	0	0	4	100%
Health Professional	6	0	2	8	100%
Provider Organizations	5	1	0	6	83%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	1	0	0	1	100%
All Councils	17	1	2	20	94%
Percentage of councils approving (>50%)					100%
Average council percentage approval					97%

*equation: Yes/ (Total - Abstain)

Measure #0381 Oncology: Treatment Summary Communication – Radiation Oncology

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	3	1	0	4	75%
Health Professional	6	0	2	8	100%
Provider Organizations	6	0	0	6	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	

QMRI	0	0	0	0	
Supplier/Industry	1	0	0	1	100%
All Councils	17	1	2	20	94%
Percentage of councils approving (>50%)					100%
Average council percentage approval					95%

Measure #0382 Oncology: Radiation Dose Limits to Normal Tissues

Measure Council	Yes	No	Abstain	Total Votes	% Approval*	
Consumer	1	0	0	1	100%	
Health Plan	4	0	0	4	100%	
Health Professional	6	0	2	8	100%	
Provider Organizations	5	1	0	6	83%	
Public/Community Health Agency	0	0	0	0		
Purchaser	0	0	0	0		
QMRI	0	0	0	0		
Supplier/Industry	1	0	0	1	100%	
All Councils	17	1	2	20	94%	
Percentage of councils approving (>50%)			100%			
Average council percentage approval			97%			

*equation: Yes/ (Total - Abstain)

Measure #0383 Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (paired with 0384)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	3	1	0	4	75%
Health Professional	7	0	1	8	100%
Provider Organizations	6	0	0	6	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	0	1	0	1	0%
All Councils	17	2	1	20	89%
Percentage of councils approving (>50%)					80%
Average council percentage approval					75%

*equation: Yes/ (Total - Abstain)

Measure #0384 Oncology: Pain Intensity Quantified – Medical Oncology and Radiation Oncology (paired with 0383)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	4	0	0	4	100%
Health Professional	7	0	1	8	100%

Provider Organizations	5	1	0	6	83%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	0	1	0	1	0%
All Councils	17	2	1	20	89%
Percentage of councils approving (>50%)					80%
Average council percentage approval					77%

Measure #0386 Oncology: Cancer Stage Documented

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	4	0	0	4	100%
Health Professional	6	0	2	8	100%
Provider Organizations	6	0	0	6	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	1	0	0	1	100%
All Councils	18	0	2	20	100%
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure #0389 Prostate Cancer: Avoidance of Overuse Measure – Bone Scan for Staging Low-Risk Patients

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	4	0	0	4	100%
Health Professional	6	0	2	8	100%
Provider Organizations	6	0	0	6	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	1	0	0	1	100%
All Councils	18	0	2	20	100%
Percentage of councils approving (>50%)			100%		
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure #0390 Prostate Cancer: Adjuvant Hormonal Therapy for High-Risk Patients

Measure Council Yes No Abstain Total Votes % Approval*
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Consumer	1	0	0	1	100%		
Health Plan	4	0	0	4	100%		
Health Professional	6	0	2	8	100%		
Provider Organizations	6	0	0	6	100%		
Public/Community Health Agency	0	0	0	0			
Purchaser	0	0	0	0			
QMRI	0	0	0	0			
Supplier/Industry	1	0	0	1	100%		
All Councils	18	0	2	20	100%		
Percentage of councils approving (>50%)		100%					
Average council percentage approval	Average council percentage approval			100%			

Measure #0562 Overutilization of Imaging Studies in Melanoma

Measure Council	Yes	No	Abstain	Total Votes	% Approval*	
Consumer	1	0	0	1	100%	
Health Plan	4	0	0	4	100%	
Health Professional	5	0	3	8	100%	
Provider Organizations	4	1	1	6	80%	
Public/Community Health Agency	0	0	0	0		
Purchaser	0	0	0	0		
QMRI	0	0	0	0		
Supplier/Industry	1	0	0	1	100%	
All Councils	15	1	4	20	94%	
Percentage of councils approving (>50%)			100%			
Average council percentage approval			96%			

*equation: Yes/ (Total - Abstain)

Measure #0650 Melanoma Continuity of Care Recall System

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	4	0	0	4	100%
Health Professional	5	0	3	8	100%
Provider Organizations	3	1	2	6	75%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	1	0	0	1	100%
All Councils	14	1	5	20	93%
Percentage of councils approving (>50%)					100%
Average council percentage approval					95%

*equation: Yes/ (Total - Abstain)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	4	0	0	4	100%
Health Professional	6	0	2	8	100%
Provider Organizations	5	0	1	6	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	1	0	0	1	100%
All Councils	17	0	3	20	100%
Percentage of councils approving (>50%)					100%
Average council percentage approval			100		

Measure #1822 External Beam Radiotherapy for Bone Metastases

*equation: Yes/ (Total - Abstain)

Measure #1853 Radical Prostatectomy Pathology Reporting

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	4	0	0	4	100%
Health Professional	5	0	3	8	100%
Provider Organizations	6	0	0	6	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	1	0	0	1	100%
All Councils	17	0	3	20	100%
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure #1854 Barrett's Esophagus

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	4	0	0	4	100%
Health Professional	5	0	3	8	100%
Provider Organizations	3	2	1	6	60%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	1	0	0	1	100%
All Councils	14	2	4	20	88%
Percentage of councils approving (>50%)					100%
Average council percentage approval					92%

Measure #1790 Risk-Ad	insted Morbidity a	nd Mortality for Lun	g Resection for Lung C	ancer
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Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	1	0	0	1	100%
Health Plan	4	0	0	4	100%
Health Professional	5	0	3	8	100%
Provider Organizations	6	0	0	6	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	0	0	0	0	
QMRI	0	0	0	0	
Supplier/Industry	1	0	0	1	100%
All Councils	17	0	3	20	100%
Percentage of councils approving (>50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

APPENDIX A: MEASURE EVALUATION SUMMARY TABLES Measure Summaries - Recommended

Hematology and Melanoma Measures

0377 Myelodysplastic Sy	yndrome (MDS) and Acute Leukemias	 Baseline Cytogenetic Testing 	Performed on Bone Marrow

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of MDS or an acute leukemia who had baseline cytogenic testing performed on bone marrow.

Numerator Statement: Patients who had baseline cytogenetic testing* performed on bone marrow

Definition: *Baseline Cytogenetic Testing- Testing that is performed at time of diagnosis or prior to initiating treatment (transfusion, growth factors, or antineoplastic therapy) for that diagnosis.

Denominator Statement: All patients aged 18 years and older with a diagnosis of MDS or an acute leukemia

Exclusions: Documentation of medical reason(s) for not performing baseline cytogenetic testing

Documentation of patient reason(s) for not performing baseline cytogenetic testing

Denominator Exclusions: Documentation of system reason(s) for not performing baseline cytogenetic testing

Adjustment/Stratification: No risk adjustment or risk stratification. No risk adjustment or risk stratification. 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.

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data : Laboratory

Measure Steward: American Medical Association - Physician Consortium for Performance Improvement Other organizations: The American Society of Hematology

Steering Committee In-Person March 13-14, 2012

1. Importance to Measure and Report: The measure meets the Importance criteria.

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-9; M-8; L-0; I-0; 1b. Performance Gap: H-11; M-6; L-0; I-0; 1c. Evidence: Y-13, N-1, I-3 Rationale:

- Myelodysplastic Syndrome (MDS) is increasingly common in an aging population and associated with high morbidity and mortality; baseline cytogenic testing performed on bone marrow is important to measure and report due to its role in evaluating and managing this patient population.
- There is a striking performance gap: 48% non-compliance was demonstrated in the CMS 2008 Physician Quality Reporting System (PQRS).
- Measurement of cytogenetics at the time of diagnosis or prior to treatment has become the standard of care since therapies are stratified based on the cytogenetic profile.
- There was concern that the literature cited and rationale provided by measure authors focuses mainly on the use of
 cytogenetics in MDS and its evolution to acute myelogenous leukemia (AML) and does not include much information on *de novo*AML. Although much of the literature presented in the application is based on retrospective reviews, there is some prospective
 randomized literature in AML that is stratified based on prognostic factors (including cytogenetics) to indicate that cytogenetic

0377 Myelodysplastic Syndrome (MDS) and Acute Leukemias – Baseline Cytogenetic Testing Performed on Bone Marrow
abnormalities predict outcome. However, this measure is based mainly on a consensus guideline from the National
Comprehensive Cancer Network (NCCN). The authors grade the literature as 2A based on lower level evidence.
Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria.</u>
(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)
2a. Reliability: H-7; M-9; L-1; I-0; 2b. Validity: H-8; M-9; L-0; I-0
Rationale:
The PCPI Testing Project shows interobserver variability is minimal.
Face validity is well demonstrated.
• The measure directs that the data be gathered in the ambulatory setting. For acute leukemia, much of the care is in the hospital
setting. The Steering Committee recommended reporting the measure with a CPT procedure code or CPT-2 code in order to
capture the inpatient setting.
 Extraction of data from separate EHRs was not addressed. The number of patients analyzed for these measures was small, and
the sample needed to be extended beyond the scope of the measure to achieve an adequate sample for analysis.
3. Usability: <u>H-10; M-6; L-1; I-0</u>
(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)
Rationale:
 The measure has been in use in the CMS Physician Quality Reporting System (PQRS) since 2007
 The data presented demonstrate a high failure rate to meet the measure, and since treatment is stratified based on the
presence of cytogenetic information prior to initiating therapy this measure represents a highly useful measure for quality
improvement.
4. Feasibility: <u>H-5; M-11; L-1; I-0</u>
(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences
identified 4d. Data collection strategy can be implemented)
Rationale:
Collection of this data is a routine part of care.
Data can be extracted, but may exist in different EHRs.
Steering Committee Recommendation for Endorsement: <u>Y-17 ; N-0</u>
Rationale:
The measure represents standard of care measure that is useful to stratify treatments, possibly decrease toxicities and costs
and assure appropriate therapies. The measure appears to be reliable, valid, useful and feasible.
and assure appropriate therapies. The measure appears to be reliable, valid, useful and reasible.
RECOMMENDATIONS
This measure is becoming outdated, as diagnostic panels for MDS and acute leukemias rely heavily upon molecular panels and Electric additionate structure and active and acute leukemias rely heavily upon molecular panels and Electric additionate structure and acute acute and acute leukemias rely heavily upon molecular panels and Electric additionate structure acute
FISH in addition to standard cytogenetics. The responsibility for these assays is also divided between pathologists (who have no
ongoing relationship with patients) and hematologists, who provide ongoing care. The Steering Committee recommended that
the measure developer consider specifying this measure in the future to capture FISH and other tests.
The Steering Committee recommended the measure developer consider specifying the measure to capture patients with MDS,
acute myelogenous leukemia and acute lymphoblastic leukemia. The Commitee believed that karyotypic data, stratified
appropriately, might provide a way to make major therapeutic decisions with respect to the patient population.
Public and Member Comment

Comments included:

- Commenters suggested the time window be further defined to specify the look back period for the measure.
- Commenters suggested that in the future, the developer specify measure to capture FISH and other tests.

Developer Response:

• The developer will look to address these concerns in future iterations of the measure.

0378 Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy

0378 Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of MDS who are receiving erythropoietin therapy with documentation of iron stores within 60 days prior to initiating erythropoietin therapy

Numerator Statement: Patients with documentation* of iron stores within 60 days prior to initiating erythropoietin therapy *Definition: documentation of iron stores which includes either: 1) bone marrow examination including iron stain OR 2) serum iron measurement including ferritin, serum iron and TIBC

Denominator Statement: All patients aged 18 years and older with a diagnosis of MDS who are receiving erythropoietin therapy **Exclusions:** Documentation of system reason(s) for not documenting iron stores prior to initiating erythropoietin therapy

Adjustment/Stratification: No risk adjustment or risk stratification 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.

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory

Measure Steward: American Medical Association - Physician Consortium for Performance Improvement **Other organizations**: American Society of Hematology

Steering Committee In-Person March 13-14, 2012

1. Importance to Measure and Report: The measure meets the Importance criteria.

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-3 ; M-11 ; L-1 ; I-0; 1b. Performance Gap: H-5 ; M-7 ; L-3 ; I-0 ; 1c. Evidence: Y-15 , N-0 , I-0 Rationale:

• This is an increasingly common condition, with diagnosis rising as the population continues to age.

- There is a significant performance gap; 58% of patients did not meet the measure as demonstrated in the PQRS testing information.
- The measure is based on a National Comprehensive Cancer Network (NCCN) consensus guideline.
- The measure only requires that iron stores be checked, not that an intervention as a result of the iron level occur (it would be far more important to document and supplement iron in patients receiving erythropoietin therapy). This is an area for future measure development.
- This patient population falls outside of FDA regulations for testing of iron stores; this may make this measure more important.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity) 2a. Reliability: H-4 ; M-10 ; L-0 ; I-1 ; 2b. Validity: H-5 ; M-9 ; L-0 ; I-1 Rationale:

- Numerator and denominator are precisely specified; clarification of the definition of "iron stores" in the numerator statement and specification of a 60-day time window the denominator allow for the measure to be precisely captured.
- Reliability data supports that the measure is reliable.
- Face validity has been demonstrated.

