



June 5, 2019

**To:** Consensus Standards Approval Committee (CSAC)  
**From:** Cancer Project Team  
**Re:** Cancer, Fall 2018 Measure Review Cycle

### CSAC Action Required

The CSAC will review recommendations from the Cancer Standing Committee at its June 5-6, 2019 meeting and vote on whether to uphold the recommendations from the Committee.

This memo includes a summary of the project, measure recommendations, themes identified and responses to the public and member comments and the results from the NQF member expression of support. The following documents accompany this memo:

1. **Cancer, Fall 2018 Draft Report.** The draft report has been updated to reflect the changes made following the Standing Committee's discussion of public and member comments. The complete draft report and supplemental materials are available on the project webpage.
2. [Comment Table](#). This table lists one comment received during the post-meeting comment period and the NQF/Standing Committee responses.

### Background

Cancer care is complex and provided in multiple settings—hospitals, outpatient clinics, ambulatory infusion centers, radiation oncology treatment centers, radiology departments, palliative and hospice care facilities—and by multiple providers including surgeons, oncologists, nurses, pain management specialists, and social workers. Due to the complexity of cancer, as well as the numerous care settings and providers, there is a need for quality measures that address the value and efficiency of care for patients and their families.

The 20-member [Cancer Standing Committee](#) oversees NQF's Cancer portfolio of 26 measures that includes measures for breast cancer, colon cancer, hematology, prostate cancer, and other general cancer measures.

### Draft Report

The Cancer fall 2018 draft report presents the results of the evaluation of three measures considered under the Consensus Development Process (CDP). Two measures are recommended for endorsement, and one measure is not recommended.

The measures were evaluated against the 2018 version of the [measure evaluation criteria](#).

	Maintenance	New	Total
Measures under consideration	1	2	3
Measures recommended for endorsement	1	1	2
Measures not recommended for endorsement	0	1	1
Reasons for not recommending		Importance - X Scientific Acceptability - 1 Use - X Overall - X Competing Measure – X	

## CSAC Action Required

Pursuant to the CDP, the CSAC is asked to consider endorsement of two candidate consensus measures.

### Measures Recommended for Endorsement

- [0384 Oncology: Medical and Radiation – Pain Intensity Quantified](#) (PCPI Foundation)

Overall Suitability for Endorsement: Yes-15; No-0

- [3490 Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy](#) (Centers for Medicare & Medicaid Services)

Overall Suitability for Endorsement: Yes-11; No-3

### Measure Not Recommended for Endorsement

(See [Appendix B](#) for the Committee’s votes and rationale)

- 3365e Treatment of Osteopenia or Osteoporosis in Men with Non-Metastatic Prostate Cancer on Androgen Deprivation Therapy (ADT) (Large Urology Group Practice Association)

## Comments and Their Disposition

NQF received one comment from one member organization pertaining to the draft report and to the measures under consideration.

A table of comments submitted during the comment period, with the responses to each comment and the actions taken by the Standing Committee and measure developers, is posted to the Cancer [project webpage](#).

## Comment Themes and Committee Responses

The comment about specific measure specifications and rationale was forwarded to the developers, who were invited to respond.

### *Measure-Specific Comment*

#### **0384 Oncology: Medical and Radiation—Pain Intensity Quantified (PCPI Foundation)**

The commenter supported the Committee’s recommendation for continued endorsement; however, the commenter asked if immunotherapy agents are included in the denominator. While patients may be treated with both chemotherapy and immunotherapy, some patients may be treated with just immunotherapy. In such cases, this measure fails to capture pain management for patients undergoing immunotherapy cancer treatment only.

#### **Developer Response**

Thank you for your comment. The PCPI’s Oncology Technical Expert Panel has reviewed the issue of expanding the measure denominator to include other therapies (e.g., immunotherapy) and recommended that we pursue the modification for future years. The PCPI is in the process of exploring the addition of other appropriate therapies and the implications for measure testing and implementation.

## Member Expression of Support

Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support (“support” or “do not support”) for each measure submitted for endorsement consideration to inform the Committee’s recommendations. Two NQF members provided their expression of support. [Appendix C](#) details the expression of support.

## Removal of NQF Endorsement

Three measures previously endorsed by NQF have not been re-submitted, and endorsement has been removed.

Measure	Measure Description	Reason for Removal of Endorsement
0391 Breast Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade	Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade	Developer deemed this measure “topped out.”

Measure	Measure Description	Reason for Removal of Endorsement
0392 Colorectal Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade	Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade	Developer deemed this measure “topped out.”
1855 Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines	Percentage of patients with quantitative breast tumor HER2 IHC evaluation using the ASCO/CAP recommended manual system or a computer-assisted system consistent with the optimal algorithm for HER2 testing as described in the current ASCO/CAP guidelines	Developer deemed this measure “topped out.”

## Appendix A: CSAC Checklist

The table below lists the key considerations to inform the CSAC's review of the measures submitted for endorsement consideration.

Key Consideration	Yes/No	Notes
Were there any process concerns raised during the CDP project? If so, briefly explain.	No	
Did the Standing Committee receive requests for reconsideration? If so, briefly explain.	No	
Did the Standing Committee overturn any of the Scientific Methods Panel's ratings of Scientific Acceptability? If so, state the measure and why the measure was overturned.	No	
If a recommended measure is a related and/or competing measure, was a rationale provided for the Standing Committee's recommendation? If not, briefly explain.	N/A	
Were any measurement gap areas addressed? If so, identify the areas.	No	
Are there additional concerns that require CSAC discussion? If so, briefly explain.	Yes	The Committee had a lengthy discussion about the quality of the evidence that demonstrates documenting pain leads to improved patient outcomes. Some Committee members questioned whether documenting pain intensity translated into a change in patient management. Other Committee members expressed concern about using different pain scales to quantify pain levels and the relationship to improved outcomes for cancer patients. Overall, the Committee agreed asking patients about their pain is important and likely leads to improved pain management and pain control. The Committee acknowledged that the evidence provided in the measure submission form is insufficient and does not meet current NQF Measure Evaluation Criteria for process measures. In the absence of empirical evidence demonstrating that documenting pain intensity improves patient outcomes, the Committee voted to pass the evidence criterion with an exception and determined it is beneficial to hold providers accountable for performance on this measure.

## Appendix B: Measure Not Recommended for Endorsement

The table below lists the Committee's vote and rationale for the measure not recommended for endorsement.

Legend: H = High; M = Moderate; L = Low; I = Insufficient

Measure	Voting Results	Standing Committee Rationale
3365e Treatment of Osteopenia or Osteoporosis in Men with Non-Metastatic Prostate Cancer on Androgen Deprivation Therapy (ADT) (Large Urology Group Practice Association)	<b>Evidence</b> H-0; M-15; L-0; I-2 <b>Gap</b> H-1; M-16; L-0; I-0 <b>Reliability</b> H-0; M-1; L-15; I-0 <b>Validity</b> H-0; M-1; L-15; I-0	<p>The Committee questioned the ability to capture the data elements required to calculate the measure, specifically the multiple numerator and denominator exclusions. The Committee expressed their confusion with the number and type of patients excluded from the numerator and denominator and the overall impact on the performance measure scores. The Committee encouraged the measure developer to work with Centers for Medicare and Medicaid Services (CMS) to make sure the measure's exclusions criteria and improvement notation are aligned. The Committee also questioned how exceptions rather than exclusions would affect the measure. The developer met the minimum testing requirement; however, due to a small sample size and the complexity of the measure, the Committee determined the measure does not meet the validity criterion.</p>

### Appendix C: NQF Member Expression of Support Results

Two NQF members provided their expression of support or nonsupport for two measures under consideration. Results for each measure are provided below.

#### 0384 Oncology; Medical and Radiation – Pain Intensity Quantified (PCPI Foundation)

Member Council	Support	Do Not Support	Total
Supplier/Industry	1	0	1

#### 3490 Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy (Centers for Medicare & Medicaid Services)

Member Council	Support	Do Not Support	Total
Provider Organization	0	1	1

## Appendix D: Details of Measure Evaluation

**Rating Scale:** H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

### Measures Recommended

---

#### 0384 Oncology: Medical and Radiation - Pain Intensity Quantified

##### Submission

**Description:** Percentage of patient visits, regardless of patient 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

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

**Exclusions:** None

**Adjustment/Stratification:** No risk adjustment or risk stratification. Consistent with the CMS Measures Management System Blueprint and recent national recommendations put forth by the IOM and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer.

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

**Setting of Care:** Other, Outpatient Services

**Type of Measure:** Process

**Data Source:** Registry Data

**Measure Steward:** PCPI

---

#### STANDING COMMITTEE MEETING [02/08/2019]

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

(1a. Evidence: 1b. Performance Gap)

1a. Evidence: **M-0; L-1; I-17**, Evidence Exception: **Y-18; N-0**, 1b. Performance Gap: **H-1; M-16; L-1; I-0**

##### Rationale:

- For the current evaluation, the developer provided an updated logic model tying symptom reporting and pain control to survival and overall quality of life. The developer also provided the updated 2018 National Comprehensive Cancer Network (NCCN) Clinical Practical Guidelines in Oncology-Adult Cancer Pain to support the relationship between documenting pain intensity and pain management and pain control, quality of life improvement, and survival. The NCCN assigned the evidence and recommendations associated with the 2018 guideline, a Category 2A grade. NCCN defines Category 2A guidelines as based upon lower-level evidence and there is uniform NCCN consensus that the intervention is appropriate. Per the developer's submission, the NCCN guideline does not provide a description of the body of evidence (quantity, quality, consistency).



- The Committee had a lengthy discussion about the quality of the evidence that demonstrates documenting pain leads to improved patient outcomes. Some Committee members questioned whether documenting pain intensity translated into a change in patient management. Other Committee members expressed concern about using different pain scales to quantify pain levels and the relationship to improved outcomes for cancer patients. Overall, the Committee agreed asking patients about their pain is important and likely leads to improved pain management and pain control. The Committee acknowledged that the evidence provided in the measure submission form is insufficient and does not meet current NQF Measure Evaluation Criteria for process measures. In the absence of empirical evidence demonstrating that documenting pain intensity improves patient outcomes, the Committee voted to pass the evidence criterion with an exception and determined it is beneficial to hold providers accountable for performance on this measure. The patient representatives on the Committee emphasized that asking patients about their pain is important and they value this measure.
- The developer provided 2016 Physician Quality Reporting System (PQRS) performance data from 216 physicians using the measure specifications. The PQRS performance data showed a mean of 0.88, median of 0.98, mode of 1.0, standard deviation of 0.21, and interquartile range of 0.12 (1.0 – 0.88). The developer also provided additional PQRS performance rates from 2015, 2014, and 2013. The average performance rates were 75.9%, 84.8%, and 82.7% respectively.
- The developer did not provide disparities data from the measure as specified as required for maintenance of endorsement. The developer noted that the measure is included in federal reporting programs; however, those programs have not yet made disparities data available to analyze and report. The developer provided a summary of data from the literature related to cancer treatment and the management of cancer-related pain.
- The Committee agreed a performance gap exists beyond the nearly topped out 2016 PQRS performance data provided by the measure developer. Since there is no disparities data available from the measure as specified, the Committee agreed that the data from the literature is sufficient.

---

## **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-0; I-0** 2b. Validity: **H-2; M-13; L-1; I-0**

### **Rationale:**

- The level of analysis (LoA) specified are for clinician groups and individual clinicians, and therefore two sets of testing are expected. NQF criteria states that testing must be provided for all the levels specified and intended for measure implementation. One of these LoA may have to be dropped from the specifications, unless the developer can clarify how to interpret the testing results. Additional testing may be required if they would like the measure to be endorsed for both levels of analysis. The developer explained that the 2016 PQRS registry data used to conduct the updated reliability

testing, provided by CMS, did not distinguish between clinician groups and individual clinicians; therefore, they were unable to perform two sets of testing.