3. Usability: <u>H-5; M-8; L-2; I-0</u>

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) Rationale:

- The measure has been in use in PQRS since 2007.
- The measure should be moderately understandable for public reporting.

4. Feasibility: <u>H-7; M-8; L-0; I-0</u>

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

• Collection of this data is a routine part of care.

0378 Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy

• Data can be extracted but may exist in different EHRs.

Steering Committee Recommendation for Endorsement: <u>Rationale</u>: Y-14; N-1

- The Committee's initial evaluation supported endorsement with clarification of iron measurements, which were addressed by the developer. The Committee noted that erythropoietin works sub optimally without adequate iron stores, and that the measure reflects FDA recommendations.
- The measure was improved with the addition of a testing time window, as the diagnosis of MDS may precede decision to use erythropoietin by many months if not years.
- This measure does not carry a high risk of unintended consequences.

RECOMMENDATIONS: The measure was not voted on at the in-person meeting due to ambiguity in the measure specifications. The Steering Committee asked the developer to clarify the definition of "iron stores" in the numerator statement and to specify time window the denominator. On a follow up call, the Steering Committee reviewed the measure with the clarified numerator and the addition of a 60-day time window to the denominator for the documentation of iron stores prior to the initiation of erythropoietin therapy. The Committee agreed with the changes and recommended the measure for endorsement.

Public & Member Comment

• Commenters indicated support for the measure.

0379 Chronic Lymphocytic Leukemia (CLL) – Baseline Flow Cytometry

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of CLL who had baseline flow cytometry studies performed

Numerator Statement: Patients who had baseline flow cytometry* studies performed

Definition: *Baseline flow cytometry studies: Refer to testing that is performed at time of diagnosis or prior to initiating treatment for that diagnosis. Treatment may include antineoplastic therapy.

Denominator Statement: All patients aged 18 years and older seen within a 12 month reporting period, with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period

Exclusions: Documentation of medical reason(s) for not performing baseline flow cytometry

Documentation of patient reason(s) for not performing baseline flow cytometry

Documentation of system reason(s) for not performing baseline flow cytometry

Adjustment/Stratification: No risk adjustment or risk stratification. 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.

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory

Measure Steward: American Medical Association - Physician Consortium for Performance Improvement **Other organizations:** American Society of Hematology

Steering Committee In-Person March 13-14, 2012

1. Importance to Measure and Report: <u>The measure meets the Importance criteria.</u>

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-7; M-5; L-3; I-0; 1b. Performance Gap: H-2; M-10; L-2; I-1; 1c. Evidence: Y-14, N-0, I-1 Rationale:

- This is the most common leukemia and involves high resource use.
- There is a performance gap: a 38% failure to perform shown in PQRS testing.
- Flow cytometry is important in diagnosis and treatment planning, but the data provided do not provide adequate rationale for measure. They discuss delays in diagnosis but measure is for flow cytometry following diagnosis or before treatment. So it is

0379 Chronic Lymphocytic Leukemia (CLL) – Baseline Flow Cytometry

unclear how this would shorten time to diagnosis.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria.</u>

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-5; M-9; L-0; I-1; 2b. Validity: H-5; M-9; L-0; I-1

Rationale:

- The measure is confusing. It specifies a 12-month reporting period in which all patients with CLL are captured in the denominator. However, flow cytometry may have been performed years prior to the initiation of treatment and reporting event. The numerator therefore may not correspond to the same reporting period as the denominator. The measure may be relying upon interventions done many years earlier. Per the Steering Committee's recommendation, the developer will clarify the time window for flow cytometry studies to be performed.
- The Steering Committee noted that the clarification that flow cytometry baseline studies should take place at the time of diagnosis or prior to initiating treatment, and not necessarily within the time window for the measure, adds the necessary clarity to the measure specifications to make it easily captured.

3. Usability: H-5; M-7; L-2; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) Rationale:

- The measure has been in use in PQRS since 2007.
- The measure should be moderately understandable for public reporting.

4. Feasibility: <u>H-3; M-11; L-1; I-0</u>

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- Collection of this data is a routine part of care.
- Data can be extracted but may exist in different EHRs.

Steering Committee Recommendation for Endorsement

Rationale: Y-13; N-2

- The measure is improved with clarification of numerator/denominator.
- There is some concern about use as a quality measure as diagnosis is made based on flow cytometry results.
- Flow cytometry is sensitive and specific for diagnosis, impacts prognosis and decisions regarding follow-up; questions about time frames have been addressed.
- Even with the caveats discussed, the measure provides a reasonable assessment of quality care.
- Important to measure, and developer clarified numerator and denominator for more reliable measurement.

RECOMMENDATIONS: The Steering Committee did not recommend the measure at the in-person meeting; voting ended at 2.a Reliability. The Committee noted that the numerator should be clarified to identify patients who had documentation of the study having been performed, and that the denominator should be clarified regarding the time window. On a follow up call, the developer provided clarifications to the numerator and denominator for review and consideration by the Committee. The Committee agreed with the changes presented and recommended the measure for endorsement.

Public and Member Comment

Comments included:

- Commenters were concerned that because the diagnosis of CLL is based on the results of flow cytometry, nearly all patients with the diagnosis will be expected to have had flow cytometry.
- Commenters suggested that the measurement time period should be clarified.

Developer Response:

• We have received comments regarding clarifying the time period as well as the possibility that the flow cytometry would have taken place previously. We have incorporated these updates and comments into the measure language.

0379 Chronic Lymphocytic Leukemia (CLL) – Baseline Flow Cytometry

Steering Committee Response:

• The Steering Committee agrees with the developer's response, which is in line with discussions that occurred at the in-person meeting and on related conference calls.

0380 Multiple Myeloma – Treatment with Bisphosphonates

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonates within the 12 month reporting period

Numerator Statement: Patients who were prescribed or received intravenous bisphosphonate therapy* within the 12 month reporting period.

Definition: *Bisphosphonate Therapy: Includes the following medications: pamidronate and zoledronate

Denominator Statement: All patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission **Exclusions:** Documentation of medical reason(s) for not prescribing bisphosphonates (eg, patients who do not have bone disease, patients with dental disease, patients with renal insufficiency)

Documentation of patient reason(s) for not prescribing bisphosphonates

Adjustment/Stratification: No risk adjustment or risk stratification 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.

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Records **Measure Steward:** American Medical Association - Physician Consortium for Performance Improvement **Other organizations:** American Society of Hematology

Steering Committee In-Person March 13-14, 2012

1. Importance to Measure and Report: The measure meets the Importance criteria.

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-9; M-8; L-0; I-0; 1b. Performance Gap: H-11; M-6; L-0; I-0; 1c. Evidence: Y-13, N-1, I-3 Rationale:

- The measure developer cites an American Cancer Society publication to show that this is an issue of high impact that affects large numbers of patients (approximately 20,000 patients diagnosed annually)
- The gap in care for prescribing bisphosphonates for patients in the measure was striking, with 47.4% of patients reported on not meeting the measure.
- Supporting literature is of moderate to high quality and quantity.
- Use of bisphosphonates increases quality of life, though it does not decrease mortality.
- Intervention should occur more often; however, reporting annually on the measure is acceptable.
- 2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-7; M-9; L-1; I-0; 2b. Validity: H-8; M-9; L-0; I-0

Rationale:

- Previously endorsed measure; interval study data demonstrated a high degree of reliability (100%)
- Face validity of the measure was well demonstrated.
- The measure is well specified and will be easy to extract.

3. Usability: <u>H-7; M-10; L-0; I-0</u>

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) **Rationale**:

- The measure will be useful for QI, particularly given the performance gap.
- The measure should be moderately understandable for public reporting.

4. Feasibility: <u>H-5; M-12; L-0; I-0</u>

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences

0380 Multiple Myeloma – Treatment with Bisphosphonates

identified 4d. Data collection strategy can be implemented) **Rationale**:

• Data easily extracted from EHR or paper chart

Steering Committee Recommendation for Endorsement: Y-17; N-0

<u>Rationale</u>: The Steering Committee found the intervention addressed by this measure affects a large patient population and is important in improving patient quality of life. There is a significant performance gap in meeting the measure, allowing room for improvement in patient care.

Public & Member Comment

• Commenters indicated support for the measure.

0562 Overutilization of Imaging Studies in Melanoma

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of patients, regardless of age, with a current diganosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signes or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period, for whom no diagnostic imaging studies were ordered

Numerator Statement: Patients for whom no diagnostic imaging studies* were ordered

Denominator Statement: All patients, regardless of age, with a current diagnosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signs or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period

Exclusions: Documentation of medical reason(s) for ordering diagnostic imaging studies (e.g., patient has comorbid condition that warrants imaging, other medical reasons); Documentation of system reason(s) for ordering diagnostic imaging studies (e.g., requirement for clinical trial enrollment, ordered by another provider, other system reasons)

Adjustment/Stratification: No risk adjustment or risk stratification No risk adjustment or risk stratification. 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.

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Imaging/Diagnostic Study, Electronic Clinical Data : Registry, Paper Records

Measure Steward: American Medical Association - Physician Consortium for Performance Improvement Other organizations:

American Academy of Dermatology and National Committee for Quality Assurance

Steering Committee In-Person March 13-14, 2012 1. Importance to Measure and Report:

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-9; M-4; L-2; I-0; 1b. Performance Gap: H-7; M-7; L-1; I-0; 1c. Evidence: Y-8, N-4, I-3 Rationale:

- The Steering Committee agreed that there is no question that imaging use and cost are rising; however, it is less clear to what extent that is true for this population.
- The measure is based mainly on consensus guidelines with a high volume of studies cited and limited data presented to specifically support measure. Literature is graded according NCCN guidelines and recommendations are not based solely on literature support.
- The body of evidence as noted above is larger for the general group of all patients when looking at hospital to outpatient settings. If this is restricted to melanoma patients and if it involves outpatient to outpatient settings, the body of evidence is low. However, there is no evidence for harm.
- The Steering Committeed discussed that the measure assumes that treatment for metastatic melanoma is futile therapy, but two
 new agents have been FDA-approved for melanoma since this measure was adopted and future studies may indicate a new
 role for surveillance in the future.

0562 Overutilization of Imaging Studies in Melanoma

2. Scientific Acceptability of Measure Properties: <u>The measure does not meet the Scientific Acceptability Criteria</u> (2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)
2a. Reliability: H-2; M-4; L-6; I-2; 2b. Validity: H-1; M-4; L-5; I-2

3. Usability: <u>N/A</u>

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

4. Feasibility: <u>N/A</u>

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Steering Committee Recommendation for Endorsement: The measure failed the Scientific Acceptability criteria and will not be recommended for endorsement.

- The Steering Committee expressed concerns regarding the reliability of the measure: the measure does not adequately address the distinction between initial stage and recurrence, and the definitions of these in data sources
- The measure reflects updated NCCN guidelines, impacts large numbers, and is important to address overuse.
- The topic is too narrow; one could argue for this type of measure for every type of primary cancer.
- The Committee disagreed with inclusion of downstream patients in the measure, as they felt it confounds reliability; data presented by the developers appears to show this.

RATIONALE: The Steering Committee did not recommend the measure at the in-person meeting; voting ended at 1.c Evidence. The Committee noted that the denominator should be limited to patients with a new diagnosis and asked the developer for analysis of the data on newly diagnosed patients versus patients with a history of melanoma. The developer presented reliability testing analysis showing an approximately 10% difference in reliability, but the SC noted that the testing was done on a relatively small sample size of 148. On a follow up call, the Committee reviewed the analysis presented by the developer again and discussed the measure. The Committee noted that cancer staging follows patients from the point of diagnosis; the stage should not migrate as the patient's disease changes. Instead the stage carries with notations denoting clinical or pathological observations. Because of this, the testing analysis demonstrating reliability of the measure was not persuasive, as the stage is from diagnosis and thus cannot be easily extracted for measurement. The Committee found that the information provided by developer did not allay concerns about ambiguities in the measure and did not recommend the measure for endorsement.

Public and Member Comment Importance

- The Steering Committee members stated that there is limited evidence of overuse of imaging in this patient population, as no study has ever been undertaken.
 - The measure developers presented evidence that the measure was based on both the AAD and NCCN guidelines (please reference attached letter, section 1).
 - The developers noted that the measure is supported by evidence based guidelines (AAD and NCCN) that recommend that both newly diagnosed patients with stage 0-IIC melanoma without signs or symptoms suggesting systemic spread and patients with a history of melanoma at any stage without signs or symptoms suggesting systemic spread not receive unnecessary imaging. The developers emphasized that patients with signs or symptoms suggesting systemic spread would not be counted in the denominator and thus would be eligible for imaging, allowing providers to exercise clinical judgment when signs or symptoms are present.