- The developer noted changes to the measure specifications since the last measure update beginning with 2019 implementation. The developer divided the patient population based on the type of treatment the patient is receiving: chemotherapy or radiation therapy. The measure still requires only one performance rate for reporting.
- For the current evaluation, the developer provided updated reliability and validity testing as required for maintenance measures to meet current NQF Measure Evaluation Criteria. The developer tested reliability using a beta-binomial model to calculate the computed measure score as the ratio of signal to noise. Testing results indicated that the reliability above the minimum level of quality reporting events (10) for 251 physicians reporting on this measure through the registry option for CMS' PQRS in 2016 was 0.97. Reliability testing was limited to providers with 10 or more patients eligible for this measure – this minimum threshold is not included in the specifications.
- The developer empirically tested the validity of the measure score by performing a correlation analysis on this measure and another measure with similar patient populations and domain. The developer hypothesized that there exists a positive association between patients with a diagnosis of cancer receiving chemotherapy or radiation therapy in which pain intensity is quantified (NQF # 0384) and those with a diagnosis of cancer receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain (PQRS #144). The developer reported a coefficient correlation of 0.69, p-value = >0.001 and the number of shared providers was 111. The developer did not perform an empirical analysis on the applicable threats to validity including missing data and statistically significant and meaningful differences in performance.
- One of the Committee members questioned the reliability of the measure due to the variation in measuring pain intensity. The Committee noted that a patient with infrequent visits and documented pain intensity on every visit is not comparable to a patient with frequent visits where pain intensity is not documented on every visit. The Committee recommended the developer revise the denominator before the next maintenance review to increase comparability across providers and decrease burden.
- The Committee accepted the developer's explanation for providing one set of testing although the measure specifications include two levels of analysis. The Committee stated they had no additional concerns and the updated reliability and validity testing meet NQF criteria.

---

### 3. Feasibility: H-12; M-3; L-0; I-0

*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*

#### Rationale:

- The Committee agreed the data is routinely collected and the measure is feasible.

---

### 4. Use and Usability

*(4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)*

4a. Use: **Pass-15; No Pass-0**, 4b. Usability: **H-8; M-6; L-1; I-0**

Rationale:

- The measure was previously in the Physician Quality Reporting System (PQRS) and it is currently in the Merit-based Incentive Payment System (MIPS). The measure is scheduled for public reporting on Physician Compare in late 2019.
- The developer did not provide sufficient information to determine the usability of the measure. However, the Committee agreed that the measure can improve performance and the overuse of pain medications is a potential unintended consequence.

---

**5. Related and Competing Measures**

- 0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment (National Hospice and Palliative Care Organization)
- 1637 Hospice and Palliative Care -- Pain Assessment (University of North Carolina-Chapel Hill)
- 1634 Hospice and Palliative Care -- Pain Screening (University of North Carolina-Chapel Hill)
- 1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits (RAND)
- 0383 Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (paired with 0384) (ASCO)
- 0420 Pain Assessment and Follow-Up (CMS)

The Committee will discuss the related measures on the post-comment call on May 7, 2019.

---

**6. Standing Committee Recommendation for Endorsement: Y-15; N-0**

---

**7. Public and Member Comment**

A commenter stated that their support of the Committee's recommendation. However, the commenter requested clarification as to whether or not cancer immunotherapy agents were included in the measure denominator. It was noted that some patients' pain management may only be treated with immunotherapy.

- Developer Response  
Thank you for your comment. The PCPI's Oncology Technical Expert Panel has reviewed the issue of expanding the measure denominator to include other therapies (e.g., immunotherapy) and recommended that we pursue the modification for future years. The PCPI is in the process of exploring the addition of other appropriate therapies and the implications for measure testing and implementation.

---

**8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X**

---

## 3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy

### [Submission](#)

**Description:** The Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Measure, hereafter referred to as the chemotherapy measure, estimates hospital-level, risk-adjusted rates of inpatient admissions or ED visits for cancer patients ≥18 years of age for at least one of the following diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of hospital-based outpatient chemotherapy treatment. Rates of admission and ED visits are calculated and reported separately.

**Numerator Statement:** This measure involves calculating two mutually exclusive outcomes among cancer patients receiving chemotherapy treatment in a hospital outpatient setting: (1) one or more inpatient admissions for any of the following 10 diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of chemotherapy treatment or (2) one or more ED visits for any of the following 10 diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of chemotherapy treatment. These 10 conditions are potentially preventable through appropriately managed outpatient care. To be counted as an outcome, the qualifying diagnosis on the admission or ED visit claim must be (1) the principal diagnosis or (2) a secondary diagnosis accompanied by a principal diagnosis of cancer.

**Denominator Statement:** The measure cohort includes Medicare Fee-for-Service (FFS) patients, aged 18 years and older at the start of the performance period, with a diagnosis of any cancer (except leukemia), who received at least one outpatient chemotherapy treatment at the reporting hospital during the performance period.

**Exclusions:** The measure excludes the following patients from the cohort:

- 1) Patients with a diagnosis of leukemia at any time during the performance period.
- 2) Patients who were not enrolled in Medicare FFS Parts A and B in the year prior to the any outpatient chemotherapy treatment during the performance period.
- 3) Patients who were not enrolled in Medicare FFS Parts A and B for the 30 days following any chemotherapy treatment.
- 4) Cases in which patients receive chemotherapy to treat conditions other than cancer. Note that this is a case-level exclusion; as long as the patient has additional cases that meet inclusion criteria, they will remain in the cohort.

**Adjustment/Stratification:** Statistical risk model. Not applicable. This measure is not stratified.

**Level of Analysis:** Facility

**Setting of Care:** Outpatient Services

**Type of Measure:** Outcome

**Data Source:** Claims, Enrollment Data

**Measure Steward:** Centers for Medicare and Medicaid Services (CMS)

---

**STANDING COMMITTEE MEETING [02/08/2019]**

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

(1a. Evidence: 1b. Performance Gap)

1a. Evidence: **Pass-13; No Pass-1**, 1b. Performance Gap: **H-1; M-10; L-3; I-0**

Rationale:

- Admissions and ED visits for the ten diagnoses captured in the measure—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—are among the most common reasons that cancer patients receiving chemotherapy visit the hospital. Treatment plans and guidelines exist to support the management of these conditions. The developer provided data that showed improved symptom management and coordination of care reduces hospital visits.
- The Committee agreed that timely access to chemotherapy side effect management leads to decreased likelihood of preventable admissions and ED visits for patients receiving outpatient chemotherapy.
- The patient representatives on the Committee emphasized the importance of communication from their providers when receiving chemotherapy and additional support services for better symptom management. The patients on the Committee noted the importance of providers proactively preparing patients for the side effects of chemotherapy and how/where to manage them (e.g., ED, clinic, etc.). The patient representatives also shared that from the patient perspective, going to the ED is not ideal and creates fear in cancer patients.
- The developer provided performance data from national Medicare Fee-for-Service (FFS) claims and enrollment data for short-term acute hospitals using a period of performance of October 1, 2015 to September 30, 2016. The risk-standardized inpatient admission rate (RSAR) for non-cancer hospitals ranged from 8.9% to 18.5% (median 12.5%, 25th and 75th percentiles are 12.2% and 13.0%, respectively) while the risk-standardized inpatient admission rate for PCHs ranged from 12.3% to 15.2% (median 13.7%, 25th and 75th percentiles are 13.4% and 14.8%, respectively). The risk-standardized ED visit rate (RSEDR) for non-cancer hospitals ranged from 2.9% to 15.2% (median 5.6%, 25th and 75th percentiles are 5.6% and 6.2%, respectively) while the risk-standardized ED visit rate for PCHs ranged from 3.6% to 9.1% (median 6.7%, 25th and 75th percentiles are 4.4% and 8.9%, respectively). The developer also provided distributions of facility scores (RSARs for non-cancer and cancer hospitals, RSEDRs for cancer and non-cancer hospitals).
- The developer did not provide disparities data from the measure as specified but did examine associations between outcomes and social risk factors. The developer evaluated two indicators of social risk for impact on the measure score: race, specifically African American or not; and the Agency for Healthcare Research and Quality (AHRQ) Socio-Economic Status (SES) Composite index. At the patient level, the developer found that black patients are more likely to have an inpatient admission or ED visit than non-black patients and low AHRQ SES Composite Index patients are more likely to have an inpatient admission or ED visit than higher SES Composite Index patients. At the hospital level there was no significant impact of disparities on hospital-level measure scores.
- The Committee noted that there is a smaller gap in care for non-cancer hospitals vs. cancer hospitals but overall agreed 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-0; M-11; L-4; I-0** 2b. Validity: **M-12; L-2; I-0**

### **Rationale:**

- The Scientific Methods Panel evaluated the reliability and validity testing for this measure and was satisfied with the results. The measure developer updated the measure specifications based on the recommendations that the Committee provided in its initial review in 2016.
- Reliability was tested at the measure score level using the signal-to-noise ratio (SNR) and a split-sample ICC (2,1). Testing was limited to hospitals with at least 25 and 50 patients for both the signal-to-noise and split-sample, respectively. The Scientific Methods Panel noted that testing was not consistent with the measure's specifications. The developer clarified that the testing thresholds were used for public reporting. The signal-to-noise and split-sample results for the cancer hospitals and non-cancer hospitals showed:
  - Signal-to-noise results:
    - Cancer hospitals (n=11): Admissions measure median reliability=0.7848; ED measure median reliability=0.9808
    - Non-cancer hospitals (n=1,524): Admissions measure median reliability=0.6027; ED measure median reliability=0.7326
  - Split-sample results:
    - Cancer hospitals (n=11): Admissions measure ICC=0.6704; ED measure ICC=0.8904
    - Non-cancer hospitals (n=1,099): Admissions measure ICC=0.4314; ED measure ICC=0.3585
- The Committee noted that the SNR and ICC was higher for the cancer hospitals and questioned whether that was due to low-volume non-cancer hospitals. The Committee also noted that oral chemotherapy is not included in the measure specifications which may also be contributing to the lower reliability scores.
- The developer conducted an assessment by the 2018 Expert Workgroup (EWG) to demonstrate face validity. NQF staff informed the developer and Committee that, if the measure is endorsed, empirical validity testing is required when the measure returns for maintenance review.
- The Committee agreed that the updated specifications, the signal-to-noise and split-sample results for cancer and non-cancer hospitals, and face validity meet NQF criteria.

---

## **3. Feasibility: H-7; M-7; L-0; I-0**

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic))

### **Rationale:**

- The Committee did not express any concerns about the feasibility of the measure because the outcomes are reported using routinely collected Medicare claims data.

---

#### 4. Use and Usability

*(4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)*

4a. Use: **Pass-11; No Pass-3**, 4b. Usability: **H-5; M-8; L-1; I-0**

Rationale:

- The measure has been adopted for use in two Centers for Medicare and Medicaid Services (CMS) programs, the Hospital Outpatient Quality Reporting (OQR) Program and PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. PCHQR confidential reporting is scheduled to start in January 2019 and OQR public reporting in January 2020.

---

#### 5. Related and Competing Measures

- 3188: 30 Day Unplanned Readmissions for Cancer Patients (Seattle Cancer Care Alliance)

The Committee will discuss the related measure on the post-comment call on May 7, 2019.

---

#### 6. Standing Committee Recommendation for Endorsement: Y-11; N-3

---

#### 7. Public and Member Comment

NQF did not receive any comments following the Committee's evaluation of the measure.

---

#### 8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

## Measure Not Recommended

### 3365e Treatment of Osteopenia or Osteoporosis in Men with Non-Metastatic Prostate Cancer on Androgen Deprivation Therapy

#### Submission

**Description:** Men with non-metastatic prostate cancer and current or recent use of androgen deprivation therapy (ADT) and who also have a diagnosis of osteopenia or osteoporosis. The patient has an active order for a bisphosphonate or denosumab. The patient is taking Calcium and Vitamin D supplementation, after an initial Calcium and Vitamin D level measurement. The measure scoring is proportion.

The measure focuses on this population because androgen suppression, as a treatment for prostate cancer, can cause osteoporosis. It increases bone turnover, decreases bone mineral density, and increases the risk of bone fractures in men with prostate cancer. Denosumab reduces the risk of vertebral fractures in men with prostate cancer treated with androgen deprivation therapy. Bisphosphonates increase bone mineral density, a surrogate for fracture risk, during ADT. The Endocrine Society recommends that men at high risk of fracture be treated with medication approved by regulatory agencies; at this time, alendronate, risedronate, zoledronic acid, teriparatide and denosumab for men receiving ADT for prostate cancer.

Bisphosphonates inhibit bone resorption by suppressing osteoclast activity. The addition of an osteoclast inhibitor (bisphosphonate, denosumab 60 mg every six months) in men without bone metastases who are treated with long-term ADT is indicated when the 10-year probability of hip fracture is  $\geq 3$  percent or the 10-year probability of a major osteoporosis-related fracture is  $\geq 20$  percent. Denosumab is a monoclonal antibody and binds to RANKL. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function, and survival, thereby decreasing bone resorption and increasing bone mass and strength in both cortical and trabecular bone. The Prolia trial studied both osteoporosis and osteopenia. At 36 months, denosumab significantly increased bone density at all measured sites (lumbar, spine, hip, femoral neck, and distal third of radius) compared with placebo. The increase in bone density was progressive over the course of time at all sites and statistically significant beginning one month after the start of treatment. Hypocalcemia must be corrected before a patient receives a bisphosphonate or denosumab. All patients should be adequately supplemented with Calcium and Vitamin D.

This measure identifies the patient with a diagnosis of osteoporosis or osteopenia who also has prostate cancer and is being placed on ADT. Osteoporosis or osteopenia treatment must start during the measurement period.

This measure is a natural progression from CMS645v2. That measure is Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy. If the bone density shows osteoporosis or osteopenia, and the patient is being placed on ADT, then this measure is applicable and ultimate pairing with CMS645 is desired.

**Numerator Statement:** Active order for osteoporosis medications (bisphosphonates or denosumab) AND Vitamin D and Calcium level prior to the start of osteoporosis medication AND currently taking Vitamin D and Calcium.



**Denominator Statement:** The denominator equals the initial population. That is, males age 18 years and older with prostate cancer AND osteoporosis or osteopenia AND prior and/or current androgen deprivation therapy (ADT) AND office encounter during the measurement period. This is also the initial population.

There is no age cut off for this measure as prostate cancer can affect younger men, although it is a disease that normally occurs after the age of 40. According to the NCCN Prostate Cancer Early Detection guidelines, a cut off at 40 could miss those unfortunate patients who developed the disease in their late 20's and 30's. At the upper end, very healthy men over age 75 may choose to seek more aggressive treatment. Cancer genetics show an increased risk if the patient is a BRCA1/2 pathogenic mutation carrier which can lead to earlier detection of prostate cancers (and other cancers as well). When a family member is diagnosed with prostate cancer, another first degree relative is recommended to be screened at age 40 or 10 years prior to the age of the relative when prostate cancer was discovered, whichever is soonest.

**Exclusions:** Denominator Exclusions are metastatic prostate cancer to the bone OR terminally ill patients on hospice OR osteonecrosis of the jaw OR known hypersensitivity to osteoporosis medications (bisphosphonates or denosumab) OR hypocalcemia until corrected OR history of and/or planned radiation therapy to the jaw OR patient refused osteoporosis medications.

**Adjustment/Stratification:** No risk adjustment or risk stratification. Stratification is not required as this is not an outcome measure. It is a process measure.

**Level of Analysis:** Clinician : Individual

**Setting of Care:** Outpatient Services

**Type of Measure:** Process

**Data Source:** Electronic Health Records

**Measure Steward:** Large Urology Group Practice Association

---

## STANDING COMMITTEE MEETING [02/15/2019]

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

(1a. Evidence: 1b. Performance Gap)

1a. Evidence: **H-0; M-15; L-0; I-2**, 1b. Performance Gap: **H-1; M-16; L-0; I-0**

#### Rationale:

- The Committee initially reviewed this measure during the spring 2018 cycle. At that time, the measure met the Importance criteria; however, the developer withdrew the measure during the Scientific Acceptability discussion to revise the measure specifications as recommended by the Committee ([see spring 2018 cycle report](#)).
- During the spring 2018 cycle, the Committee noted that there was ample evidence that androgen deprivation therapy (ADT) contributes to loss of bone density, which in turn increases risk of bone fracture. The Committee also noted that the evidence underlying the National Comprehensive Cancer Network (NCCN) guideline and citations submitted with the measure appear sufficient to support the measure and link to preferred patient outcomes (i.e., a relationship between initiation of osteoporosis/osteopenia treatment and the bone health of patients with prostate cancer undergoing ADT). The Committee also noted that urologists typically treat early stage prostate cancer patients, who may be less familiar with giving chronic therapies to their early stage patients than physicians

who have more experience providing long-term care treatment to patients who present at a general oncology office.

- In the current cycle, the Committee questioned why the measure is specified for men 18 years and older, yet the NCCN guideline focuses on men 50 years and older. The developer responded that prostate cancer can affect younger men and specifying the measure for 50 years and older could miss younger patients that develop the disease. The Committee agreed the underlying evidence for the measure has not changed since the spring 2018 cycle but asked the measure developer to provide additional evidence to support the younger age range included in the measure specifications.
- During the spring 2018 cycle, while discussing performance gap and disparities, the Committee's discussion included:
  - Inquiring if there is additional data demonstrating that untreated osteoporosis/osteopenia in prostate cancer patients on ADT is a widespread issue across urology practices in the United States.
  - Acknowledging that ordering DEXA (Dual X-ray Absorptiometry) scans is not a normal practice within urology practices because urologists are treating early stage prostate cancer and are administering ADT, but do not typically treat osteoporosis/osteopenia.
  - The importance of this measure, especially when paired with an osteopenia/osteoporosis screening measure.
  - Unless there is a mandated consult to medical oncology--as there might be in large teaching hospital-- it is unlikely that most patients will receive appropriate care (i.e., treatment with bisphosphonates or denosumab) when treated in the community or in local urology practices – this is indicative of a large gap in performance.
- In the previous submission, the developer stated a disparity in care for this condition exists in the treatment between men and women. Providers recognize osteoporosis in women especially with the onset of menopause. On the contrary, providers often overlook secondary osteoporosis in men due to ADT.
- The Committee agreed that the previous information the developer provided is sufficient and the measure still meets the Performance Gap criterion.

---

## **2. Scientific Acceptability of Measure Properties: The measure does not meet the Scientific Acceptability criteria**

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

2a. Reliability: **See rating from Validity** 2b. Validity: **M-1; L-15; I-0**

### **Rationale:**

- During the spring 2018 cycle, the Committee had a lengthy discussion about the measure specifications, including asking the measure developer to provide multiple clarifications throughout the discussion. The Committee's concerns included the complexity of the measure description, numerator, and denominator as written in the measure submission form. The Committee voiced their support for the measure; however, was reluctant to vote on Scientific Acceptability due to the confusion about the measure specifications. The Committee asked the measure developer to revise the measure specifications, so providers can consistently implement the measure. The

measure developer agreed to withdraw the measure from the spring 2018 cycle and revise the measure specifications as recommended.

- In the current cycle (Fall 2018), the Standing Committee evaluated the revised measure specifications and agreed they were less ambiguous, yet still had concerns about the complexity of the measure. The Committee questioned the ability to capture the data elements required to calculate the measure, specifically the multiple numerator and denominator exclusions. The Committee expressed their confusion with the number and type of patients excluded from the numerator and denominator and the overall impact on the performance measure scores. Numerator exclusions are a specific type of exclusion that can be used in eQMs that have proportion and ratio scoring. eQMs also specify an improvement notation, which indicates whether a higher or lower score indicates better quality. Part of the confusion on whether the measure should use numerator exclusions or denominator exclusions is how the different type of exclusions are impacted by the measure's improvement notation. The Committee encouraged the measure developer to work with Centers for Medicare and Medicaid Services (CMS) to make sure the measures exclusions criteria and improvement notation are aligned. The Committee also questioned how exceptions rather than exclusions would affect the measure.
- NQF requires that eQMs be tested in a minimum of two electronic health records (EHR) to demonstrate reliability and/or validity. The developer met the minimum testing requirement; however, due to a small sample size and the complexity of the measure, the Committee determined the measure does not meet the validity criterion.

---

### **3. Feasibility: Not discussed as the measure did not pass Scientific Acceptability**

*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*

---

### **4. Use and Usability: Not discussed as the measure did not pass Scientific Acceptability**

*(4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)*

---

### **5. Related and Competing Measures: Not discussed as the measure did not pass Scientific Acceptability**

- 0390 Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer (American Urological Association)
- 

### **6. Standing Committee Recommendation for Endorsement: Not discussed as measure did not pass Scientific Acceptability**

---

### **7. Public and Member Comment**

NQF did not receive any comments following the Committee's evaluation of the measure.

---

**8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X**



# Cancer

## Fall 2018 Cycle

CSAC Review and Endorsement

*June 5-6, 2019*

# Project Name

Measures under Consideration: 3

0384 Oncology: Medical and Radiation – Pain Intensity Quantified

3490 Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy

3365e Treatment of Osteopenia or Osteoporosis in Men with Non-Metastatic Prostate Cancer on Androgen Deprivation Therapy (ADT)

# of Maintenance  
Measures: 1

# of New Measures: 2

# of Measures submitted  
to the Scientific Methods  
Panel for review: 1

Sub-topic areas:

Pain Intensity Quantified  
Preventable Admissions  
and ED Visits

Bone Health in Patients  
with Prostate Cancer

# Measure Review Challenges

0384 Oncology: Medical and  
Radiation - Pain Intensity  
Quantified

- Quality of evidence that demonstrates documenting pain leads to change in patient management and improved patient outcomes
- Use of different pain scales to quantify pain levels and relationship to improved outcomes
- Lack of empirical evidence for documentation measures

# Standing Committee Recommendations: Measure Evaluation Summary

	Maintenance Measures	New Measures	TOTAL Measures
Submitted	1	2	3
Measures Recommended	1	1	2
Measures Not Recommended	0	1	1
Reasons for not recommending:	Importance – X Scientific Acceptability -X Use– X Overall – X	Importance – X Scientific Acceptability - 1 Overall – 0	



# Public and NQF Member Comments Received

## 1 public comment received for measure 0384

- Requested clarification if immunotherapy agents are included in the denominator.
  - ▣ *Measure developer response:*
    - » The PCPI's Oncology Technical Expert Panel has reviewed the issue of expanding the measure denominator to include other therapies (e.g., immunotherapy) and recommended that we pursue the modification for future years. The PCPI is in the process of exploring the addition of other appropriate therapies and the implications for measure testing and implementation.

# Member Expression of Support

## Two members expressed support

- 0384 Oncology; Medical and Radiation – Pain Intensity Quantified
  - ▣ *NQF member does support the measure*
- 3490 Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy
  - ▣ *NQF member does not support the measure*

# Timeline and Next Steps

Process Step	Timeline
<b>Appeals Period</b>	June 10 - July 9, 2019
<b>Adjudication of Appeals</b>	July 10 - August 6, 2019
<b>Final Report</b>	September 2019

# Questions?

## **Project team:**

- Melissa Mariñelarena, Senior Director
- Katie Goodwin, Senior Project Manager
- Hannah Bui, Project Analyst

## **Project webpage:**

<http://www.qualityforum.org/Cancer.aspx>

**Project email address:** [cancerem@qualityforum.org](mailto:cancerem@qualityforum.org)

# Cancer, Fall 2018 Review Cycle: CDP Report

DRAFT REPORT FOR CSAC REVIEW

June 5, 2019



NATIONAL  
QUALITY FORUM

This report is funded by the Department of Health  
and Human Services under contract HHSM-500-  
2017-00060I Task Order HHSM-500-T0001.