Scientific Acceptability

- Steering Committee members raised concerns that the measure would restrict imaging of patients with recurrence of melanoma, not taking into account patients who are seen many years out for follow up who present with symptoms or signs of illness. Steering Committee members noted that these patients should be followed up with utilizing imaging, in accordance with NCCN guidelines.
 - The measure developers noted that the measure provides explicit denominator exceptions for patients with signs or symptoms of systemic spread to be evaluated using imaging (see denominator exclusion details, section 2a1.9 of the

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- measure submission form and also section 3 of the attached letter). These patients who have a history of melanoma who present with signs or symptoms of systemic spread would not be included in the denominator and would be eligible for imaging.
- Signs are defined as: "Signs-For the purposes of this measure, signs include tenderness, jaundice, localized neurologic signs such as weakness, or any other sign"
- Symptoms are defined as: "Symptoms-For the purposes of this measure, symptoms include cough, dyspnea, pain, paresthesia, or any other symptom"
- Steering Committee members questioned whether providers would game the system and create exceptions in order to justify ordering imaging.
 - The developers noted that there have been several studies on exception methodology, with very high concordance between what is documented and what is considered an acceptable exception as defined by a group of experts.
 - With respect to this measure, for patients with newly diagnosed melanoma, the exception agreement was 100%. For
 patients with existing diagnoses of melanoma, the exception agreement was 74.59%. The developer cautioned that this
 was calculated using a small sample size (please reference attached letter, section 2).

In light of the information presented on the follow up conference call, Steering Committee members motioned to formally vote on the measure. A SurveyMonkey link was sent to the Steering Committee members along with a summary of the discussion on the conference call. The voting results are presented below:

1. Importance to Measure and Report: The measure meets the Importance criteria.

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-4; M-9; L-1; I-0; 1b. Performance Gap: H-1; M-11; L-1; I-1; 1c. Evidence: Y-11; N-2; I-1

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-2; M-10; L-2; I-0; 2b. Validity: H-2; M-10; L-2; I-0

3. Usability: H-1; M-11; L-2; I-0

(*Meaningful*, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) **4. Feasibility:** <u>H-1; M-13; L-0; I-0</u>

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Steering Committee Recommendation for Endorsement: Y-9; N-5

Rationale:

- Steering Committee members voted to recommend measure 0562 for endorsement, noting that the evidence presented by the measure developer alleviated concerns regarding the evidence base for overuse of imaging in patients with asymptomatic localized melanoma.
- Steering Committee member concerns that the measure specifications would limit the ability of providers to use clinical judgment when ordering imaging were addressed by the clarifying language regarding signs or symptoms of melanoma.
- Steering Committee member concerns that the reliability of the measure was different for patients with a new diagnosis versus patients with a history of melanoma were addressed by the additional stratified reliability testing provided demonstrating that the measure is reliable in both patient populations and that the exception rate is not markedly different between the two patient groups.

0650 Melanoma Continuity of Care – Recall System

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month reporting period into a recall system that includes:

A target date for the next complete physical skin exam , AND

• A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment

Numerator Statement: Patients whose information is entered, at least once within a 12 month period, into a recall system* that includes:
 A target date for the next complete physical skin exam , AND

• A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment

Denominator Statement: All patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma.

Exclusions: Documentation of system reason(s) for not entering patients into a recall system (eg, melanoma being monitored by another physician provider)

Adjustment/Stratification: No risk adjustment or risk stratification Not applicable 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.

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Structure

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Registry, Other, Paper Records Measure Steward: American Medical Association - Physician Consortium for Performance Improvement Other organizations: American Academy of Dermatology and National Committee for Quality Assurance

Steering Committee In-Person March 13-14, 2012

1. Importance to Measure and Report: The measure meets the Importance criteria.

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-9; M-8; L-0; I-0; 1b. Performance Gap: H-4; M-11; L-1; I-1; 1c. Evidence: Y-7, N-1, I-9; Evidence Exception: Y-16, N-1 Rationale:

- Studies presented do not specifically address the melanoma recall system.
- Measure is likely an opportunity for improvement but data is unclear about performance gap with regard to a recall system. Authors cite that 9% did not meet measure; however, the Steering Committee views this as a "never event."
- The body of evidence as noted above is larger for the general group of all patients when looking at hospital to outpatient settings. If this is restricted to melanoma patients and if it involves outpatient to outpatient settings, the body of evidence is low. However, there is no evidence for harm.
- Steering Committee members stated that the link between the process of utilizing a recall system and increased screening/examination of patients can be inferred.
- Steering Committee members stated that this is a valuable intervention because of the prevalence of the diagnosis, the increasing incidence of melanoma and the opportunity for impacting the outcome of patients by early diagnosis of a new primary melanoma, and chose to invoke the exception to empirical evidence rule because of this.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-7; M-9; L-0; I-1; 2b. Validity: H-4; M-12; L-0; I-1

Rationale:

- The measure developer reports moderate reliability regarding a diagnosis of melanoma but high reliability for all other data elements including documentation of enrollment in a recall system
- Measure specifications are reasonably precise.
- Face validity was demonstrated.

3. Usability: <u>H-4; M-12; L-1; I-0</u>

(*Meaningful*, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) <u>**Rationale**</u>:

- Measure is currently in use for PQRS.
- Measure is easily understood.

0650 Melanoma Continuity of Care – Recall System

4. Feasibility: <u>H-6; M-11; L-0; I-0</u>

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- Data elements relate to office procedures, not directly to care.
- Recall procedure may not be in EHR, may be in practice management software, other tracking software, or non-electronic.
- All criteria should be feasible within an EHR, but extracting information may be difficult.

Steering Committee Recommendation for Endorsement: Y-15; N-2

<u>Rationale</u>: The Steering Committee found that the intervention addressed by this measure affects a large patient population and is important in ensuring continuity of care.

Public and Member Comment

Comments included:

- Commenters suggested the measure be expanded to capture data regarding multiple types of skin cancers so that continuity of care can be achieved.
- It was suggested that the measure capture how many patients had a follow-up appointment rather than how many patients were entered into a recall system.

Developer Response:

• The Work Group will consider expanding the measure population, when the measure undergoes formal review and maintenance, according to the AMA-PCPI measure development/maintenance methodology, in the future.

Steering Committee Response:

• The Steering Committee agrees with the developer's response, which is in line with discussions that occurred at the in-person meeting and on related conference calls.

Oncology Measures

0381 Oncology: Treatment Summary Communication – Radiation Oncology

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of patients, regardless of age, with a diagnosis of cancer who have undergone brachytherapy or external beam radiation therapy who have a treatment summary report in the chart that was communicated to the physician(s) providing continuing care and to the patient within one month of completing treatment

Numerator Statement: Patients who have a treatment summary* report in the chart that was communicated to the physician(s) providing continuing care and to the patient within one month of completing treatment

Definition: *Treatment Summary: a report that includes mention of all of the following components: 1) dose delivered; 2) relevant assessment of tolerance to and progress towards the treatment goals; and 3) subsequent care plans

Numerator Instructions: This measure should be reported once per course of radiation treatment – less than or equal to 30 days from the end of treatment.

Denominator Statement: All patients, regardless of age, with a diagnosis of cancer who have undergone brachytherapy or external beam radiation therapy

Exclusions: Documentation of a patient reason(s) for not communicating the treatment summary report to the physician(s) providing continuing care (eg, patient requests that report not be sent) and to the patient within one month of completing treatment

Documentation of a system reason(s) for not communicating the treatment summary report to the physician(s) providing continuing care (eg, patient does not have any physician responsible for providing continuing care) and to the patient within one month of completing treatment

Adjustment/Stratification: No risk adjustment or risk stratification None 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. Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

0381 Oncology: Treatment Summary Communication – Radiation Oncology

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records

Measure Steward: American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) Other organizations: The measure set was developed in collaboration with the American Society of Clinical Oncology and the American Society for Radiation Oncology.

Steering Committee In-Person March 13-14, 2012

1. Importance to Measure and Report: The measure meets the Importance criteria.

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-7; M-10; L-0; I-0; 1b. Performance Gap: H-4; M-10; L-1; I-2; 1c. Evidence: Y-9, N-1, I-7

Rationale:

- Radiation therapy treatment summaries have been a routine practice for years and are a requirement for payment.
- Many radiation therapy treatment summaries currently lack critical information, such as the site of radiation.
- Summary of evidence of impact is not specific to the focus of the measure. Most evidence is related to incidence, cancer-related death rates, and cancer costs. The most closely related statistic is that two-thirds of all cancer patients will receive radiation. However, there is no data on outcomes associated with the lack of a treatment summary.
- Steering Committee members noted that the information from a treatment summary is very important to disseminate amongst providers caring for the patient receiving radiation therapy.
- The measure affects a large number of patients, and there is demonstrated evidence of a performance gap.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-7; M-10; L-0; I-0; 2b. Validity: H-1; M-14; L-1; I-1

Rationale:

- Inter-rater reliability is described as 100% accurate.
- Measure addresses an important priority area: coordination of care. The proximal relationship between performance on the measure and desired outcome is not addressed by available data, however, face validity was demonstrated.

3. Usability: H-6; M-10; L-1; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) Rationale:

• The measure is being used in a QI program with plans for use in PQRS.

4. Feasibility: <u>H-5; M-10; L-2; I-0</u>

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

• Data elements are available in an EHR and generated during the provision of care.

Steering Committee Recommendation for Endorsement: Y-14; N-3

Rationale: The intervention addressed by this measure affects a large patient population and is important in ensuring continuity of care.

RECOMMENDATIONS:

The Steering Committee recommended the measure developer consider including the site and stage in the measure in the future.

Public and Member Comment

Comments included:

• Commenters were concerned that the measure only assesses standard practice that should be occurring routinely.

Developer Response:

 The radiation oncology treatment summary should include many details regarding the treatment course and follow-up plan, which is critical to ensuring proper coordination of care among patient's current and future physicians, including oncologists and primary care physicians. This is especially important for radiation oncology given that cancer patients treated with radiation typically receive multimodality treatment and many patients receive care that is fragmented among several facilities. Unfortunately, as indicated by performance rates for this measure and medical literature on the topic, adherence remains

0381 Oncology: Treatment Summary Communication – Radiation Oncology

suboptimal demonstrating a significant opportunity to improve the care provided to cancer patients. Specifically, results of the National Initiative for Cancer Care Quality indicated that across five metropolitan statistical areas, only 50% of radiation therapy medical records for patients with breast cancer included information regarding the total dose of radiation, dose per fraction, number of fractions, and the site treated. While this data does not speak to the existence of the report itself, it does speak to the completeness of the report which is a secondary component to the measure. Additionally, among physicians participating in ASTRO's Performance Assessment for the Advancement of Radiation Oncology Treatment (PAAROT) program, an average performance rate of 92% was reported for this measure with variation among physicians ranging from 0-100%. PAAROT is a practice improvement program that enables a physician to analyze their practice and evaluate their strengths and areas for improvement.

Steering Committee Response:

• The Steering Committee agrees with the developer's response, which is in line with discussions that occurred at the in-person meeting and on related conference calls.

0382 Oncology: Radiation Dose Limits to Normal Tissues

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of patients, regardless of age, with a diagnosis of pancreatic or lung cancer who receive 3D conformal radiation therapy with documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues

Numerator Statement: Patients who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues

Denominator Statement: All patients, regardless of age, with a diagnosis of pancreatic or lung cancer who receive 3D conformal radiation therapy

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification None 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. Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records

Measure Steward: American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) Other organizations: This measure set was developed in collaboration with the American Society of Clinical Oncology and the American Society for Radiation Oncology.

0382 Oncology: Radiation Dose Limits to Normal Tissues

Steering Committee In-Person March 13-14, 2012

1. Importance to Measure and Report: The measure meets the Importance criteria.

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-12; M-4; L-0; I-0; 1b. Performance Gap: H-2; M-12; L-2; I-0; 1c. Evidence: Y-14, N-2, I-0 Rationale:

- The measure applies to lung and pancreatic cancer, with lung especially being a prevalent cancer with high morbidity and mortality. Radiation is a commonly used treatment.
- There was evidence cited showing 89% compliance with the PQRS measure, which highlights some, but not much room for improvement. The Steering Committee considered this a "never event" and felt compliance should be 100%.
- The Steering Committee stated the importance of calculating dose limits when giving radiation to a patient and noted that there is evidence to support this practice.

Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria.</u>
 (2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)
 2a. Reliability: H-11; M-5; L-0; I-0; 2b. Validity: H-7; M-9; L-0; I-0

0382 Oncology: Radiation Dose Limits to Normal Tissues

Rationale:

- The measure contains specifications that allow for reliable ascertainment and data on reliability.
- The measure includes data on face validity from an expert panel.

3. Usability: H-10; M-6; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) Rationale:

- The measure has been succesfully implemented in PQRS.
- The measure should be easily understood for public reporting.

4. Feasibility: <u>H-11; M-5; L-0; I-0</u>

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

• The data elements are all feasibly extracted from an EHR and generated during routine care delivery.

Steering Committee Recommendation for Endorsement: Y-16; N-0

<u>Rationale</u>: The Steering Committee noted that there is near universal concordance from an expert panel, excellent reliability, usability, and feasibility, and the target population comprises large numbers. There is no contradictory evidence for the measure.

Public and Member Comment

Comments included:

• Commenters were concerned that the measure only assesses standard practice that should be occurring routinely.

Developer Response:

Identifying normal tissue dose constraints is an important step in the process of care for patients receiving radiation therapy
treatments with significant impact on outcomes including reducing the toxic effects of radiation to normal tissues and
subsequently reducing the long term potential for late carcinogenesis and a second malignancy, while delivering the desired
dose distribution of radiation to target tissue. Unfortunately, as indicated by performance rates for this measure noted in the
submission form, adherence remains suboptimal demonstrating a significant opportunity to improve the care provided to cancer
patients.

Steering Committee Response:

• The Steering Committee agrees with the developer's response, which is in line with discussions that occurred at the in-person meeting and on related conference calls.

0383 Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (paired with 0384)

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain

Numerator Statement: Patient visits that included a documented plan of care* to address pain

Numerator Instructions: *A documented plan of care may include: use of opioids, nonopioid analgesics, psychological support, patient and/or family education, referral to a pain clinic, or reassessment of pain at an appropriate time interval.

Denominator Statement: All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification None 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. Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Other, Paper Records

0383 Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (paired with 0384)
Measure Steward: American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) Other
organizations: This measure set was developed in collaboration with the American Society of Clinical Oncology and the American
Society for Radiation Oncology.
Steering Committee In-Person March 13-14, 2012
1. Importance to Measure and Report: The measure meets the Importance criteria.
(1a. High Impact; 1b. Performance Gap; 1c. Evidence)
1a. Impact: H-15; M-2; L-0; I-0; 1b. Performance Gap: H-12; M-5; L-0; I-0; 1c. Evidence: Y-15, N-0, I-2
Rationale:
 It is well documented that many cancer patients will experience pain during the course of treatment. The measure affects a
large patient population.
 A performance gap was demonstrated, with performance in the ASCO QOPI study achieving the measure at 78.29% and in
PQRS for 2009 at 91.24%.
Concern that including any report of pain, even mild, may dilute the impact of this measure. However, the Steering Committee
stated that simply noting that the patient was experiencing mild pain and the need to follow up on it would be sufficient to meet
this measure, alleviating concerns.
2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.
(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)
2a. Reliability: H-4; M-12; L-1; I-0; 2b. Validity: H-3; M-12; L-1; I-1
Rationale:
 Reliability was adequately demonstrated, albeit with a small sample size.
Face validity was demonstrated.
3. Usability: <u>H-6; M-9; L-2; I-0</u>
(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)
Rationale:
 The measure is currently being used in PQRS 2012; also used from 2009-2011.
• The measure is currently in use in ASCO's Quality Oncology Practice Initiative (QOPI ®) program and ASTRO's Performance
Assessment for the Advancement of Radiation Oncology Treatment (PAAROT) program.
4. Feasibility: <u>H-4; M-13; L-0; I-0</u>
(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences
identified 4d. Data collection strategy can be implemented)
Rationale:
 Data elements are available in an EHR and generated during the provision of care.
Steering Committee Recommendation for Endorsement: Y-16; N-1
<u>Rationale:</u> The Steering Committee found that the intervention addressed by this measure affects a large patient population. There is
room for improvement in performance of this measure.
Public and Member Comment
Comments included:
 Commenters recommended the measure be harmonized with other measures of pain management, including QOPI and ACCIENT which are released as a service of fearmed based to a surger a size.
ASSIST which specify that a plan of care be required for moderate to severe pain.
Commenters were concerned about the burden on providers to provide a documented plan of care for pain that is insignificant

- Commenters were concerned about the burden on providers to provide a documented plan of care for pain that is insignificant, and were concerned about potential problems differentiating quality of care for moderate to severe pain patients.
- Commenters were concerned that the measure only assesses standard practice that should be occurring routinely.

Developer Response:

The NCCN guideline recommendations for the management of cancer related pain in adults, upon which this measure is based, are categorized according to three levels of pain intensity - mild pain (1-3); moderate pain (4-6); and severe pain (7-10). Therefore, the plan of care for pain should be initiated at the lowest level of pain intensity. It is also important to recognize that the scope of the plan is broad and may include use of opioids, nonopioid analgesics, psychological support, patient and/or family education, referral to a pain clinic, or reassessment of pain at an appropriate time interval. Consistent with NCCN

0383 Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (paired with 0384)

- guidelines, the specific plan of care for an individual patient's pain required by the measure is at the discretion of the individual clinician based on the needs and preferences of that specific patient.
- Pain is one of the most common symptoms associated with cancer. Pain occurs in approximately one quarter of patients with newly diagnosed malignancies, one third of patients undergoing treatment, and three quarters of patients with advanced disease. Proper pain management is critical to achieving pain control. This measure aims to improve attention to pain management and requires a plan of care for cancer patients who report having pain to allow for individualized treatment based on clinical circumstances and patient wishes. Unfortunately, as indicated by performance rates for this measure noted in the submission form and medical literature on the topic, adherence remains suboptimal demonstrating a significant opportunity to improve the care provided to cancer patients.

Steering Committee Response:

- The Steering Committee agreed with the commenter that patients with mild pain likely do not require documented care plans for addressing the pain. The Steering Committee stated that documentation of a care plan for patients with mild pain in this patient population may very well present a substantial burden to the provider, as many patients being actively treated with chemotherapy or radiation therapy for cancer have mild pain.
- The Steering Committee questioned whether there are other measures that address pain for this patient population in the NQF portfolio. NQF staff stated that there are measures that may overlap with patients in this population that address moderate to severe pain; however, there are no measures that target the entirety of the patient population (patients with cancer being treated at an outpatient facility) addressed by this measure. Consequently, the Steering Committee determined that they would like to move this measure forward with a recommendation for endorsement; however, the Steering Committee made several recommendations for future iterations of the measure. Those recommendations are as follows:
 - Remove specifications for documenting a care plan for patients with mild pain, in order to focus on patients who most need an intervention (patients with moderate to severe pain).
 - Further define what constitutes a plan of care, to remove ambiguity about what "counts" for the measure. This will move the measure away from being a "check the box" measure and further assist in defining the measure as we move toward integration into electronic health records.

0384 Oncology: Pain Intensity Quantified – Medical Oncology and Radiation Oncology (paired with 0383)

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified

Numerator Statement: Patient visits in which pain intensity is quantified*

* Pain intensity should be quantified using a standard instrument, such as a 0-10 numerical rating scale, a categorical scale, or the pictorial scale

Denominator Statement: All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification None 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. Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Other, Paper Records

Measure Steward: American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) Other organizations: This measure set was developed in collaboration with the American Society of Clinical Oncology and the American Society for Radiation Oncology.

Steering Committee In-Person March 13-14, 2012

1. Importance to Measure and Report: The measure meets the Importance criteria.

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

0384 Oncology: Pain Intensity Quantified – Medical Oncology and Radiation Oncology (paired with 0383)

1a. Impact: H-16; M-1; L-0; I-0; 1b. Performance Gap: H-11; M-6; L-0; I-0; 1c. Evidence: Y-16, N-1, I-0 Rationale:

- Measure developer presented good evidence showing the prevalence of pain; the measure will impact a large number of patients.
- Performance was documented at 89.49% in the ASCO QOPI study, 57% in ASTRO's PAAROT program, and 66.83% in PQRS. There is an opportunity for improvement.
- 2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-7; M-10; L-0; I-0; 2b. Validity: H-6; M-11; L-0; I-0 Rationale:

- The measure is precisely specified.
- Reliability testing demonstrates almost perfect reliability.
- Face validity is demonstrated.

3. Usability: H-10; M-7; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) **Rationale**:

- The measure is currently in use in PQRS.
- 4. Feasibility: H-9; M-8; L-0; I-0

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

• Data elements are available in an EHR and generated during the provision of care..

Steering Committee Recommendation for Endorsement: Y-17; N-0

<u>Rationale</u>: The Steering Committee found that the intervention addressed by this measure affects a large patient population. There is room for improvement in performance of this measure.

<u>RECOMMENDATIONS</u>: The Steering Committee recommended that the developer harmonize the definition of a standardized quantitative pain tool with that used in measure 1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits and measure 1634: Hospice and Palliative Care – Pain Screening. The definition used by those measures is as follows: Pain screening with a standardized quantitative tool during the primary care or cancer-related/specialty outpatient visit(s). Screening may be completed using verbal, numeric, visual analog, rating scales designed for use with nonverbal patients, or other standardized tools.

Public and Member Comment

Comments included:

- With regard to harmonizing pain measures, a commenter noted that pain measures are appropriate for all populations, noting
 that measure 1628 is specific to adult patients, while measures 1634 and 0384 appear to apply to all ages. The commenter
 noted that the discussion on harmonization under measure 0384 notes that the PICU pain assessment measures "do not
 require use of a standardized instrument," and stated that the PICU pain measure calls for use of a nationally recognized pain
 assessment scale that is age and developmentally appropriate. The commenter was supportive of the inclusion of a pictorial in
 the measure.
- A commenter was concerned that the measure only assesses standard practice that should be occurring routinely.

Developer Response:

- As the commenter noted, there are a number of NQF-endorsed measures focusing on the assessment of pain in a variety of unique settings and circumstances. With the clarification regarding measures 0341 and 0342 in the PICU setting, it appears that all of these measures refer to conducting the assessment using a standardized tool. Similarly, measure 0384 suggests that pain should be quantified using a standard instrument, such as a 0-10 numerical rating scale, a categorical scale, or the pictorial scale.
- Initial and ongoing pain assessments, the focus of the measure, are essential to ensure proper pain management among patients with cancer. As noted in the NCCN cancer pain guidelines, failure to adequately assess pain frequently leads to poor control. Unrelieved pain denies [patients] comfort and greatly affects their activities, motivation, interactions with family and

0384 Oncology: Pain Intensity Quantified – Medical Oncology and Radiation Oncology (paired with 0383)

friends, and overall quality of life. Unfortunately, as indicated by performance rates for this measure and medical literature on the topic, adherence remains suboptimal demonstrating a significant opportunity to improve the care provided to cancer patients.

Steering Committee Response:

• The Steering Committee agrees with the developer's response, which is in line with discussions that occurred at the in-person meeting and on related conference calls.

0386 Oncology: Cancer Stage Documented

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of patients, regardless of age, with a diagnosis of breast, colon, or rectal cancer who are seen in the ambulatory setting who have a baseline AJCC cancer stage or documentation that the cancer is metastatic in the medical record at least once during the 12 month reporting period

Numerator Statement: Patients who have a baseline AJCC cancer stage* or documentation that the cancer is metastatic in the medical record at least once during the 12 month reporting period

Numerator Instructions: *Cancer stage refers to stage at diagnosis

Denominator Statement: All patients, regardless of age, with a diagnosis of breast, colon, or rectal cancer who are seen in the ambulatory setting

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification None 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. Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Pharmacy, Paper Records

Measure Steward: American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI) **Other organizations:** This measure is jointly copyrighted by the AMA-PCPI and American Society of Clinical Oncology. The measure set was also developed in collaboration with the American Society for Radiation Oncology.

Steering Committee In-Person March 13-14, 2012

1. Importance to Measure and Report: The measure meets the Importance criteria.

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-14; M-2; L-1; I-0; 1b. Performance Gap: H-13; M-4; L-0; I-0; 1c. Evidence: Y-12, N-2, I-3 Rationale:

- Breast and colorectal cancer affect large numbers of patients and are leading causes of morbidity/mortality.
- Information presented related to the impact of the measure is specific to the general topic area (breast and colorectal cancer)
 rather than specific to importance of documenting stage of disease or to the consequences of poor quality in this area. Steering
 Committee agreed that documentation of stage is essential for any treatment planning in oncology, representing a "floor" for
 improvement, however.
- The developer provided data from the QOPI measure showing an average performance rate of 83%, with a range of 35% to 100%. Data was also presented from ASTRO's PAAROT program, which has an average performance rate of 87% with a range of 10% to 100%.
- Evidence for the measure is exclusively based on clinical practice guidelines; however, there is uniform NCCN consensus that the intervention is appropriate.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria.</u>

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-5; M-9; L-1; I-2; 2b. Validity: H-2; M-13; L-1; I-1 Rationale:

• Staging is critical for any cancer diagnosis; the measure specifications should be broadened to include all patients with a cancer diagnosis.

0386 Oncology: Cancer Stage Documented

- The Steering Committee was concerned that while it is important to know the stage of cancer at diagnosis, it is also important to know the stage over the course of treatment.
- The Steering Committee agreed that it is important to include clinical and pathological stage wherever possible.
- The measure is clearly specified.
- Reliability testing was adequate.
- Face validity was demonstrated.

3. Usability: H-10; M-7; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) **<u>Rationale</u>**:

- The measure developer has collected performance data; however, the measure has not been publicy reported.
- The measure is currently only being used in QI initiatives.
- The Steering Committee was concerned that patients do not always understand the concept of staging, which could limit use of the meausre for public reporting.

4. Feasibility: <u>H-7; M-9; L-1; I-0</u>

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

• Data is generated during the provision of care and all data elements are found in an EHR.

Steering Committee Recommendation for Endorsement: Y-17; N-0

<u>Rationale</u>: The Steering Committee found that the intervention addressed by this measure affects a large patient population and is important in ensuring that patients are treated appropriately based on diagnosis. This measure is important for treatment planning.