## Contents

<b>Executive Summary .....</b>	<b>3</b>
<b>Introduction.....</b>	<b>4</b>
<b>NQF Portfolio of Performance Measures for Cancer Conditions .....</b>	<b>4</b>
Table 1. NQF Cancer Portfolio of Measures .....	4
<b>Cancer Measure Evaluation .....</b>	<b>4</b>
Table 2. Cancer Measure Evaluation Summary .....	5
Comments Received Prior to Committee Evaluation .....	5
Summary of Measure Evaluation .....	5
Measures Withdrawn from Consideration.....	7
Table 3. Measures Withdrawn from Consideration .....	<u>87</u>
<b>Reference .....</b>	<b><u>98</u></b>
<b>Appendix A: Details of Measure Evaluation.....</b>	<b><u>109</u></b>
Measures Recommended .....	<u>109</u>
0384 Oncology: Medical and Radiation - Pain Intensity Quantified.....	<u>109</u>
3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy .....	<u>1413</u>
Measure Not Recommended .....	<u>1817</u>
3365e Treatment of Osteopenia or Osteoporosis in Men with Non-Metastatic Prostate Cancer on Androgen Deprivation Therapy.....	<u>1817</u>
<b>Appendix B: Cancer Portfolio—Use in Federal Programs .....</b>	<b><u>2221</u></b>
<b>Appendix C: Cancer Standing Committee and NQF Staff.....</b>	<b><u>2423</u></b>
<b>Appendix D: Measure Specifications.....</b>	<b><u>2625</u></b>
0384 Oncology: Medical and Radiation - Pain Intensity Quantified.....	<u>2625</u>
3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy .....	<u>3029</u>
<b>Appendix E1: Related and Competing Measures (tabular version) .....</b>	<b><u>3837</u></b>
<b>Appendix E2: Related and Competing Measures (narrative version) .....</b>	<b><u>4544</u></b>
<b>Appendix F: Pre-Evaluation Comments.....</b>	<b><u>5756</u></b>

# Cancer, Fall 2018 Review Cycle

## DRAFT REPORT FOR CSAC REVIEW

### Executive Summary

Cancer is the second most common cause of death in the U.S., exceeded only by heart disease.<sup>1</sup> The National Cancer Institute estimates that in 2018, 1.7 million new cases of cancer will be diagnosed in the United States, and over 600,000 people will die from the disease.<sup>2</sup> Furthermore, nearly half of all men and one-third of all women in the U.S. will develop cancer during their lifetime.<sup>3</sup> In addition, diagnosis and treatment of cancer has great economic impact on patients, their families, and society. The National Cancer Institute estimated that in 2010 the costs for cancer care in the U.S. totaled nearly \$157 billion and could reach \$174 billion in 2020.<sup>4</sup>

The National Quality Forum's (NQF) portfolio of measures for cancer includes measures addressing cancer screening and appropriate treatment (including surgery, chemotherapy, and radiation therapy).

For this project, the Standing Committee evaluated two newly submitted measures and one measure undergoing maintenance review against NQF's standard evaluation criteria. The Committee recommended two measures for endorsement and did not recommend one measure. The Standing Committee recommended the following two measures:

- 0384 Oncology: Medical and Radiation – Pain Intensity Quantified (PCPI)
- 3490 Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy (Centers for Medicare and Medicaid Services)

The Committee did not recommend the following measure:

- 3365e Treatment of Osteopenia or Osteoporosis in Men with Non-Metastatic Prostate Cancer on Androgen Deprivation Therapy (ADT) (Large Urology Group Practice Association)

The body of this report summarizes the measures currently under review; [Appendix A](#) provides detailed summaries of the Committee's discussion and ratings of the criteria for each measure.

## Introduction

Cancer is the second most common cause of death in the U.S., exceeded only by heart disease.<sup>5</sup> The National Cancer Institute estimates that in 2018, 1.7 million new cases of cancer will be diagnosed in the United States, and over 600,000 people will die from the disease.<sup>6</sup> Furthermore, nearly half of all men and one-third of all women in the U.S. will develop cancer during their lifetime.<sup>7</sup> In addition, diagnosis and treatment of cancer has great economic impact on patients, their families, and society. The National Cancer Institute estimated that in 2010 the costs for cancer care in the U.S. totaled nearly \$157 billion and could reach \$174 billion in 2020.<sup>8</sup>

Cancer care is complex and provided in multiple settings—hospitals, outpatient clinics, ambulatory infusion centers, radiation oncology treatment centers, radiology departments, palliative and hospice care facilities—and by multiple providers including surgeons, oncologists, nurses, pain management specialists, and social workers. Due to the complexity of cancer, as well as the numerous care settings and providers, there is a need for quality measures that address the value and efficiency of care for patients and their families.

## NQF Portfolio of Performance Measures for Cancer Conditions

The Cancer Standing Committee ([Appendix C](#)) oversees NQF's portfolio of Cancer measures ([Appendix B](#)) that includes measures for breast cancer, colon cancer, hematology, prostate cancer, and other general cancer measures. This portfolio contains 26 measures.

**Table 1. NQF Cancer Portfolio of Measures**

	Process/Structure	Outcome	Composite
<b>Breast Cancer</b>	11	0	0
<b>Colon Cancer</b>	6	0	0
<b>Hematology</b>	2	0	0
<b>Lung/Thoracic Cancer</b>	1	0	0
<b>Prostate Cancer</b>	3	0	0
<b>General Cancer Measures</b>	3	0	0
<b>Total</b>	26	0	0

Additional measures related to cancer care are assigned to the Geriatrics and Palliative Care, Surgery, and Prevention and Population Health portfolios. The additional measures address appropriateness of care, cancer screening, screening for pain, pain related to chemotherapy or radiation therapy, and surgical care.

## Cancer Measure Evaluation

In February 2019, the Cancer Standing Committee evaluated two new measures and one measure undergoing maintenance review against [NQF's standard evaluation criteria](#).



**Table 2. Cancer Measure Evaluation Summary**

	Maintenance	New	Total
Measures under consideration	1	2	3
Measures recommended for endorsement	1	1	2
Measure not recommended for endorsement		1	1
Reasons for not recommending		Importance – 0 Scientific Acceptability – 1 Overall Suitability – 0 Competing Measure – 0	

## Comments Received Prior to Committee Evaluation

NQF solicits comments on endorsed measures on an ongoing basis through the [Quality Positioning System \(QPS\)](#). In addition, NQF solicits comments for a continuous 16-week period during each evaluation cycle via an online tool located on the project webpage. For this evaluation cycle, the commenting period opened on December 11, 2018 and will close on April 19, 2019. As of January 30, 2019, two comments were submitted and shared with the Committee prior to the measure evaluation meetings ([Appendix F](#)).

## Comments Received After Committee Evaluation

[The continuous 16-week public commenting period with NQF member support closed on April 19, 2019. Following the Committee’s evaluation of the measures under consideration, NQF received one comment from one member organization pertaining to the draft report and to the measures under consideration. The comment for the measure under consideration has been summarized in Appendix A.](#)

[Throughout the 16-week continuous public commenting period, NQF members had the opportunity to express their support \(‘support’ or ‘do not support’\) for each measure submitted for endorsement consideration to inform the Committee’s recommendations. Two NQF members provided their expression of support.](#)

## Summary of Measure Evaluation

The following brief summaries of the measure evaluation highlight the major issues that the Committee considered. Details of the Committee’s discussion and ratings of the criteria for each measure are included in [Appendix A](#).

### **0384 Oncology: Medical and Radiation - Pain Intensity Quantified (PCPI): Recommended**

**Description:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified; **Measure Type:** Process; **Level of Analysis:** Clinician : Group/Practice, Clinician : Individual; **Setting of Care:** Other, Outpatient Services; **Data Source:** Registry Data

The Committee had a lengthy discussion about the quality of evidence that demonstrates documenting pain leads to improved patient outcomes. The Committee ultimately agreed that asking patients about their pain is important; therefore, in the absence of empirical evidence, it is beneficial to hold providers accountable for performance on this measure. The Committee agreed that a performance gap exists beyond the nearly topped out 2016 Physician Quality Reporting System (PQRS) performance data provided by the measure developer. The Committee agreed that the updated reliability and validity testing results met NQF criteria. The data are routinely collected, and the measure is feasible. The measure was previously used in the Physician Quality Reporting System (PQRS), is currently used in the Merit-based Incentive Payment System (MIPS), and scheduled to be publicly reported on Physician Compare in late 2019. The Standing Committee recommended the measure for continued endorsement. One commenter supported the Committee’s recommendation for continued endorsement; however, asked if immunotherapy agents are included in the denominator. The measure developer responded they are in the process of exploring the addition of other appropriate therapies.

### **3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy (Centers for Medicare and Medicaid Services): Recommended**

**Description:** The Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Measure, hereafter referred to as the chemotherapy measure, estimates hospital-level, risk-adjusted rates of inpatient admissions or ED visits for cancer patients ≥18 years of age for at least one of the following diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of hospital-based outpatient chemotherapy treatment. Rates of admission and ED visits are calculated and reported separately. **Measure Type:** Outcome; **Level of Analysis:** Facility; **Setting of Care:** Outpatient Services; **Data Source:** Claims, Enrollment Data

The Committee agreed that timely access to chemotherapy side effect management leads to decreased likelihood of preventable admissions and ED visits for patients receiving outpatient chemotherapy. The patient representatives on the Committee emphasized the importance of communication from their providers when receiving chemotherapy and additional support services for better symptom management. The Committee noted that there is a smaller gap in care for noncancer hospitals vs. cancer hospitals but overall agreed that there is an opportunity for improvement. The Scientific Methods Panel evaluated the reliability and validity testing for this measure and was satisfied with the results. The measure developer updated the measure specifications based on the recommendations that the Committee provided in its initial review in 2016. The Committee agreed that the updated specifications, reliability testing, and validity testing meet NQF criteria. The Committee did not express any concerns about the feasibility of the measure because the outcomes are reported using routinely collected Medicare claims data. The measure has been adopted for use in two Centers for Medicare and Medicaid Services (CMS) programs, the Hospital Outpatient Quality Reporting (OQR) Program and PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. PCHQR confidential reporting is scheduled to start in January 2019 and OQR public reporting, in January 2020. The Standing Committee recommended the measure for NQF endorsement.

### 3365e Treatment of Osteopenia or Osteoporosis in Men with Non-Metastatic Prostate Cancer on Androgen Deprivation Therapy (Large Urology Group Practice Association): Not Recommended

**Description:** Men with non-metastatic prostate cancer and current or recent use of androgen deprivation therapy (ADT) and who also have a diagnosis of osteopenia or osteoporosis. The measure focuses on this population because androgen suppression, as a treatment for prostate cancer, can cause osteoporosis. It increases bone turnover, decreases bone mineral density, and increases the risk of bone fractures in men with prostate cancer; **Measure Type:** Process; **Level of Analysis:** Clinician : Individual; **Setting of Care:** Outpatient Services; **Data Source:** Electronic Health Records

The Standing Committee initially reviewed this measure during the spring 2018 cycle. During the current evaluation cycle, the Committee noted that the evidence underlying the National Comprehensive Cancer Network (NCCN) guideline and citations submitted with the measure appear sufficient to support the link to preferred patient outcomes (i.e., a relationship between initiation of osteoporosis/osteopenia treatment and the bone health of patients with prostate cancer undergoing androgen deprivation therapy). The measure is specified for men 18 years and older; however, the NCCN guideline focuses on men 50 years and older. The Committee asked the measure developer to provide additional evidence to support the younger age range included in the measure specifications. The Committee agreed that a gap in care remains. During the spring 2018 cycle, the Committee had a lengthy discussion about the measure specifications, including asking the measure developer to provide multiple clarifications throughout the discussion. The Committee's concerns included the complexity of the measure description, numerator, and denominator as written in the measure submission form. The measure developer agreed to withdraw the measure from the spring 2018 cycle and revise the measure specifications as recommended. In the current cycle, the Standing Committee evaluated the revised measure specifications and agreed that they were less ambiguous, yet they still had concerns about the complexity of the measure. The Committee discussed their concerns about the effect of the multiple numerator and denominator exclusions on the measure performance. The Committee expressed low confidence that the data used in the measure are valid due to the number and representativeness of patients and entities and analysis of the threats to validity. The Standing Committee did not vote on the recommendation for endorsement because the measure did not pass the Validity criterion—a must-pass criterion.