RECOMMENDATIONS:

The Steering Committee recommended the developer consider broadening measure specifications to include all patients with a cancer diagnosis. Additional experience with the measure should begin to show stronger evidence related to important outcomes.

Public and Member Comment

Comments included:

• A commenter was concerned that the measure only assesses standard practice that should be occurring routinely.

Developer Response:

Cancer stage is key to the implementation of therapeutic interventions demonstrated to improve survival and decrease the risk
of recurrence. The documentation of cancer stage is therefore critical as it provides a means by which this information can
readily be communicated to others, to assist in therapeutic decisions, and to help estimate prognosis. Unfortunately, as
indicated by performance rates for this measure and medical literature on the topic, adherence remains suboptimal
demonstrating a significant opportunity to improve the care provided to cancer patients.

Steering Committee Response:

• The Steering Committee agrees with the developer's response, which is in line with discussions that occurred at the in-person meeting and on related conference calls.

1854 Barrett's Esophagus (Eligible for Time-Limited Endorsement)

New Measure

Measure Evaluation and Specifications

Description: Percentage of patients with esophageal biopsy reports for Barrett's esophagus that contain a statement about dysplasia. **Numerator Statement:** Numerator: Esophageal biopsy reports with the histologic finding of Barrett's mucosa that contain a statement about dysplasia (present, absent, or indefinite; and if present, contains appropriate grading.)

3125F Esophageal biopsy report with a statement about dysplasia (present, absent, or indefinite)

Denominator Statement: Denominator (Eligible Population): All esophageal biopsy reports that document the presence of Barrett's mucosa.
1854 Barrett's Esophagus (Eligible for Time-Limited Endorsement)
CPT codes:
88305 Level IV – Surgical pathology, gross and microscopic examination
AND
ICD-9 codes:
530.85 Barrett's esophagus
Exclusions: Documentation of medical reason for not reporting the histologic finding of Barrett's mucosa (eg, malignant neoplasm or
absence of intestinal metaplasia).
Adjustment/Stratification: No risk adjustment or risk stratification Not applicable Not applicable
Level of Analysis: Clinician : Group/Practice, Clinician : Individual
Type of Measure: Process
Data Source: Administrative claims, Other, Paper Records
Measure Steward: College of American Pathologists
Steering Committee In-Person March 13-14, 2012
1. Importance to Measure and Report: The measure meets the Importance criteria.
(1a. High Impact; 1b. Performance Gap; 1c. Evidence)
1a. Impact: H-6; M-10; L-1; I-0; 1b. Performance Gap: H-2; M-12; L-1; I-2; 1c. Evidence: Y-11, N-2, I-4
Rationale:
A clear link between Barrett's Esophagus and esophageal adenocarcinoma was demonstrated. Identifying those at risk could
allow for appropriate screening of high risk patients.
This measure will have a substantial impact for a smaller patient population (those diagnosed with Barrett's Esophagus).
2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability requirement for untested
measures.
(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)
Precise Specifications: Y-16; N-1
Rationale:
 The measure is well specified; however, the Steering Committee noted the importance of reporting not only the presence or
absence of dysplasia, but also the grade of dyplasia. The measure developer addressed this recommendation and modified the
numerator.
 Plans for reliability and validity testing are in process.
3. Usability: <u>H-3; M-14; L-0; I-0</u>
(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)
Rationale:
 The measure has been included in the 2012 PQRS program with plans to publicly report performance results.
4. Feasibility: <u>H-8; M-9; L-0; I-0</u>
(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences
identified 4d. Data collection strategy can be implemented)
Rationale:
 The data elements are generated during patient care; the measure should be feasible to implement.
Stearing Committee Decommondation for Time Limited Endorcements V 1E, N 2
Steering Committee Recommendation for Time-Limited Endorsement: Y-15; N-2 <u>Rationale:</u> The Steering Committee found that the intervention addressed by this measure will greatly impact the target patient
population, albeit a smaller population. The link between dysplasia in Barrett's Esophagus patients and incidence of esophageal
adenocarcinoma is well substantiated.
RECOMMENDATIONS: The Steering Committee asked the developer to require reporting of the grade of dysplasia (high or low) as part
of the numerator. The measure developer addressed this recommendation and provided updated the numerator to capture this
information. The Steering Committee agreed with the changes and recommended the measure for time limited endorsement.

The measure has not yet been tested for reliability and validity and is being considered for **time limited endorsement**. The measure developer will have 12 months to provide testing data if time limited endorsement is granted.

1854 Barrett's Esophagus (Eligible for Time-Limited Endorsement)

Public & Member Comment

• Commenters indicated support for the measure.

Prostate and Lung Measures

0389 Prostate Cancer: Avoidance of Overuse Measure – Bone Scan for Staging Low-Risk Patients

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of patients, regardless of age, with a diagnosis of prostate cancer, at low risk of recurrence, receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer

Numerator Statement: Patients who did not have a bone scan performed at any time since diagnosis of prostate cancer Denominator Statement: All patients, regardless of age, with a diagnosis of prostate cancer, at low risk* of recurrence, receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy Exclusions: Documentation of medical reason(s) for having a bone scan performed (including documented pain, salvage therapy, other medical reasons)

Documentation of system reason(s) for having a bone scan performed (including bone scan ordered by someone other than reporting physician)

Adjustment/Stratification: No risk adjustment or risk stratification Not applicable 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.

Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records

Measure Steward: American Medical Association - Physician Consortium for Performance Improvement Other organizations: American Urological Association and American Society for Therapeutic Radiology & Oncology

0389 Prostate Cancer: Avoidance of Overuse Measure – Bone Scan for Staging Low-Risk Patients

Steering Committee In-Person March 13-14, 2012

1. Importance to Measure and Report: The measure meets the Importance criteria.

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-8; M-8; L-0; I-0; 1b. Performance Gap: H-7; M-9; L-0; I-0; 1c. Evidence: Y-14, N-2, I-0 Rationale:

- The measure affects a high number of patients: those with low-risk prostate cancer, and the evidence presented shows the intervention is unnecessary for these patients.
- Data submitted demonstrates significant overuse of bone scans (84.31% of patients from 2008 PQRS did not meet this measure). There is an opportunity for improvement.
- 2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-9; M-6; L-1; I-0; 2b. Validity: H-7; M-8; L-1; I-0 Rationale:

- The measure is specified with ICD-9 and CPT codes that can be ascertained consistently.
- Reliability testing presented was appropriate and demonstrated reliability of the measure.
- Validity was shown using results from an expert panel, and demonstrated strong face validity.

3. Usability: H-6; M-8; L-2; I-0

(*Meaningful*, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) **<u>Rationale</u>**:

• This measure has been included in the CMS Physician Quality Reporting System (PQRS) from 2008 through 2011. The measure is also included in PQRS 2012.

0389 Prostate Cancer: Avoidance of Overuse Measure – Bone Scan for Staging Low-Risk Patients

• A plan for public reporting has been outlined by the measure developer.

4. Feasibility: <u>H-6; M-8; L-2; I-0</u>

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

• Data is generated during the provision of care and all data elements are found in an EHR.

Steering Committee Recommendation for Endorsement: Y-15; N-1

<u>Rationale</u>: The Steering Committee found that the measure addresses an intervention that is currently overused for the target patient population; improved performance on this measure will likely reduce the use of unnecessary bone scans and decrease overall costs.

Public & Member Comment

Comments included:

- Commenters indicated that the Steering Committee should consider clarifying 'low risk' status for the measure population and that classification for measurement purposes should be based on staging information available at the time of decision making regarding whether or not to order a bone scan.
- Commenters believed that the measure should clearly articulate that even those patients with a positive bone scan remain in the denominator of this measure, even though the bone scan ultimately demonstrates that they are not actually low risk.
 - Comments reflected questions on the measure specifications, specifically:
 - It is unclear how treatment interplays with this measure.
 - The numerator captures patients who did not have a 'bone scan performed prior to initiation of treatment nor at any time since diagnosis.
 - Patient eligibility for the denominator should be based on criteria known before the decision to deliver the service (the bone scan) is considered.
 - Exclusion criteria (i.e. treatment planned for future, patient preference, vulnerable health status, and poor access to care)
- Several commenters supported this measure.

Developer Response:

- The AUA/AMA-PCPI Prostate Cancer Work Group appreciates your comment. The Work Group will consider your feedback
 about the risk stratification, when the measure undergoes formal review and maintenance, according to the AMA-PCPI measure
 development/maintenance methodology, in the future. Additionally, the measure contains a medical exception, which allows
 physicians to use clinical judgment in order to have a bone scan performed on those low-risk prostate cancer patients who have
 a medical reason documented.
- The denominator was constructed so any patient that has already been stratified as a low risk patient and is being treated
 according to the low risk strata would be captured in the measure. The measure is aiming to reduce the use of bone scans that
 are clinically unnecessary, in low risk patients who generally have no indication for imaging studies. Additionally, the measure
 contains a medical exception, which allows physicians to use clinical judgment in order to have a bone scan performed on those
 low-risk prostate cancer patients who have a medical reason documented.

Steering Committee Response:

• The Steering Committee agrees with the measure developer's response. The response is in line with discussions that occurred at the in-person meeting and on related conference calls.

0390 Prostate Cancer: Adjuvant Hormonal Therapy for High-Risk Patients

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of patients, regardless of age, with a diagnosis of prostate cancer, at high risk of recurrence, receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH agonist or antagonist)

Numerator Statement: Patients who were prescribed adjuvant hormonal therapy (GnRH [gonadotropin-releasing hormone] agonist or antagonist)

0390 Prostate Cancer: Adjuvant Hormonal Therapy for High-Risk Patients
Denominator Statement: All patients, regardless of age, with a diagnosis of prostate cancer, at high risk of recurrence, receiving
external beam radiotherapy to the prostate
Note: Only patients with prostate cancer with high risk of recurrence will be counted in the denominator of this measure
Exclusions: Documentation of medical reason(s) for not prescribing adjuvant hormonal therapy (eg, salvage therapy)
Documentation of patient reason(s) for not prescribing adjuvant hormonal therapy
Adjustment/Stratification: No risk adjustment or risk stratification Not applicable 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.
Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Type of Measure: Process
Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data
: Registry, Paper Records
Measure Steward: American Medical Association - Physician Consortium for Performance Improvement Other organizations:
American Urological Association and American Society for Therapeutic Radiology & Oncology
0390 Prostate Cancer: Adjuvant Hormonal Therapy for High-Risk Patients
Steering Committee In-Person March 13-14, 2012
1. Importance to Measure and Report: <u>The measure meets the Importance criteria.</u> (1a. High Impact; 1b. Performance Gap; 1c. Evidence)
1a. Impact: H-12; M-4; L-0; I-0; Ib. Performance Gap: H-9; M-7; L-0; I-0; Ic. Evidence: Y-16, N-0, I-0
Rationale:
The measure addresses appropriateness of care for patients with high-risk prostate cancer, a prevalent condition affecting a
 The measure addresses appropriateness of care for patients with high-fisk prostate cancer, a prevalent condition anecting a large number of patients.
 The evidence provided is high level and supportive of the measure focus.
• The Steering Committee noted that the survival benefit has been better documented than the evidence submitted suggests.
 Adherence is low: 83.41% of patients from 2008 PQRS did not meet this measure; there is an opportunity for improvement. 2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.
(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)
2a. Reliability: H-7; M-8; L-1; I-0; 2b. Validity: H-4; M-11; L-1; I-0
Rationale:
The specifications are clear. The time window for reporting the measure is at each time adjuvant hormonal therapy occurs.
 The specifications are clear. The time window for reporting the measure is at cach time adjuvant hormonial therapy occurs. The Steering Committee agreed it is important that proton beam therapy is included in the denominator for this measure.

- The reliability testing presented was appropriate and demonstrated the reliability of the measure.
- Face validity was confirmed with near universal agreement from an expert panel.

3. Usability: H-11; M-4; L-1; I-0

(*Meaningful*, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) <u>**Rationale**</u>:

- This measure has been included in the PQRS from 2008 through 2011. The measure is also included in PQRS 2012.
- A plan for public reporting has been outlined by the measure developer.

4. Feasibility: <u>H-6; M-9; L-1; I-0</u>

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- Steering Committee was concerned that the low number of patients meeting the measure in 2008 PQRS may be a result of difficulties reporting the measure rather than low performance of the measure intervention. The developer agreed that as the denominator requires both ICD codes and CPT category 2 codes, it likely complicated reporting for some providers reporting on the measure. The developer expects reporting to improve as providers become more familiar with the reporting requirements.
- The information in the measure can be abstracted from EHRs.

Steering Committee Recommendation for Endorsement: Y-15; N-1

<u>Rationale</u>: The Steering Committee found that this is a prevalent condition with a level of mortality that renders it a public health priority. The measure is supported by two randomized controlled trials, bolstered by expert opinion. The measure should be able to be reliably ascertained with EHR inputs.