### Measures Withdrawn from Consideration

Three measures previously endorsed by NQF have not been re-submitted for maintenance of endorsement. Endorsement for these measures will be removed.

**Table 3. Measures Withdrawn from Consideration**

<b>Measure</b>	<b>Reason for withdrawal</b>
<b>0391 Breast Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade (College of American Pathologists)</b>	Developer deemed this measure “topped out”.
<b>0392 Colorectal Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade (College of American Pathologists)</b>	Developer deemed this measure “topped out”.
<b>1855 Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines (College of American Pathologists)</b>	Developer deemed this measure “topped out”.

## Reference

- <sup>1</sup> American Cancer Society. Economic Impact of cancer website. <http://www.cancer.org/cancer/cancerbasics/economic-impact-of-cancer>. Last accessed August 2018.
- <sup>2</sup> National Cancer Institute. Cancer statistics website. <https://www.cancer.gov/about-cancer/understanding/statistics>. Last accessed June 2018.
- <sup>3</sup> American Cancer Society. *Cancer Facts & Figures 2016*. Atlanta: National Cancer Society; 2016. <http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2016/index>. Last accessed August 2018.
- <sup>4</sup> National Cancer Institute. Cancer prevalence and cost of care projections website. <https://costprojections.cancer.gov/>. Last accessed August 2018.
- <sup>5</sup> American Cancer Society. Economic impact of cancer. <http://www.cancer.org/cancer/cancerbasics/economic-impact-of-cancer>. Last accessed August 2018.
- <sup>6</sup> National Cancer Institute. Cancer statistics website. <https://www.cancer.gov/about-cancer/understanding/statistics>. Last accessed June 2018.
- <sup>7</sup> American Cancer Society. *Cancer Facts & Figures 2016*. Atlanta: American Cancer Society; 2016. <http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2016/index>. Last accessed August 2018.
- <sup>8</sup> National Cancer Institute. Cancer Prevalence and cost of care projections website. <https://costprojections.cancer.gov/>. Last accessed August 2018.

## Appendix A: Details of Measure Evaluation

**Rating Scale:** H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable

### Measures Recommended

---

#### 0384 Oncology: Medical and Radiation - Pain Intensity Quantified

[Submission](#) | [Specifications](#)

**Description:** Percentage of patient visits, regardless of patient 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

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

**Exclusions:** None

**Adjustment/Stratification:** No risk adjustment or risk stratification. Consistent with the CMS Measures Management System Blueprint and recent national recommendations put forth by the IOM and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer.

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

**Setting of Care:** Other, Outpatient Services

**Type of Measure:** Process

**Data Source:** Registry Data

**Measure Steward:** PCPI

---

#### STANDING COMMITTEE MEETING [02/08/2019]

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

(1a. Evidence: 1b. Performance Gap)

1a. Evidence: **M-0; L-1; I-17**, Evidence Exception: **Y-18; N-0**, 1b. Performance Gap: **H-1; M-16; L-1; I-0**

Rationale:

- For the current evaluation, the developer provided an updated logic model tying symptom reporting and pain control to survival and overall quality of life. The developer also provided the updated 2018 National Comprehensive Cancer Network (NCCN) Clinical Practical Guidelines in Oncology-Adult Cancer Pain to support the relationship between documenting pain intensity and pain management and pain control, quality of life improvement, and survival. The NCCN assigned the evidence and recommendations associated with the 2018 guideline, a Category 2A grade. NCCN defines Category 2A guidelines as based upon lower-level evidence and there is uniform NCCN consensus that the intervention is appropriate. Per the developer's submission, the NCCN guideline does not provide a description of the body of evidence (quantity, quality, consistency).
- The Committee had a lengthy discussion about the quality of the evidence that demonstrates documenting pain leads to improved patient outcomes. Some Committee members questioned

whether documenting pain intensity translated into a change in patient management. Other Committee members expressed concern about using different pain scales to quantify pain levels and the relationship to improved outcomes for cancer patients. Overall, the Committee agreed asking patients about their pain is important and likely leads to improved pain management and pain control. The Committee acknowledged that the evidence provided in the measure submission form is insufficient and does not meet current NQF Measure Evaluation Criteria for process measures. In the absence of empirical evidence demonstrating that documenting pain intensity improves patient outcomes, the Committee voted to pass the evidence criterion with an exception and determined it is beneficial to hold providers accountable for performance on this measure. The patient representatives on the Committee emphasized that asking patients about their pain is important and they value this measure.

- The developer provided 2016 Physician Quality Reporting System (PQRS) performance data from 216 physicians using the measure specifications. The PQRS performance data showed a mean of 0.88, median of 0.98, mode of 1.0, standard deviation of 0.21, and interquartile range of 0.12 (1.0 – 0.88). The developer also provided additional PQRS performance rates from 2015, 2014, and 2013. The average performance rates were 75.9%, 84.8%, and 82.7% respectively.
- The developer did not provide disparities data from the measure as specified as required for maintenance of endorsement. The developer noted that the measure is included in federal reporting programs; however, those programs have not yet made disparities data available to analyze and report. The developer provided a summary of data from the literature related to cancer treatment and the management of cancer-related pain.
- The Committee agreed a performance gap exists beyond the nearly topped out 2016 PQRS performance data provided by the measure developer. Since there is no disparities data available from the measure as specified, the Committee agreed that the data from the literature is sufficient.

---

## **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-0; I-0** 2b. Validity: **H-2; M-13; L-1; I-0**

### Rationale:

- The level of analysis (LoA) specified are for clinician groups and individual clinicians, and therefore two sets of testing are expected. NQF criteria states that testing must be provided for all the levels specified and intended for measure implementation. One of these LoA may have to be dropped from the specifications, unless the developer can clarify how to interpret the testing results. Additional testing may be required if they would like the measure to be endorsed for both levels of analysis. The developer explained that the 2016 PQRS registry data used to conduct the updated reliability testing, provided by CMS, did not distinguish between clinician groups and individual clinicians; therefore, they were unable to perform two sets of testing.
- The developer noted changes to the measure specifications since the last measure update beginning with 2019 implementation. The developer divided the patient population based on the type of treatment the patient is receiving: chemotherapy or radiation therapy. The measure still requires only one performance rate for reporting.
- For the current evaluation, the developer provided updated reliability and validity testing as required for maintenance measures to meet current NQF Measure Evaluation Criteria. The developer tested reliability using a beta-binomial model to calculate the computed measure

score as the ratio of signal to noise. Testing results indicated that the reliability above the minimum level of quality reporting events (10) for 251 physicians reporting on this measure through the registry option for CMS' PQRS in 2016 was 0.97. Reliability testing was limited to providers with 10 or more patients eligible for this measure – this minimum threshold is not included in the specifications.

- The developer empirically tested the validity of the measure score by performing a correlation analysis on this measure and another measure with similar patient populations and domain. The developer hypothesized that there exists a positive association between patients with a diagnosis of cancer receiving chemotherapy or radiation therapy in which pain intensity is quantified (NQF # 0384) and those with a diagnosis of cancer receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain (PQRS #144). The developer reported a coefficient correlation of 0.69, p-value = >0.001 and the number of shared providers was 111. The developer did not perform an empirical analysis on the applicable threats to validity including missing data and statistically significant and meaningful differences in performance.
- One of the Committee members questioned the reliability of the measure due to the variation in measuring pain intensity. The Committee noted that a patient with infrequent visits and documented pain intensity on every visit is not comparable to a patient with frequent visits where pain intensity is not documented on every visit. The Committee recommended the developer revise the denominator before the next maintenance review to increase comparability across providers and decrease burden.
- The Committee accepted the developer's explanation for providing one set of testing although the measure specifications include two levels of analysis. The Committee stated they had no additional concerns and the updated reliability and validity testing meet NQF criteria.

---

### **3. Feasibility: H-12; M-3; L-0; I-0**

*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*

#### Rationale:

- The Committee agreed the data is routinely collected and the measure is feasible.

---

### **4. Use and Usability**

*(4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)*

4a. Use: **Pass-15; No Pass-0**, 4b. Usability: **H-8; M-6; L-1; I-0**

#### Rationale:

- The measure was previously in the Physician Quality Reporting System (PQRS) and it is currently in the Merit-based Incentive Payment System (MIPS). The measure is scheduled for public reporting on Physician Compare in late 2019.
- The developer did not provide sufficient information to determine the usability of the measure. However, the Committee agreed that the measure can improve performance and the overuse of pain medications is a potential unintended consequence.



---

## 5. Related and Competing Measures

- 0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment (National Hospice and Palliative Care Organization)
- 1637 Hospice and Palliative Care -- Pain Assessment (University of North Carolina-Chapel Hill)
- 1634 Hospice and Palliative Care -- Pain Screening (University of North Carolina-Chapel Hill)
- 1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits (RAND)
- 0383 Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (paired with 0384) (ASCO)
- 0420 Pain Assessment and Follow-Up (CMS)

~~The Committee will discuss the related measures on the post-comment call on May 7, 2019.~~

The Committee did not discuss related measures during this evaluation cycle. Related measures will be discussed during the Spring Cycle 2019.

---

## 6. Standing Committee Recommendation for Endorsement: Y-15; N-0

---

## 7. Public and Member Comment

- One commenter supported the Committee's recommendation for continued endorsement; however, asked if immunotherapy agents are included in the denominator. While patients may be treated with both chemotherapy and immunotherapy, some patients may be treated with just immunotherapy. In such cases, this measure fails to capture pain management for patients undergoing immunotherapy cancer treatment only.
- Developer Response  
Thank you for your comment. The PCPI's Oncology Technical Expert Panel has reviewed the issue of expanding the measure denominator to include other therapies (e.g., immunotherapy) and recommended that we pursue the modification for future years. The PCPI is in the process of exploring the addition of other appropriate therapies and the implications for measure testing and implementation.

---

## 8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X

---

## 3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy

[Submission](#) | [Specifications](#)

**Description:** The Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Measure, hereafter referred to as the chemotherapy measure, estimates hospital-level, risk-adjusted rates of inpatient admissions or ED visits for cancer patients  $\geq 18$  years of age for at least one of the following diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of hospital-based outpatient chemotherapy treatment. Rates of admission and ED visits are calculated and reported separately.

**Numerator Statement:** This measure involves calculating two mutually exclusive outcomes among cancer patients receiving chemotherapy treatment in a hospital outpatient setting: (1) one or more inpatient admissions for any of the following 10 diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of chemotherapy treatment or (2) one or more ED visits for any of the following 10 diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of chemotherapy treatment. These 10 conditions are potentially preventable through appropriately managed outpatient care. To be counted as an outcome, the qualifying diagnosis on the admission or ED visit claim must be (1) the principal diagnosis or (2) a secondary diagnosis accompanied by a principal diagnosis of cancer.

**Denominator Statement:** The measure cohort includes Medicare Fee-for-Service (FFS) patients, aged 18 years and older at the start of the performance period, with a diagnosis of any cancer (except leukemia), who received at least one outpatient chemotherapy treatment at the reporting hospital during the performance period.

**Exclusions:** The measure excludes the following patients from the cohort:

- 1) Patients with a diagnosis of leukemia at any time during the performance period.
- 2) Patients who were not enrolled in Medicare FFS Parts A and B in the year prior to the any outpatient chemotherapy treatment during the performance period.
- 3) Patients who were not enrolled in Medicare FFS Parts A and B for the 30 days following any chemotherapy treatment.
- 4) Cases in which patients receive chemotherapy to treat conditions other than cancer. Note that this is a case-level exclusion; as long as the patient has additional cases that meet inclusion criteria, they will remain in the cohort.

**Adjustment/Stratification:** Statistical risk model. Not applicable. This measure is not stratified.

**Level of Analysis:** Facility

**Setting of Care:** Outpatient Services

**Type of Measure:** Outcome

**Data Source:** Claims, Enrollment Data

**Measure Steward:** Centers for Medicare and Medicaid Services (CMS)

---

### STANDING COMMITTEE MEETING [02/08/2019]

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

(1a. Evidence: 1b. Performance Gap)

1a. Evidence: **Pass-13; No Pass-1**, 1b. Performance Gap: **H-1; M-10; L-3; I-0**

Rationale:

- Admissions and ED visits for the ten diagnoses captured in the measure—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—are among the most common reasons that cancer patients receiving chemotherapy visit the hospital. Treatment plans and guidelines exist to support the management of these conditions. The developer provided data that showed improved symptom management and coordination of care reduces hospital visits.
- The Committee agreed that timely access to chemotherapy side effect management leads to decreased likelihood of preventable admissions and ED visits for patients receiving outpatient chemotherapy.
- The patient representatives on the Committee emphasized the importance of communication from their providers when receiving chemotherapy and additional support services for better symptom management. The patients on the Committee noted the importance of providers proactively preparing patients for the side effects of chemotherapy and how/where to manage them (e.g., ED, clinic, etc.). The patient representatives also shared that from the patient perspective, going to the ED is not ideal and creates fear in cancer patients.
- The developer provided performance data from national Medicare Fee-for-Service (FFS) claims and enrollment data for short-term acute hospitals using a period of performance of October 1, 2015 to September 30, 2016. The risk-standardized inpatient admission rate (RSAR) for non-cancer hospitals ranged from 8.9% to 18.5% (median 12.5%, 25th and 75th percentiles are 12.2% and 13.0%, respectively) while the risk-standardized inpatient admission rate for PCHs ranged from 12.3% to 15.2% (median 13.7%, 25th and 75th percentiles are 13.4% and 14.8%, respectively). The risk-standardized ED visit rate (RSEDR) for non-cancer hospitals ranged from 2.9% to 15.2% (median 5.6%, 25th and 75th percentiles are 5.6% and 6.2%, respectively) while the risk-standardized ED visit rate for PCHs ranged from 3.6% to 9.1% (median 6.7%, 25th and 75th percentiles are 4.4% and 8.9%, respectively). The developer also provided distributions of facility scores (RSARs for non-cancer and cancer hospitals, RSEDRs for cancer and non-cancer hospitals).
- The developer did not provide disparities data from the measure as specified but did examine associations between outcomes and social risk factors. The developer evaluated two indicators of social risk for impact on the measure score: race, specifically African American or not; and the Agency for Healthcare Research and Quality (AHRQ) Socio-Economic Status (SES) Composite index. At the patient level, the developer found that black patients are more likely to have an inpatient admission or ED visit than non-black patients and low AHRQ SES Composite Index patients are more likely to have an inpatient admission or ED visit than higher SES Composite Index patients. At the hospital level there was no significant impact of disparities on hospital-level measure scores.
- The Committee noted that there is a smaller gap in care for non-cancer hospitals vs. cancer hospitals but overall agreed 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-0; M-11; L-4; I-0** 2b. Validity: **M-12; L-2; I-0**

Rationale:

- The Scientific Methods Panel evaluated the reliability and validity testing for this measure and was satisfied with the results. The measure developer updated the measure specifications based on the recommendations that the Committee provided in its initial review in 2016.
- Reliability was tested at the measure score level using the signal-to-noise ratio (SNR) and a split-sample ICC (2,1). Testing was limited to hospitals with at least 25 and 50 patients for both the signal-to-noise and split-sample, respectively. The Scientific Methods Panel noted that testing was not consistent with the measure's specifications. The developer clarified that the testing thresholds were used for public reporting. The signal-to-noise and split-sample results for the cancer hospitals and non-cancer hospitals showed:
  - Signal-to-noise results:
    - Cancer hospitals (n=11): Admissions measure median reliability=0.7848; ED measure median reliability=0.9808
    - Non-cancer hospitals (n=1,524): Admissions measure median reliability=0.6027; ED measure median reliability=0.7326
  - Split-sample results:
    - Cancer hospitals (n=11): Admissions measure ICC=0.6704; ED measure ICC=0.8904
    - Non-cancer hospitals (n=1,099): Admissions measure ICC=0.4314; ED measure ICC=0.3585
- The Committee noted that the SNR and ICC was higher for the cancer hospitals and questioned whether that was due to low-volume non-cancer hospitals. The Committee also noted that oral chemotherapy is not included in the measure specifications which may also be contributing to the lower reliability scores.
- The developer conducted an assessment by the 2018 Expert Workgroup (EWG) to demonstrate face validity. NQF staff informed the developer and Committee that, if the measure is endorsed, empirical validity testing is required when the measure returns for maintenance review.
- The Committee agreed that the updated specifications, the signal-to-noise and split-sample results for cancer and non-cancer hospitals, and face validity meet NQF criteria.

---

### 3. Feasibility: H-7; M-7; L-0; I-0

*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*

#### Rationale:

- The Committee did not express any concerns about the feasibility of the measure because the outcomes are reported using routinely collected Medicare claims data.

---

### 4. Use and Usability

*(4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)*

4a. Use: **Pass-11; No Pass-3**, 4b. Usability: **H-5; M-8; L-1; I-0**

#### Rationale:

- The measure has been adopted for use in two Centers for Medicare and Medicaid Services (CMS) programs, the Hospital Outpatient Quality Reporting (OQR) Program and PPS-Exempt

Cancer Hospital Quality Reporting (PCHQR) Program. PCHQR confidential reporting is scheduled to start in January 2019 and OQR public reporting in January 2020.

---

#### **5. Related and Competing Measures**

- 3188: 30 Day Unplanned Readmissions for Cancer Patients (Seattle Cancer Care Alliance)

~~The Committee will discuss the related measure on the post-comment call on May 7, 2019.~~

The Committee did not discuss related measures during this evaluation cycle. Related measures will be discussed during the Spring Cycle 2019.

---

#### **6. Standing Committee Recommendation for Endorsement: Y-11; N-3**

---

#### **7. Public and Member Comment**

NQF did not receive any comments following the Committee's evaluation of the measure.

---

#### **8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X**

## Measure Not Recommended

### 3365e Treatment of Osteopenia or Osteoporosis in Men with Non-Metastatic Prostate Cancer on Androgen Deprivation Therapy

#### [Submission](#)

**Description:** Men with non-metastatic prostate cancer and current or recent use of androgen deprivation therapy (ADT) and who also have a diagnosis of osteopenia or osteoporosis. The patient has an active order for a bisphosphonate or denosumab. The patient is taking Calcium and Vitamin D supplementation, after an initial Calcium and Vitamin D level measurement. The measure scoring is proportion.

The measure focuses on this population because androgen suppression, as a treatment for prostate cancer, can cause osteoporosis. It increases bone turnover, decreases bone mineral density, and increases the risk of bone fractures in men with prostate cancer. Denosumab reduces the risk of vertebral fractures in men with prostate cancer treated with androgen deprivation therapy. Bisphosphonates increase bone mineral density, a surrogate for fracture risk, during ADT. The Endocrine Society recommends that men at high risk of fracture be treated with medication approved by regulatory agencies; at this time, alendronate, risedronate, zoledronic acid, teriparatide and denosumab for men receiving ADT for prostate cancer.

Bisphosphonates inhibit bone resorption by suppressing osteoclast activity. The addition of an osteoclast inhibitor (bisphosphonate, denosumab 60 mg every six months) in men without bone metastases who are treated with long-term ADT is indicated when the 10-year probability of hip fracture is  $\geq 3$  percent or the 10-year probability of a major osteoporosis-related fracture is  $\geq 20$  percent. Denosumab is a monoclonal antibody and binds to RANKL. Prevention of the RANKL/RANK interaction inhibits osteoclast formation, function, and survival, thereby decreasing bone resorption and increasing bone mass and strength in both cortical and trabecular bone. The Prolia trial studied both osteoporosis and osteopenia. At 36 months, denosumab significantly increased bone density at all measured sites (lumbar, spine, hip, femoral neck, and distal third of radius) compared with placebo. The increase in bone density was progressive over the course of time at all sites and statistically significant beginning one month after the start of treatment. Hypocalcemia must be corrected before a patient receives a bisphosphonate or denosumab. All patients should be adequately supplemented with Calcium and Vitamin D.

This measure identifies the patient with a diagnosis of osteoporosis or osteopenia who also has prostate cancer and is being placed on ADT. Osteoporosis or osteopenia treatment must start during the measurement period.

This measure is a natural progression from CMS645v2. That measure is Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy. If the bone density shows osteoporosis or osteopenia, and the patient is being placed on ADT, then this measure is applicable and ultimate pairing with CMS645 is desired.

**Numerator Statement:** Active order for osteoporosis medications (bisphosphonates or denosumab) AND Vitamin D and Calcium level prior to the start of osteoporosis medication AND currently taking Vitamin D and Calcium.

**Denominator Statement:** The denominator equals the initial population. That is, males age 18 years and older with prostate cancer AND osteoporosis or osteopenia AND prior and/or current androgen

deprivation therapy (ADT) AND office encounter during the measurement period. This is also the initial population.

There is no age cut off for this measure as prostate cancer can affect younger men, although it is a disease that normally occurs after the age of 40. According to the NCCN Prostate Cancer Early Detection guidelines, a cut off at 40 could miss those unfortunate patients who developed the disease in their late 20's and 30's. At the upper end, very healthy men over age 75 may choose to seek more aggressive treatment. Cancer genetics show an increased risk if the patient is a BRCA1/2 pathogenic mutation carrier which can lead to earlier detection of prostate cancers (and other cancers as well). When a family member is diagnosed with prostate cancer, another first degree relative is recommended to be screened at age 40 or 10 years prior to the age of the relative when prostate cancer was discovered, whichever is soonest.

**Exclusions:** Denominator Exclusions are metastatic prostate cancer to the bone OR terminally ill patients on hospice OR osteonecrosis of the jaw OR known hypersensitivity to osteoporosis medications (bisphosphonates or denosumab) OR hypocalcemia until corrected OR history of and/or planned radiation therapy to the jaw OR patient refused osteoporosis medications.

**Adjustment/Stratification:** No risk adjustment or risk stratification. Stratification is not required as this is not an outcome measure. It is a process measure.

**Level of Analysis:** Clinician : Individual

**Setting of Care:** Outpatient Services

**Type of Measure:** Process

**Data Source:** Electronic Health Records

**Measure Steward:** Large Urology Group Practice Association

---

## STANDING COMMITTEE MEETING [02/15/2019]

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

(1a. Evidence: 1b. Performance Gap)

1a. Evidence: **H-0; M-15; L-0; I-2**, 1b. Performance Gap: **H-1; M-16; L-0; I-0**

#### Rationale:

- The Committee initially reviewed this measure during the spring 2018 cycle. At that time, the measure met the Importance criteria; however, the developer withdrew the measure during the Scientific Acceptability discussion to revise the measure specifications as recommended by the Committee ([see spring 2018 cycle report](#)).
- During the spring 2018 cycle, the Committee noted that there was ample evidence that androgen deprivation therapy (ADT) contributes to loss of bone density, which in turn increases risk of bone fracture. The Committee also noted that the evidence underlying the National Comprehensive Cancer Network (NCCN) guideline and citations submitted with the measure appear sufficient to support the measure and link to preferred patient outcomes (i.e., a relationship between initiation of osteoporosis/osteopenia treatment and the bone health of patients with prostate cancer undergoing ADT). The Committee also noted that urologists typically treat early stage prostate cancer patients, who may be less familiar with giving chronic therapies to their early stage patients than physicians who have more experience providing long-term care treatment to patients who present at a general oncology office.
- In the current cycle, the Committee questioned why the measure is specified for men 18 years and older, yet the NCCN guideline focuses on men 50 years and older. The developer responded

that prostate cancer can affect younger men and specifying the measure for 50 years and older could miss younger patients that develop the disease. The Committee agreed the underlying evidence for the measure has not changed since the spring 2018 cycle but asked the measure developer to provide additional evidence to support the younger age range included in the measure specifications.