0390 Prostate Cancer: Adjuvant Hormonal Therapy for High-Risk Patients

Public & Member Comment

Comments included:

- For quality improvement purposes, commenters felt that the measure population should be defined more specifically in order to
 avoid use of resources to identify the denominator population; as specified it may include cases that are exceedingly rare or
 non-occurring for hospitals that care for children.
- Commenters referenced NCCN guidelines that suggest hormonal therapy for patients with advanced prostate cancer. They
 noted that the evidence for this measure is supported by a variety of articles that range from complete support to lack of efficacy
 of hormonal therapy and felt that developers need to reconsider this measure based on the variation in clinical evidence in
 support of hormonal therapy.

Developer Response:

- The AUA/AMA-PCPI Prostate Cancer Work Group appreciates your comment. The Work Group will reconsider the measure population, when the measure undergoes formal review and maintenance, according to the AMA-PCPI measure development/maintenance methodology, in the future.
- The PQRS data included in the measure submission and the medical literature clearly indicate a remaining performance gap, with respect to adjuvant hormonal therapy in high risk prostate cancer patients. Therefore, the measure is still being put forth for accountability and quality improvement. Additionally, both the AUA and NCCN guidelines recommend adjuvant hormonal therapy with radiotherapy for high risk prostate cancer patients, for prolonged survival.

Steering Committee Response:

• The Steering Committee agrees with the measure developer's response. The response is in line with discussions that occurred at the in-person meeting and on related conference calls.

1790 Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer

New Measure

Measure Evaluation and Specifications

Description: Percentage of patients \geq 18 years of age undergoing elective lung resection (Open or VATS wedge resection, segmentectomy, lobectomy, bilobectomy, sleeve lobectomy, pneumonectomy) for lung cancer who developed any of the following postoperative complications: reintubation, need for tracheostomy, initial ventilator support > 48 hours, ARDS, pneumonia, pulmonary embolus, bronchopleural fistula, bleeding requiring reoperation, myocardial infarction or operative mortality.

Numerator Statement: Number of patients \geq 18 years of age undergoing elective lung resection for lung cancer who developed any of the following postoperative complications: reintubation, need for tracheostomy, initial ventilator support > 48 hours, ARDS, pneumonia, pulmonary embolus, bronchopleural fistula, bleeding requiring reoperation, myocardial infarction or operative mortality.

Denominator Statement: Number of patients \geq 18 years of age undergoing elective lung resection for lung cancer.

Exclusions: Emergency procedures

Adjustment/Stratification: Statistical risk model Bayesian hierarchical modeling was used to assess the statistical reliability of hospitalspecific standardized incidence ratio (SIR) estimates derived from the January 1, 2008 – December 31, 2010 STS data. All hospitals regardless of sample size were included in the estimation of model parameters. Reliability measures were initially calculated including all the hospitals and were subsequently calculated in subsets of hospitals having at least 10, 20, 30, 50, 100, or 200 eligible cases.

Three separate multivariable risk models were constructed (mortality, major morbidity, and composite mortality or major morbidity). The risk-adjustment models created for this measure and study have excellent performance characteristics and identify important predictors of mortality and major morbidity for lung cancer resections. These models may be used to inform clinical decisions and to compare risk-adjusted outcomes for quality improvement purposes. For additional information see the attachment:

Kozower BD, Sheng S, O'Brien SM, Liptay MJ, Lau CL, Jones DR, Shahian DM, Wright CD. STS Database Risk Models: Predictors of Mortality and Major Morbidity for Lung Cancer Resection. Ann Thorac Surg. 2010;90:875–83. n/a

Level of Analysis: Clinician : Group/Practice, Clinician : Team, Facility

Type of Measure: Outcome

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records

1790 Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer
Measure Steward: Society of Thoracic Surgeons
1790 Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer Steering Committee In-Person March 13-14, 2012
 Importance to Measure and Report: <u>The measure meets the Importance criteria.</u> (1a. High Impact; 1b. Performance Gap; 1c. Evidence)
1a. Impact: H-17; M-0; L-0; I-0; 1b. Performance Gap: H-11; M-6; L-0; I-0; 1c. Evidence: Y-17, N-0, I-0
Rationale:
 Developer presented solid evidence for importance of the measure.
 The measure provides a good look at the spectrum of procedures done across a spectrum of hospitals, and a wide range of
morbidities/mortalities.
 Evidence was submitted demonstrating substantial variation in morbidity and mortality after lung cancer surgery.
 The measure is a first step in developing a measure capturing long term survival rates.
2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.
(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)
2a. Reliability: H-8; M-9; L-0; I-0; 2b. Validity: H-9; M-8; L-0; I-0
Rationale:
The measure is clearly defined and well specified.
Reliability of the measure was well demonstrated with a signal to noise ratio.
 Validity was demonstrated through testing, as well as having face validity assessed by an expert panel.
• The Steering Committee noted that many of these surgeries are performed by non-thoracic surgeons, a population this measure
may not capture.
3. Usability: <u>H-15; M-1; L-0; I-1</u>
(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)
Rationale:
 The developer has provided a detailed plan for representation of measure results, usability for QI, and public reporting of the
measure within the next 2-3 years.
4. Feasibility: <u>H-10; M-7; L-0; I-0</u>
(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences
identified 4d. Data collection strategy can be implemented)
Rationale:
The Steering Committee noted that this is somewhat arduous to capture, but the data add significant value
Steering Committee Recommendation for Endorsement: Y-17; N-0
Rationale: The Steering Committee found that the measure will capture the spectrum of procedures done in a spectrum of hospitals-
wide range of morbidities/mortalities. The evidence for the measure is high level, and capturing the measure will allow for development
of an outcome measure in the future.
Public & Member Comment
Commenters indicated support for the measure.
• Commenters indicated support for the measure.
1853 Radical Prostatectomy Pathology Reporting (Eligible for Time-Limited Endorsement)
New Measure

Measure Evaluation and Specifications

Description: Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.

Numerator Statement: Numerator: Radical prostatectomy pathology reports that include the pT category, the pN category, Gleason score and a statement about margin status

Report the following CPT Category II code to confirm the inclusion of the designated elements in a radical prostatectomy pathology report: 3267F –pathology report

Denominator Statement: All radical prostatectomy pathology reports

1853 Radical Prostatectomy Pathology Reporting (Eligible for Time-Limited Endorsement)
Exclusions: Documentation of medical reason for exclusion (e.g. specimen originated from other malignant neoplasms, secondary site
prostatic carcinomas, and transurethral resections of the prostate (TURP)
Adjustment/Stratification: No risk adjustment or risk stratification Not applicable Not applicable
Level of Analysis: Clinician : Group/Practice, Clinician : Individual
Type of Measure: Process
Data Source: Administrative claims, Other, Paper Records
Measure Steward: College of American Pathologists
1853 Radical Prostatectomy Pathology Reporting
Steering Committee In-Person March 13-14, 2012
1. Importance to Measure and Report: The measure meets the Importance criteria.
(1a. High Impact; 1b. Performance Gap; 1c. Evidence)
1a. Impact: H-9; M-7; L-0; I-0; 1b. Performance Gap: H-3; M-12; L-1; I-0; 1c. Evidence: Y-15, N-1, I-0
Rationale:
• The Steering Committee agreed the measure would have a high impact as a large number of men are affected by this disease;
this is a major health issue with significant mortality.
 The measure developer presented two studies that showed a performance gap of 11.6% noncompliance. The Steering
Committee agreed compliance should be 100% on the measure, and so there is an opportunity for improvement.
 The measure developer presented consistent evidence that a variation exists in pathological reporting that impacts the quality of
 The measure developer presented consistent evidence that a variation exists in pathological reporting that impacts the quality of care provided to patients.
 Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability requirement for untested</u>
<u>measures.</u> (2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)
Precise Specifications: Y-16; N-0
Rationale:
The measure is precisely specified. The Charling Committee and that this highly literate that the the theory of the measure will demonstrate a birth rate of article literate and the theory of the measure will demonstrate a birth rate of article literate and the theory of the measure will demonstrate a birth rate of article literate and the theory of the measure will demonstrate a birth rate of article literate and the theory of the measure will demonstrate a birth rate of article literate and the theory of the measure will demonstrate a birth rate of article literate and the theory of the measure will demonstrate a birth rate of article literate and the theory of the measure will demonstrate a birth rate of article literate and the state of the measure will demonstrate a birth rate of the measure will demonstra
• The Steering Committee agreed that it is highly likely that testing of the measure will demonstrate a high rate of reliability and
validity.
3. Usability: <u>H-9; M-7; L-0; I-0</u>
(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)
Rationale:
 Usability has not yet been demonstrated; however, the Steering Committee believes that the measure will be useful for QI.
 The measure is useful for public reporting: there is high interest, and there is ongoing active surveillance
4. Feasibility: <u>H-12; M-4; L-0; I-0</u>
(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences
identified 4d. Data collection strategy can be implemented)
Rationale:
 The data elements are all available and may be implemented using an EHR.
 Steering Committee members agreed that the measure will be feasible due to the availability of this information in tumor
registries and pathology reports.
Steering Committee Recommendation for Time-Limited Endorsement: Y-16; N-0
Rationale: Steering Committee noted that staging information and a Gleason score are very important for patients with prostate cancer.
There is a strong evidence base for this measure. There is a performance gap in meeting the measure and a need for improvement.
RECOMMENDATIONS: The measure has not yet been tested for reliability and validity and is being considered for time limited
endorsement. The measure developer will have 12 months to provide testing data if time limited endorsement is granted.
Public & Member Comment

• Commenters indicated support for the measure.

Palliative Measures

0210 Proportion receiving chemotherapy in the last 14 days of life

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life **Numerator Statement:** Patients who died from cancer and received chemotherapy in the last 14 days of life

Denominator Statement: Patients who died from cancer.

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification No risk adjustment or risk stratification is necessary because a) the measure is intended to be used for comparison among similar providers; unless there is a reason to believe that one providers' patients have significantly different risks than others, it will not affect relative comparisons, and b) comorbidity risks will if anything decrease the likelihood of experiencing this process of care. None

Level of Analysis: Clinician : Group/Practice, Facility, Health Plan, Integrated Delivery System, Population : County or City, Population : National, Population : Regional, Population : State

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Pharmacy, Electronic Clinical Data : Registry, Management Data, Paper Records

Measure Steward: American Society of Clinical Oncology

Steering Committee In-Person March 13-14, 2012

1. Importance to Measure and Report: The measure meets the Importance criteria.

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-12; M-4; L-0; I-1; 1b. Performance Gap: H-9; M-8; L-0; I-0; 1c. Evidence: Y-13, N-3, I-1 Rationale:

- The measure affects a large number of patients and will have a high impact.
- The Steering Committee noted that in some cases it is appropriate for a patient to receive chemotherapy in the last 14 days of life. The measure is useful for detecting variation in performance and identifying outliers when comparing similar practices with similar patient populations.
- The measure is important because it addresses patient preferences and over-treatment at the end of life.
- The struggle between aggressive care and futile care often plays out in the amount of chemotherapy delivered to patients with advanced disease and poor performance status.
- The measure also reflects disparities in access to care and the capacity of a local healthcare system to treat patients appropriately at the end of life.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria.</u>

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-9; M-6; L-2; I-0; 2b. Validity: H-4; M-9; L-3; I-1 Rationale:

- Steering Committee members agreed that the measure was well specified.
- The Steering Committee members raised concerns about how case mix would be accounted for in the measure. The also questioned whether facilities with a high number of patients enrolled in clinical trials would skew the measure results, so that those facilities would appear not to do as well on the measure. It was explained that the measure is intended for use in comparing like facilities, such as major cancer centers to other major cancer centers, where the case mix would be expected to be very similar.
- The reliability testing presented for the measure is appropriate and demonstrates the reliability of the measure.
- Face validity of the measure was demonstrated.

3. Usability: <u>H-6; M-7; L-2; I-2</u>

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) **Rationale**:

- The Steering Committee agreed the measure is useful for QI, particularly when comparing facilities with similar patient populations to see if there are irregularities in achieving the measure.
- The measure is easily understandable for public reporting.
- The measure is currently in use in ASCO's QOPI program.

4. Feasibility: <u>H-7; M-6; L-2; I-2</u>

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences

0210 Proportion receiving chemotherapy in the last 14 days of life

identified 4d. Data collection strategy can be implemented) **Rationale:**

• The measure is reported using claims data and is feasible to implement.

Steering Committee Recommendation for Endorsement: Y-15; N-2

<u>Rationale</u>: The Steering Committee found that the measure is important because it addresses patient preferences and over-treatment at the end of life.

Public & Member Comment

Comments included:

- Commenters noted that while overtreatment of terminally ill patients is an important area for study and measurement, there are concerns that the measures imply that patients receiving such treatments as chemotherapy in the last 14 days of life, or patients with more than one ER visit in the last days of life, are receiving poor care.
- The commenters expressed concern that grouping all patient populations together in these measures results in patients who are appropriately receiving said treatments being counted in the numerator against the reporting facility.
- Further, commenters indicated that prognostication of death is limited; in addition to being unable to determine accurately in
 advance a patient's expected death, the measures do not distinguish between patients who were terminally ill and those who
 died suddenly.
- Commenters also indicated that it was unclear by the description provided how the measure of chemotherapy received in the last 14 days of life would 'reflect disparities in access to care.' Commenters felt, that for palliative care, measuring disparities in its access should be evaluated more directly than through assessing chemotherapy use for terminally ill patients and suggested that terminally ill patients receiving chemotherapy may have greater access to medical care in general.
- Several comments supported the use of these measures in order to reduce inappropriate end-of-life care.