- During the spring 2018 cycle, while discussing performance gap and disparities, the Committee's discussion included:
  - Inquiring if there is additional data demonstrating that untreated osteoporosis/osteopenia in prostate cancer patients on ADT is a widespread issue across urology practices in the United States.
  - Acknowledging that ordering DEXA (Dual X-ray Absorptiometry) scans is not a normal practice within urology practices because urologists are treating early stage prostate cancer and are administering ADT, but do not typically treat osteoporosis/osteopenia.
  - The importance of this measure, especially when paired with an osteopenia/osteoporosis screening measure.
  - Unless there is a mandated consult to medical oncology--as there might be in large teaching hospital-- it is unlikely that most patients will receive appropriate care (i.e., treatment with bisphosphonates or denosumab) when treated in the community or in local urology practices – this is indicative of a large gap in performance.
- In the previous submission, the developer stated a disparity in care for this condition exists in the treatment between men and women. Providers recognize osteoporosis in women especially with the onset of menopause. On the contrary, providers often overlook secondary osteoporosis in men due to ADT.
- The Committee agreed that the previous information the developer provided is sufficient and the measure still meets the Performance Gap criterion.

---

## **2. Scientific Acceptability of Measure Properties: The measure does not meet the Scientific Acceptability criteria**

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

2a. Reliability: **See rating from Validity** 2b. Validity: **M-1; L-15; I-0**

### Rationale:

- During the spring 2018 cycle, the Committee had a lengthy discussion about the measure specifications, including asking the measure developer to provide multiple clarifications throughout the discussion. The Committee's concerns included the complexity of the measure description, numerator, and denominator as written in the measure submission form. The Committee voiced their support for the measure; however, was reluctant to vote on Scientific Acceptability due to the confusion about the measure specifications. The Committee asked the measure developer to revise the measure specifications, so providers can consistently implement the measure. The measure developer agreed to withdraw the measure from the spring 2018 cycle and revise the measure specifications as recommended.
- In the current cycle (Fall 2018), the Standing Committee evaluated the revised measure specifications and agreed they were less ambiguous, yet still had concerns about the complexity of the measure. The Committee questioned the ability to capture the data elements required to calculate the measure, specifically the multiple numerator and denominator exclusions. The Committee expressed their confusion with the number and type of patients excluded from the numerator and denominator and the overall impact on the performance measure scores.



Numerator exclusions are a specific type of exclusion that can be used in eQMs that have proportion and ratio scoring. eQMs also specify an improvement notation, which indicates whether a higher or lower score indicates better quality. Part of the confusion on whether the measure should use numerator exclusions or denominator exclusions is how the different type of exclusions are impacted by the measure's improvement notation. The Committee encouraged the measure developer to work with Centers for Medicare and Medicaid Services (CMS) to make sure the measures exclusions criteria and improvement notation are aligned. The Committee also questioned how exceptions rather than exclusions would affect the measure.

- NQF requires that eQMs be tested in a minimum of two electronic health records (EHR) to demonstrate reliability and/or validity. The developer met the minimum testing requirement; however, due to a small sample size and the complexity of the measure, the Committee determined the measure does not meet the validity criterion.

---

### **3. Feasibility: Not discussed as the measure did not pass Scientific Acceptability**

*(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)*

---

### **4. Use and Usability: Not discussed as the measure did not pass Scientific Acceptability**

*(4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)*

---

### **5. Related and Competing Measures: Not discussed as the measure did not pass Scientific Acceptability**

- 0390 Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer (American Urological Association)

---

### **6. Standing Committee Recommendation for Endorsement: Not discussed as measure did not pass Scientific Acceptability**

---

### **7. Public and Member Comment**

[NQF did not receive any comments following the Committee's evaluation of the measure.](#)

---

### **8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X**

## Appendix B: Cancer Portfolio—Use in Federal Programs<sup>1</sup>

NQF #	Title	Federal Programs: Finalized or Implemented as of February 25, 2019
0389e	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	Merit-Based Incentive Payment System (MIPS) Program (Implemented), Medicaid Promoting Interoperability Program (Proposed)
0219	Post Breast Conservation Surgery Irradiation	Prospective Payment System-Exempt Cancer Hospital Quality Reporting (Considered)
0220	Adjuvant Hormonal Therapy	Hospital Compare (Implemented)
0223	Adjuvant Chemotherapy is Recommended or Administered Within 4 Months (120 Days) of Diagnosis to Patients Under the Age of 80 with AJCC III (Lymph Node Positive) Colon Cancer	Hospital Compare (Implemented)
0225	At Least 12 Regional Lymph Nodes Are Removed and Pathologically Examined for Resected Colon Cancer	Prospective Payment System-Exempt Cancer Hospital Quality Reporting (Considered)
0377	Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow	MIPS Program (Finalized)
0378	Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy	MIPS Program (Finalized)
0383	Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (paired with 0384)	Hospital Compare (Implemented); Prospective Payment System-Exempt Cancer Hospital Quality Reporting (Implemented); MIPS Program (Finalized)
0384	Oncology: Medical and Radiation - Pain Intensity Quantified	MIPS Program (Finalized), Medicaid Promoting Interoperability Program (Proposed)
0385	Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients	N/A
0386	Oncology: Cancer Stage Documented	N/A
0387	Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer	N/A
0389	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	MIPS Program (Finalized), Medicaid Promoting Interoperability Program (Proposed)
0390	Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer	Hospital Compare (Implemented), Merit-Based Incentive Payment System (MIPS) Program (Finalized)

<sup>1</sup> Per CMS Measures Inventory Tool as of February 25, 2019

NQF #	Title	Federal Programs: Finalized or Implemented as of February 25, 2019
0391	Breast Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade	N/A
0392	Colorectal Cancer Resection Pathology Reporting- pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade	N/A
0508	Diagnostic Imaging: Inappropriate Use of “Probably Benign” Assessment Category in Screening Mammograms	Merit-Based Incentive Payment System (MIPS) Program (Finalized)
0509	Diagnostic Imaging: Reminder System for Screening Mammograms	Merit-Based Incentive Payment System (MIPS) Program (Finalized)
0559	Combination Chemotherapy is Recommended or Administered Within 4 Months (120 Days) of Diagnosis for Women Under 70 with AJCC T1cN0M0, or Stage IB - III Hormone Receptor Negative Breast Cancer	Merit-Based Incentive Payment System (MIPS) Program (Finalized)
1853	Radical Prostatectomy Pathology Reporting	Merit-Based Incentive Payment System (MIPS) Program (Finalized)
1854	Barrett's Esophagus	Merit-Based Incentive Payment System (MIPS) Program (Finalized)
1855	Quantitative HER2 Evaluation by IHC Uses the System Recommended by the ASCO/CAP Guidelines	N/A
1857	HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies	Merit-Based Incentive Payment System (MIPS) Program (Finalized)
1858	Trastuzumab Administered to Patients with AJCC Stage I (T1c) – III and Human Epidermal Growth Factor Receptor 2 (HER2) Positive Breast Cancer Who Receive Adjuvant Chemotherapy	Merit-Based Incentive Payment System (MIPS) Program (Finalized)
1859	KRAS Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer Who Receive Anti-Epidermal Growth Factor Receptor Monoclonal Antibody Therapy	Merit-Based Incentive Payment System (MIPS) Program (Implemented)
1860	Patients with Metastatic Colorectal Cancer and KRAS Gene Mutation Spared Treatment with Anti-Epidermal Growth Factor Receptor Monoclonal Antibodies	Merit-Based Incentive Payment System (MIPS) Program (Finalized)
1878	HER2 Testing for Overexpression or Gene Amplification in Patients with Breast Cancer	N/A
2930	Febrile Neutropenia Risk Assessment Prior to Chemotherapy	Merit-Based Incentive Payment System (MIPS) Program (Considered)

## Appendix C: Cancer Standing Committee and NQF Staff

### STANDING COMMITTEE

**Karen Fields, MD (CO-CHAIR)**

Moffitt Cancer Center  
Tampa, Florida

**Shelley Fuld Nasso, MPP (CO-CHAIR)**

CEO, National Coalition for Cancer Survivorship  
Washington DC

**Gregary Bocsi, DO, FCAP**

University of Colorado Hospital Clinical Laboratory  
Denver, Colorado

**Brent Braveman, Ph.D, OTR/L, FAOTA**

University of Texas M.D. Anderson Cancer Center  
Houston Texas

**Steven Chen, MD, MBA, FACS**

OasisMD  
Duarte, California

**Matthew Facktor, MD, FACS**

Geisinger Medical Center  
Danville, Pennsylvania

**Heidi Floyd**

Patient Advocate  
Washington, District of Columbia

**Bradford Hirsch, MD**

SIGNALPATH  
Raleigh, North Carolina

**Jette Hogenmiller, PhD, MN, APRN/ARNP, CDE, NTP, TNCC, CEE**

Oncology Nurse Practitioner  
Idaho Springs, Colorado

**J. Leonard Lichtenfeld, MD, MACP**

American Cancer Society  
Atlanta, Georgia

**Stephen Lovell, MS**

Seattle Cancer Care Alliance Patient and Advisory Council  
Washington, District of Columbia

**Jennifer Malin, MD, PhD**

Anthem, Inc.  
Thousand Oaks, California

**Jodi Maranchie, MD, FACS**

University of Pittsburgh  
Pittsburgh, Pennsylvania

**Ali McBride, PharmD, MS, BCPS**

The University of Arizona Cancer Center  
Tucson, Arizona

**Benjamin Movsas, MD**

Henry Ford Health System  
Detroit, Michigan

**Diane Otte, RN, MS, OCN**

Mayo Clinic Health System - Franciscan Healthcare  
La Crosse, Wisconsin

**Beverly Reigle, PhD, RN**

University of Cincinnati College of Nursing  
Cincinnati, Ohio

**David J. Sher, MD, MPH**

UT Southwestern Medical Center  
Dallas, Texas

**Danielle Ziernicki, PharmD**

Dedham Group  
New York, New York

**NQF STAFF**

**Elisa Munthali, MPH**

Senior Vice President, Quality Measurement

**Melissa Mariñelarena, RN, MPA, CPHQ**

Senior Director

**Kathryn Goodwin, MS**

Senior Project Manager

**Katherine de Bienassis, MPH**

Senior Project Manager

**Tara Murphy, MPAP**

Project Manager

## Appendix D: Measure Specifications

---

### 0384 Oncology: Medical and Radiation - Pain Intensity Quantified

#### STEWARD

PCPI

#### DESCRIPTION

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

#### TYPE

Process

#### DATA SOURCE

Registry Data

#### LEVEL

Clinician : Group/Practice, Clinician : Individual

#### SETTING

Other, Outpatient Services Oncology/Outpatient Clinic; Radiation Oncology Dept/Clinic

#### NUMERATOR STATEMENT

Patient visits in which pain intensity is quantified

#### NUMERATOR DETAILS

Time Period for Data Collection: At each visit within the measurement period

Guidance: Pain intensity should be quantified using a standard instrument, such as a 0-10 numerical rating scale, visual analog scale, a categorical scale, or pictorial scale. Examples include the Faces Pain Rating Scale and the Brief Pain Inventory (BPI).

The Oncology: Medical and Radiation - Pain Intensity Quantified measure is specified for both registry (this measure) and for EHR (NQF #384e) implementation. The registry version has two submission criteria to capture 1) patients undergoing chemotherapy and 2) patients undergoing radiation therapy, and to align with the specifications for the EHR version of this measure.

For the Submission Criteria 1 and Submission Criteria 2 numerators, report one of the following CPT Category II codes to submit the numerator option for patient visits in which pain intensity was quantified:

1125F: Pain severity quantified; pain present

OR

1126F: Pain severity quantified; no pain present

#### DENOMINATOR STATEMENT

All patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy

## DENOMINATOR DETAILS

Time Period for Data Collection: 12 consecutive months

The registry version has two submission criteria to capture 1) patients undergoing chemotherapy and 2) patients undergoing radiation therapy, and to align with the specifications for the EHR version of this measure.

Guidance: For patients receiving radiation therapy, pain intensity should be quantified at each radiation treatment management encounter where the patient and physician have a face-to-face interaction. Due to the nature of some applicable coding related to the radiation therapy (eg, delivered in multiple fractions), the billing date for certain codes may or may not be the same as the face-to-face encounter date. For patients receiving chemotherapy, pain intensity should be quantified at each face-to-face encounter with the physician while the patient is currently receiving chemotherapy. For purposes of identifying eligible encounters, patients "currently receiving chemotherapy" refers to patients administered chemotherapy within 30 days prior to the encounter AND administered chemotherapy within 30 days after the date of the encounter.