Developer Response:

- The measures are not intended to imply that any single incidence of these care processes is wrong, but rather to identify consistently outlying practice which could raise a 'red flag' about either practice style (not having realistic discussions about the end-of-life in a timely fashion) or access to palliative or hospice care (lack of access has been consistently shown to be associated with more acute and aggressive care near the end of life). Lastly, while it is true that prognostication is difficult, if a provider's practice is an outlier because they are particularly poor at prognostication, which may be a problem as well.
- Identifying the end of life phase prospectively in administrative data is challenging as the definition always creates a biased sub cohort (a particular stage at diagnosis, using particular services, etc.).
- Users may make adjustments to the numerator and denominator definitions as they see fit.
- The access issue is that these measures of potentially aggressive care near the end of life are associated with less availability of hospice.

Steering Committee Response:

- These issues were discussed extensively during the Cancer Steering Committee in-person meeting. In that discussion, the
 measure developer noted that at times the interventions can and should occur for many patients. The measures are intended to
 compare similar providers who have similar patient mixes and identify outlying patterns of care. Consequently, relative incidence
 of the situations should be similar. For example, grouping patients receiving palliative chemotherapies at the end of life with
 those receiving curative chemotherapies should not result in markedly different performance rates between two facilities with a
 similar case mix. This reasoning may also be applied to grouping patients who are terminally ill and those who died suddenly.
- Further, the Steering Committee respectfully disagreed with the statement that prognostication of death is limited, and believed that taking this stance would severely limit measures of this type, which are very important quality indicators for patient preference and the availability of resources at the end of life.
- The Steering Committee also noted that though there are a limited number of studies, it has been demonstrated that patients
 who receive palliative care earlier have lower rates of chemotherapy at the end of life, lending credence to the importance of
 palliative interventions in reducing overtreatment.

0211 Proportion with more than one emergency room visit in the last days of life

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of patients who died from cancer with more than one emergency room visit in the last days of life **Numerator Statement**: Patients who died from cancer and had >1 ER visit in the last 30 days of life

Denominator Statement: Patients who died from cancer.

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification No risk adjustment or risk stratification is necessary because the measure is intended to be used for comparison among similar providers; unless there is a reason to believe that one providers' patients have significantly different risks than others, it will not affect relative comparisons. Since, however, comorbidity risks coule increase the likelihood of experiencing this process of care, stratification or adjustment as described above can be considered.

No risk adjustment is necessary. The Deyo modification of the Charlson score can be applied to claims as this measure may be sensitive to comorbidity, omitting 'Cancer' as a comorbid condition in the calcluation, and used as an independent variable in a regression model to predict an adjusted rate. No stratification was used in the measure's development or evaluation, however, it would be reasonable to apply the Deyo modification of the Charlson score (Deyo RA, Cherkin DC, Ciol MA: Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases. J Clin Epidemiol 45:613-619, 1992)to claims and stratifying for comorbidities, e.g., scores of 0, 1, or 2+.

Level of Analysis: Clinician : Group/Practice, Facility, Health Plan, Integrated Delivery System, Population : County or City, Population : National, Population : Regional, Population : State

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Management Data, Paper Records

Measure Steward: American Society of Clinical Oncology

Steering Committee In-Person March 13-14, 2012

1. Importance to Measure and Report: <u>The measure meets the Importance criteria.</u>

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-10; M-4; L-1; I-1; 1b. Performance Gap: H-10; M-3; L-3; I-0; 1c. Evidence: Y-11, N-3, I-2 Rationale:

- The Steering Committee agreed the measure affects a large number of patients and is high impact.
- In most cases, overutilization of emergency department services for the actively dying is inappropriate and distressing for patients.
- The Steering Committee noted that in some cases more than one visit to the ER during the last days of life is appropriate. The measure is useful for detecting variations in performance and identifying outliers when comparing similar practices with similar patient populations.
- The measure is important because it addresses patient preferences and overtreatment at the end of life.
- The measure also reflects disparities in access to care and the capacity of a local healthcare system to treat patients appropriately at the end of life.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity) 2a. Reliability: H-7; M-3; L-5; I-1; 2b. Validity: H-5; M-5; L-5; I-1

Rationale:

- Steering Committee members raised concerns about use of the measure given the current systemic issues with access to
 quality hospice facilities. The Committee believed patients may utilize emergency department services when good hospice care
 is not available. In areas where performance of the measure is poor, it will call attention to a lack of resources available for
 patients at the end of life.
- The measure is well specified.
- The reliability testing presented for the measure is appropriate and demonstrates the reliability of the measure.
- Face validity of the measure is demonstrated.

3. Usability: <u>H-5; M-4; L-6; I-1</u>

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) **<u>Rationale</u>**:

• The measure is usable for public reporting, as it captures the preference of patients to die in a setting other than the emergency

0211 Proportion with more than one emergency room visit in the last days of life

department, or to avoid distressing ER visits at the end of life.

- The measure is useful for QI, particularly when comparing facilities with similar patient populations to see if there are irregularities in achieving the measure.
- The measure is in use in Cancer Care Ontario's Cancer System Quality Index.

4. Feasibility: <u>H-6; M-7; L-3; I-1</u>

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

The measure is reported using claims data and is feasible to implement.

Steering Committee Recommendation for Endorsement: Y-10; N-6

<u>Rationale</u>: The Steering Committee found that the measure is important because it addresses patient preferences and overtreatment at the end of life.

Public & Member Comment

Comments included:

- Commenters noted that while overtreatment of terminally ill patients is an important area for study and measurement, there are concerns that the measures imply that patients receiving such treatments as chemotherapy in the last 14 days of life, or patients with more than one ER visit in the last days of life, are receiving poor care.
- The commenters expressed concern that grouping all patient populations together in these measures results in patients who are appropriately receiving said treatments being counted in the numerator against the reporting facility.
- Further, commenters indicated that prognostication of death is limited; in addition to being unable to determine accurately in advance a patient's expected death, the measures do not distinguish between patients who were terminally ill and those who died suddenly.
- For the measures of chemotherapy, ER and ICU use in the last days before death, eligibility for the denominator is defined as 'patients who died from cancer.' All types and stages of cancer are combined, ranging from those that are highly treatable to those that are functionally incurable. At the extremes, the measure makes no distinction between a patient who has a benign skin condition (code 216) and a patient with pancreatic cancer (code 157). If interested in capturing service utilization for terminally ill patients, the measures should focus on pre-specified patient populations with poor prognosis.
- Several comments supported the use of these measures in order to reduce inappropriate end-of-life care and patient-centered care.

Developer Response:

- The measures are not intended to imply that any single incidence of these care processes is wrong, but rather to identify consistently outlying practice which could raise a 'red flag' about either practice style (not having realistic discussions about the end-of-life in a timely fashion) or access to palliative or hospice care (lack of access has been consistently shown to be associated with more acute and aggressive care near the end of life). Lastly, while it is true that prognostication is difficult, if a provider's practice is an outlier because they are particularly poor at prognostication, which may be a problem as well.
- Identifying the end of life phase prospectively in administrative data is challenging as the definition always creates a biased sub cohort (a particular stage at diagnosis, using particular services, etc.).
- Users may make adjustments to the numerator and denominator definitions as they see fit.
- The access issue is that these measures of potentially aggressive care near the end of life are associated with less availability of hospice.

Steering Committee Response:

- These issues were discussed extensively during the Cancer Steering Committee in-person meeting. In that discussion, the
 measure developer noted that at times the interventions can and should occur for many patients. The measures are intended to
 compare similar providers who have similar patient mixes and identify outlying patterns of care. Consequently, relative incidence
 of the situations should be similar. For example, grouping patients receiving palliative chemotherapies at the end of life with
 those receiving curative chemotherapies should not result in markedly different performance rates between two facilities with a
 similar case mix. This reasoning may also be applied to grouping patients who are terminally ill and those who died suddenly.
- Further, the Steering Committee respectfully disagreed with the statement that prognostication of death is limited, and believed

0211 Proportion with more than one emergency room visit in the last days of life

that taking this stance would severely limit measures of this type, which are very important quality indicators for patient preference and the availability of resources at the end of life.

• The Steering Committee also noted that though there are a limited number of studies, it has been demonstrated that patients who receive palliative care earlier have lower rates of chemotherapy at the end of life, lending credence to the importance of palliative interventions in reducing overtreatment.

0213 Proportion admitted to the ICU in the last 30 days of life

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life

Numerator Statement: Patients who died from cancer and were admitted to the ICU in the last 30 days of life

Denominator Statement: Patients who died from cancer.

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification No risk adjustment or risk stratification is necessary because the measure is intended to be used for comparison among similar providers; unless there is a reason to believe that one providers' patients have significantly different risks than others, it will not affect relative comparisons. Since, however, comorbidity risks coule increase the likelihood of experiencing this process of care, stratification or adjustment as described above can be considered.

The Deyo modification of the Charlson score can be applied to claims as this measure may be sensitive to comorbidity, omitting 'Cancer' as a comorbid condition in the calcluation, and used as an independent variable in a regression model to predict an adjusted rate. No stratification was used in the measure's development or evaluation, however, it would be reasonable to apply the Deyo modification of the Charlson score (Deyo RA, Cherkin DC, Ciol MA: Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases. J Clin Epidemiol 45:613-619, 1992)to claims and stratifying for comorbidities, e.g., scores of 0, 1, or 2+.

Level of Analysis: Clinician : Group/Practice, Facility, Health Plan, Integrated Delivery System, Population : County or City, Population : National, Population : Regional, Population : State

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Management Data, Paper Records

Measure Steward: American Society of Clinical Oncology

Steering Committee In-Person March 13-14, 2012

1. Importance to Measure and Report: The measure meets the Importance criteria.

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-14; M-2; L-0; I-0; 1b. Performance Gap: H-8; M-8; L-0; I-0; 1c. Evidence: Y-16, N-0, I-0

Rationale:

- The Steering Committee agreed the measure affects a large number of patients and will have a high impact.
- Patients overwhelmingly would prefer to not die in the ICU; it is distressing for the patient and the patient's family.
- The Steering Committee noted that in some cases occurrence of this event is appropriate. The measure is useful for detecting variation in performance and identifying outliers when comparing similar practices with similar patient populations.
- The measure is important because it addresses patient preferences and over-treatment at the end of life.
- The measure also reflects disparities in access to care and the capacity of a local healthcare system to treat patients appropriately at the end of life.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-12; M-4; L-0; I-0; 2b. Validity: H-11; M-5; L-0; I-0

Rationale:

- Steering Committee members were concerned about use of the measure given current issues related to access to quality hospice facilities. Patients may utilize ICU at the end of life when quality hospice care is not available. In areas where performance of the measure is poor, it will call attention to the lack of resources available for patients at the end of life.
- The measure is well specified.
- The reliability testing presented for the measure is appropriate and demonstrates the reliability of the measure.

0213 Proportion admitted to the ICU in the last 30 days of life

• Face validity of the measure was demonstrated.

3. Usability: <u>H-9; M-7; L-0; I-0</u>

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) Rationale:

- The measure is usable for public reporting, as it captures the preference of patients to die in a setting other than the emergency department, or to avoid distressing ER visits at the end of life.
- The measure is useful for QI, particularly when comparing facilities with similar patient populations to see if there are irregularities in achieving the measure.
- The measure is in use in <u>Cancer Care Ontario's Cancer System Quality Index</u>.

4. Feasibility: <u>H-13; M-3; L-0; I-0</u>

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

• The measure is reported using claims data and is feasible to implement.

Steering Committee Recommendation for Endorsement: Y-16; N-0

<u>Rationale</u>: The Steering Committee strongly agreed that patients generally do not wish to die in the ICU and believe this intervention should be avoided if at all possible. The measure captures patient preference as well as disparities in access to quality hospice care at the end of life.

Public & Member Comment

Comments included:

- Commenters noted that while overtreatment of terminally ill patients is an important area for study and measurement, there are concerns that the measures imply that patients receiving such treatments as chemotherapy in the last 14 days of life, or patients with more than one ER visit in the last days of life, are receiving poor care.
- The commenters expressed concern that grouping all patient populations together in these measures results in patients who are appropriately receiving said treatments being counted in the numerator against the reporting facility.
- Further, commenters indicated that prognostication of death is limited; in addition to being unable to determine accurately in advance a patient's expected death, the measures do not distinguish between patients who were terminally ill and those who died suddenly.
- For the measures of chemotherapy, ER and ICU use in the last days before death, eligibility for the denominator is defined as 'patients who died from cancer.' All types and stages of cancer are combined, ranging from those that are highly treatable to those that are functionally incurable. At the extremes, the measure makes no distinction between a patient who has a benign skin condition (code 216) and a patient with pancreatic cancer (code 157). If interested in capturing service utilization for terminally ill patients, the measures should focus on pre-specified patient populations with poor prognosis.
- Several comments supported the use of these measures in order to reduce inappropriate end-of-life care and patient-centered care.

Developer Response:

- The measures are not intended to imply that any single incidence of these care processes is wrong, but rather to identify consistently outlying practice which could raise a 'red flag' about either practice style (not having realistic discussions about the end-of-life in a timely fashion) or access to palliative or hospice care (lack of access has been consistently shown to be associated with more acute and aggressive care near the end of life). Lastly, while it is true that prognostication is difficult, if a provider's practice is an outlier because they are particularly poor at prognostication, which may be a problem as well.
- Identifying the end of life phase prospectively in administrative data is challenging as the definition always creates a biased sub cohort (a particular stage at diagnosis, using particular services, etc.).
- Users may make adjustments to the numerator and denominator definitions as they see fit.
- The access issue is that these measures of potentially aggressive care near the end of life are associated with less availability of hospice.

Steering Committee Response:

0213 Proportion admitted to the ICU in the last 30 days of life

- These issues were discussed extensively during the Cancer Steering Committee in-person meeting. In that discussion, the measure developer noted that at times the interventions can and should occur for many patients. The measures are intended to compare similar providers who have similar patient mixes and identify outlying patterns of care. Consequently, relative incidence of the situations should be similar. For example, grouping patients receiving palliative chemotherapies at the end of life with those receiving curative chemotherapies should not result in markedly different performance rates between two facilities with a similar case mix. This reasoning may also be applied to grouping patients who are terminally ill and those who died suddenly.
- Further, the Steering Committee respectfully disagreed with the statement that prognostication of death is limited, and believed that taking this stance would severely limit measures of this type, which are very important quality indicators for patient preference and the availability of resources at the end of life.
- The Steering Committee also noted that though there are a limited number of studies, it has been demonstrated that patients
 who receive palliative care earlier have lower rates of chemotherapy at the end of life, lending credence to the importance of
 palliative interventions in reducing overtreatment.

0215 Proportion not admitted to hospice

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of patients who died from cancer not admitted to hospice

Numerator Statement: Patients who died from cancer without being admitted to hospice

Denominator Statement: Patients who died from cancer.

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification. No risk adjustment or risk stratification is necessary because a) the measure is intended to be used for comparison among similar providers; unless there is a reason to believe that one providers' patients have significantly different risks than others, it will not affect relative comparisons, and b) comorbidity risks will if anything decrease the likelihood of experiencing this process of care. None

Level of Analysis: Clinician : Group/Practice, Facility, Health Plan, Integrated Delivery System, Population : County or City, Population : National, Population : Regional, Population : State

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Management Data, Paper Records

Measure Steward: American Society of Clinical Oncology

Steering Committee In-Person March 13-14, 2012

1. Importance to Measure and Report: The measure meets the Importance criteria.

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-10; M-3; L-2; I-1; 1b. Performance Gap: H-9; M-5; L-1; I-2; 1c. Evidence: Y-10, N-2, I-5 Rationale:

• The Steering Committee agreed the measure affects a large number of patients and has a high impact.

- Many cancer patients die in a hospital receiving futile care until the end. Referring patients to hospice, when appropriate, addresses patient preferences, improves quality of care, and reduces cost of care.
- The Steering Committee noted that poor performance on the measure would indicate that providers may be failing to have direct conversations with patients about the futility of further treatment and the benefits of hospice care.
- The Committee agreed the measure developer provided good evidence to support that hospice referral would mean increased quality of care.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.

(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)

2a. Reliability: H-4; M-9; L-3; I-1; 2b. Validity: H-6; M-7; L-3; I-1

Rationale:

- The measure is well specified.
- The reliability testing presented for the measure is appropriate and demonstrates the reliability of the measure.
- Face validity of the measure is demonstrated.

3. Usability: <u>H-6; M-5; L-3; I-3</u>

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) Rationale:

- The measure is usable for public reporting, as it captures the use of hospice for appropriate patients.
- The measure is useful for QI, particularly when comparing facilities with similar patient populations to see if there are irregularities in achieving this measure.
- The measure is in use through ASCO's QOPI program.

4. Feasibility: <u>H-6; M-8; L-2; I-1</u>

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- The measure is reported using claims data and is feasible to implement.
- Steering Committee members noted that this measure—in conjunction with measure #0216: Proportion admitted to hospice for less than 3 days—would prevent providers from making patient care decisions about sending patients to hospice based on measure performance.

Steering Committee Recommendation for Endorsement: Y-11; N-6

<u>Rationale</u>: The Steering Committee noted that the measure affects a large patient population and will help identify when facilities are providing overly aggressive, futile care to patients rather than referring patients to hospice.

<u>RECOMMENDATIONS</u>: Steering Committee members recommended that the developer consider stratifying patients with hematologic cancers, as the patient population is different from most other cancer patient populations and their responsiveness to therapies varies.

Public & Member Comment

• Commenters indicated support for the measure.

0216 Proportion admitted to hospice for less than 3 days

Maintenance Measure

Measure Evaluation and Specifications

Description: Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there

Numerator Statement: Patients who died from cancer and spent fewer than three days in hospice.

Denominator Statement: Patients who died from cancer who were admitted to hospice

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification No risk adjustment or risk stratification is necessary because a) the measure is intended to be used for comparison among similar providers; unless there is a reason to believe that one providers' patients have significantly different risks than others, it will not affect relative comparisons, and b) comorbidity risks will if anything decrease the likelihood of experiencing this process of care. None

Level of Analysis: Clinician : Group/Practice, Facility, Health Plan, Integrated Delivery System, Population : County or City, Population : National, Population : Regional, Population : State

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Management Data, Paper Records

Measure Steward: American Society of Clinical Oncology

Workgroup Preliminary Evaluations

1. Importance to Measure and Report: The measure meets the Importance criteria.

(1a. High Impact; 1b. Performance Gap; 1c. Evidence)

1a. Impact: H-14; M-3; L-0; I-0; 1b. Performance Gap: H-13; M-3; L-1; I-0; 1c. Evidence: Y-16, N-1, I-0 Rationale:

- It is well documented that short lengths of stay in hospice compromises patients' quality of care and that there is a subsantial portion of hospice patients that are referred within 1-3 days of death.
- The measure affects a large number of patients and is high impact.
- Many cancer patients die in a hospital receiving futile care until the end. Referring patients to hospice, when appropriate,

0216 Proportion admitted to hospice for less than 3 days

addresses patient preferences, improves quality of care, and reduces health care costs.

- The Steering Committee noted that poor performance on this measure would indicate that providers are failing to have direct conversations with their patients about the futility of further treatment and the benefits of hospice care.
- The committee felt the measure developer provided good evidence to support that the concept that hospice referral would mean increased quality of care.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: H-14; M-3; L-1; I-0; 2b. Validity: H-13; M-4; L-0; I-0

Rationale:

- Steering Committee members questioned why three days was selected as the numerator. The developer noted that three days is the minimum lowest bar; seven days may be a better indicator of quality of care. Also, data was more easily obtained with the three day threshold than the seven day threshold.
- The measure is well specified.
- The reliability testing for the measure is appropriate and demonstrates the reliability of the measure.
- Face validity of the measure was demonstrated.

3. Usability: <u>H-11; M-6; L-0; I-0</u>

(*Meaningful*, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement) **<u>Rationale</u>**:

- The measure is usable for public reporting, as it captures the use of hospice for appropriate patients.
- The measure is useful for QI, particularly when comparing facilities with similar patient populations to see if there are irregularities in achieving this measure.
- The measure is in use through ASCO's QOPI program.

4. Feasibility: <u>H-12; M-5; L-0; I-0</u>

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- The measure is reported using claims data and is feasible to implement.
- Steering Committee members noted that this measure in conjunction with measure #0215 would prevent providers from not sending patients to hospice because of the fear that the patient would die in the next 3 days and prevents providers from making patient care decisions about sending patients to hospice based on measure performance.

Steering Committee Recommendation for Endorsement: Y-17; N-0

<u>Rationale</u>: The Steering Committee found that the measure affects a large patient population and will help identify when facilities are providing overly aggressive, futile care to patients rather than referring them to hospice.

Public & Member Comment

• Commenters indicated support for the measure.

1822 External Beam Radiotherapy for Bone Metastases

New Measure

Measure Evaluation and Specifications

Description: This measure reports the percentage of patients, regardless of age, with a diagnosis of painful bone metastases and no history of previous radiation who receive external beam radiation therapy (EBRT) with an acceptable fractionation scheme as defined by the guideline.

Numerator Statement: All patients, regardless of age, with painful bone metastases, and no previous radiation to the same anatomic site who receive EBRT with any of the following recommended fractionation schemes: 30Gy/10fxns, 24Gy/6fxns, 20Gy/5fxns, 8Gy/1fxn. Denominator Statement: All patients with painful bone metastases and no previous radiation to the same anatomic site who receive EBRT

Exclusions: The medical reasons for denominator exclusions are:

1) Previous radiation treatment to the same anatomic site;

2) Patients with femoral axis cortical involvement greater than 3 cm in length;

1822 External Beam Radiotherapy for Bone Metastases
3) Patients who have undergone a surgical stabilization procedure; and
4) Patients with spinal cord compression, cauda equina compression or radicular pain
Adjustment/Stratification: No risk adjustment or risk stratification. Not applicable Stratification of the measure is not required.
Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Facility, Health Plan
Type of Measure: Process
Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Records
Measure Steward: American Society for Radiation Oncology (ASTRO) Other organizations: None
Steering Committee In-Person March 13-14, 2012
1. Importance to Measure and Report: The measure meets the Importance criteria.
(1a. High Impact; 1b. Performance Gap; 1c. Evidence)
1a. Impact: H-15; M-1; L-0; I-0; 1b. Performance Gap: H-13; M-3; L-0; I-0; 1c. Evidence: Y-16, N-0, I-0
Rationale:
The measure has high impact. There is a birth approximate with people a 200/ performance can noted.
There is a high opportunity for improvement, with nearly a 20% performance gap noted.
The measure represents quality care.
There is a strong supportive evidence base for this intervention.
2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria.
(2a. Reliability – precise specifications, testing; 2b. Validity – testing, threats to validity)
2a. Reliability: H-13; M-3; L-0; I-0; 2b. Validity: H-11 ; M-5 ; L-0 ; I-0
Rationale:
The measure is well specified and exclusions are appropriate, except the patient reason exclusions. The Steering Committee
asked the developer to remove those exclusions, and the developer agreed to do so.
 The reliability testing for the measure is appropriate and demonstrates the reliability of the measure.
Face validity of the measure was demonstrated.
3. Usability: <u>H-13; M-3; L-0; I-0</u>
(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)
Rationale:
• The developer has provided a detailed plan for representation of measure results, usability for QI, and public reporting of the
measure through PQRS.
4. Feasibility: <u>H-14; M-2; L-0; I-0</u>
(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences
identified 4d. Data collection strategy can be implemented)
Rationale:
Data elements are in EHR and generated during the provision of care.
Steering Committee Recommendation for Endorsement: Y-16; N-0
Rationale: The Steering Committee stated that this measure represents good care with a strong evidence base supporting the focus of
the measure. The patients affected by this measure suffer from severe pain and the intervention will help alleviate their discomfort.
the measure. The patients anected by this measure surfer norm severe pair and the intervention will help alleviate their discornion.
RECOMMENDATIONS: The Steering Committee asked the developer to remove the patient reason exclusions from the measure
denominator. The developer agreed to do so, and the Steering Committee reviewed the changes on a follow up call. The Committee
agreed with the changes and recommended the measure for endorsement.
agreed with the changes and recommended the measure for chaotsement.
Public & Member Comment
While commenters indicated general support for the measure, several issues were raised including the burden of data collection
data on whether a case meets exclusion criteria, and patient preference for other types of treatment.

Developer Response:

ASTRO appreciates your comments and support for the measure. The clinical practice guideline has identified specific exclusion criteria for patients that can receive fractionation schedules other than what is recommended and specified in the measure. Considering that the goal of the measure is to assess appropriate use and prevent overuse of treatment, it is important that the specific exclusions are outlined in the measure specifications. The measure, including its exclusions, was tested for feasibility of

1822 External Beam Radiotherapy for Bone Metastases

data collection and the measure was abstracted without difficulty at the testing sites. The following data sources have been identified for the measure exclusions: 1) Previous radiation treatment to the same anatomic site (Medical Record); Patients with femoral axis cortical involvement greater than 3 cm in length(Imaging Studies); Patients who have undergone a surgical stabilization procedure (Operative Report); Patients with spinal cord compression, cauda equina compression or radicular pain (Diagnosis/Problem list).

- We do recognize that this measure is currently not in use in any quality reporting or public reporting programs. However, ASTRO intends to submit the measure for the upcoming CMS's call for measures for potential inclusion in the proposed set of quality measures in the Physician Quality Reporting System for future rule-making years.
- The measure is specified such that the denominator includes only those patients who have consented to radiation therapy and who are receiving External Beam Radiation Therapy for bone metastases; informed consent includes the risks and benefits of the procedure.

Steering Committee Response:

• The Steering Committee agrees with the measure developer's response. The response is in line with discussions that occurred at the in-person meeting and on related conference calls.