Submission Criteria 1 denominator: Patient visits for patients with a diagnosis of cancer currently receiving chemotherapy

Diagnosis for cancer (ICD-10-CM) - Due to character limitation, please see codes in the attached Excel file in S.2b.

AND

Patient encounter during the performance period (CPT) – to be used to evaluate remaining denominator criteria and for numerator evaluation: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215

WITHOUT

Telehealth Modifier: GQ, GT, 95, POS 02

AND

Patient procedure within 30 days before denominator eligible encounter: 51720, 96401, 96402, 96405, 96406, 96409, 96411, 96413, 96415, 96416, 96417, 96420, 96422, 96423, 96425, 96440, 96446, 96450, 96521, 96522, 96523, 96542, 96549

AND

Patient procedure within 30 days after denominator eligible encounter: 51720, 96401, 96402, 96405, 96406, 96409, 96411, 96413, 96415, 96416, 96417, 96420, 96422, 96423, 96425, 96440, 96446, 96450, 96521, 96522, 96523, 96542, 96549

Submission Criteria 2 denominator: Patient visits for patients with a diagnosis of cancer currently receiving radiation therapy

DENOMINATOR NOTE: For the reporting purposes for this measure, in instances where CPT code 77427 is reported, the billing date, which may or may not be the same date as the face-to-face encounter with the physician, should be used to pull the appropriate patient population into the denominator. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face encounter during the series of treatments.

Diagnosis for cancer (ICD-10-CM) - Due to character limitation, please see codes in the attached Excel file in S.2b.

AND

Patient procedure during the performance period (CPT) – Procedure codes: 77427, 77431, 77432, 77435

#### EXCLUSIONS

None

#### EXCLUSION DETAILS

Not applicable

#### RISK ADJUSTMENT

No risk adjustment or risk stratification

#### STRATIFICATION

Consistent with the CMS Measures Management System Blueprint and recent national recommendations put forth by the IOM and NQF to standardize the collection of race and ethnicity data, we encourage the results of this measure to be stratified by race, ethnicity, administrative sex, and payer.

#### TYPE SCORE

Rate/proportion better quality = higher score

#### ALGORITHM

This measure is comprised of two submission criteria but is intended to result in one reporting rate. The reporting rate is the aggregate of Submission Criteria 1 and Submission Criteria 2, resulting in a single performance rate. For the purposes of this measure, the single performance rate can be calculated as follows:

Performance Rate = (Numerator 1 + Numerator 2)/ (Denominator 1 + Denominator 2)

Calculation algorithm for Submission Criteria 1: Patient visits for patients with a diagnosis of cancer currently receiving chemotherapy

1. Find the patients who meet the initial population (ie, the general group of patients that a set of performance measures is designed to address).
2. From the patients within the initial population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure based on defined criteria). Note: in some cases the initial population and denominator are identical.
3. From the patients within the denominator, find the patients who meet the numerator criteria (ie, the group of patients in the denominator for whom a process or outcome of care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator

If the patient does not meet the numerator, this case represents a quality failure.

Calculation algorithm for Submission Criteria 2: Patient visits for patients with a diagnosis of cancer currently receiving radiation therapy

1. Find the patients who meet the initial population (ie, the general group of patients that a set of performance measures is designed to address).
2. From the patients within the initial population criteria, find the patients who qualify for the denominator (ie, the specific group of patients for inclusion in a specific performance measure



based on defined criteria). Note: in some cases the initial population and denominator are identical.

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

If the patient does not meet the numerator, this case represents a quality failure. 140560| 141015| 143584

#### COPYRIGHT / DISCLAIMER

© 2018 PCPI® Foundation and American Medical Association. All Rights Reserved.

---

## 3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy

### STEWARD

Centers for Medicare and Medicaid Services (CMS)

### DESCRIPTION

The Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Measure, hereafter referred to as the chemotherapy measure, estimates hospital-level, risk-adjusted rates of inpatient admissions or ED visits for cancer patients  $\geq 18$  years of age for at least one of the following diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of hospital-based outpatient chemotherapy treatment. Rates of admission and ED visits are calculated and reported separately.

### TYPE

Outcome

### DATA SOURCE

Claims, Enrollment Data The numerator (outcome), denominator (cohort), and risk factors for this measure are based on Medicare administrative claims and enrollment data.

### LEVEL

Facility

### SETTING

Outpatient Services

### NUMERATOR STATEMENT

This measure involves calculating two mutually exclusive outcomes among cancer patients receiving chemotherapy treatment in a hospital outpatient setting: (1) one or more inpatient admissions for any of the following 10 diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of chemotherapy treatment or (2) one or more ED visits for any of the following 10 diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of chemotherapy treatment. These 10 conditions are potentially preventable through appropriately managed outpatient care. To be counted as an outcome, the qualifying diagnosis on the admission or ED visit claim must be (1) the principal diagnosis or (2) a secondary diagnosis accompanied by a principal diagnosis of cancer.

### NUMERATOR DETAILS

The chemotherapy measure is a risk-adjusted outcome measure and does not have a traditional numerator like a process measure; thus we use this field to define the measured outcomes of interest as this measure separately reports hospital rates of two outcomes: (1) inpatient admission and (2) ED visits.

#### Outcome Definition

The chemotherapy measure has two reported outcomes. The outcomes for this measure are:

(1) one or more inpatient admissions for any of the following 10 diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of chemotherapy treatment, and (2) one or more ED visits without an admission, for one of the 10 following diagnoses—anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis—within 30 days of receiving hospital-based outpatient chemotherapy treatment for cancer. These 10 conditions are potentially preventable through appropriately managed outpatient care.

#### Outcome Identification and Counting

Outcomes are identified using Medicare Part A Inpatient and Part B Outpatient hospital claims. The qualifying diagnosis on the admission or ED visit claim must be (1) the principal diagnosis or (2) a secondary diagnosis accompanied by a principal diagnosis of cancer. The ICD-9 and ICD-10-CM codes that identify these diagnoses are in the 2018 Chemotherapy Measure\_Data Dictionary on sheets “S.6 Numerator-Anemia,” “S.6 Numerator-Dehydration,” “S.6 Numerator-Diarrhea,” “S.6 Numerator-Emesis,” “S.6 Numerator-Fever,” “S.6 Numerator-Nausea,” “S.6 Numerator-Neutropenia,” “S.6 Numerator-Pain,” “S.6 Numerator-Pneumonia,” and “S.6 Numerator-Sepsis.” The ICD-9 codes were used during development and testing of the measure; the Data Dictionary also includes the mapping from these ICD-9 codes to ICD-10 codes.

Inpatient admissions that are considered always planned do not qualify for the measure. Planned admissions are defined as those planned by providers for anticipated medical treatment or procedures that must be provided in the inpatient setting. The measure counts only unplanned admissions in the measure outcome because variation in planned admissions does not reflect quality differences. For the chemotherapy measure, inpatient hospital admissions with the following AHRQ CCS procedures or diagnoses are considered always planned and do not qualify for the measure:

#### Procedures

- 64 – Bone marrow transplant
- 105 – Kidney transplant
- 176 – Other organ transplantation (other than bone marrow corneal or kidney) Diagnoses
- 45 – Maintenance chemotherapy; radiotherapy
- 254 – Rehabilitation care; fitting of prostheses; and adjustment of devices

Outcomes are counted separately for the inpatient admission and ED visit categories; a patient can only qualify for an outcome in either category, but not both. Patients who experience both an inpatient admission and an ED visit during the performance period are counted towards the inpatient admission outcome. Among those with no qualifying inpatient admissions, qualifying ED visits are counted. As a result, the rates can be viewed as additive to provide a comprehensive performance estimate of quality of care following hospital-based outpatient chemotherapy treatment. The rates are calculated separately because the severity and cost of an inpatient admission is different from that of an ED visit, but both adverse events are important signals of quality and represent important outcomes of care.

#### Outcome Time Frame

The measure limits the outcome time frame to the 30 days following the date of each chemotherapy treatment (including the day of treatment) in an outpatient setting for four reasons. First, existing literature suggests the vast majority of adverse events occur within 30 days after treatment [1, 2, 3, 4], indicating that a 30-day period is a reasonable timeframe to observe the side effects of treatment. Second, we observed in our own data that the highest

rates of hospital visits occur within 30 days after chemotherapy treatment. Third, restricting the time period ensures that patients' experiences are attributed to the hospitals that provided their recent treatment while accounting for variations in duration between outpatient treatments. Fourth, relating the time frame to a specific chemotherapy administration supports the idea that the admission stems from the management of side effects of treatment and ongoing care, rather than progression of the disease or other unrelated events.

#### Citations

1. Aprile, G., F.E. Pisa, A. Follador, L. Foltran, F. De Pauli, M. Mazzer, S. Lutrino, C.S. Sacco, M. Mansutti, and G. Fasola. "Unplanned Presentations of Cancer Outpatients: A Retrospective Cohort Study." *Supportive Care in Cancer*, vol. 21, no. 2, 2013, pp. 397–404.
2. Foltran, L., G. Aprile, F.E. Pisa, P. Ermacora, N. Pella, E. Iaiza, E. Poletto, S.E. Lutrino, M. Mazzer, M. Giovannoni, G.G. Cardellino, F. Puglisi, and G. Fasola. "Risk of Unplanned Visits for Colorectal Cancer Outpatients Receiving Chemotherapy: A Case-Crossover Study." *Supportive Care in Cancer*, vol. 22, no. 9, 2014, pp. 2527–2533.
3. McKenzie, H., L. Hayes, K. White, K. Cox, J. Fethney, M. Boughton, and J. Dunn. "Chemotherapy Outpatients' Unplanned Presentations to Hospital: A Retrospective Study." *Supportive Care in Cancer*, vol. 19, no. 7, 2011, pp. 963–969.
4. Oatley, M., M. Fry, and L. Mullen. "A Cross-Sectional Study of the Clinical Characteristics of Cancer Patients Presenting to One Tertiary Referral Emergency Department." *International Emergency Nursing*, vol. 24, 2016, pp. 35 – 38.

#### DENOMINATOR STATEMENT

The measure cohort includes Medicare Fee-for-Service (FFS) patients, aged 18 years and older at the start of the performance period, with a diagnosis of any cancer (except leukemia), who received at least one outpatient chemotherapy treatment at the reporting hospital during the performance period.

#### DENOMINATOR DETAILS

The target population is Medicare Fee-for-Service (FFS) patients aged 18 and older with a diagnosis of cancer receiving chemotherapy treatment in a hospital outpatient setting at any point during the measurement year.

The measure uses the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9) and ICD-10 codes that identify cancer diagnoses. The measure identifies chemotherapy treatment using ICD-9 and ICD-10 procedure and encounter codes; and Current Procedural Terminology (CPT®)/Healthcare Common Procedure Coding System (HCPCS) procedure and medication procedure codes.

Code sets used for cohort identification are attached in the 2018 Chemotherapy Measure\_Data Dictionary on sheets "S.9 Denominator-Cancer," "S.9 Denominator-Chemo Procedure," "S.9 Denominator – Chemo Encounter," and "S.9 Denominator – Chemo Medicine".

#### EXCLUSIONS

The measure excludes the following patients from the cohort:

- 1) Patients with a diagnosis of leukemia at any time during the performance period.
- 2) Patients who were not enrolled in Medicare FFS Parts A and B in the year prior to the any outpatient chemotherapy treatment during the performance period.

- 3) Patients who were not enrolled in Medicare FFS Parts A and B for the 30 days following any chemotherapy treatment.
- 4) Cases in which patients receive chemotherapy to treat conditions other than cancer. Note that this is a case-level exclusion; as long as the patient has additional cases that meet inclusion criteria, they will remain in the cohort.

#### EXCLUSION DETAILS

1) Patients with a diagnosis of leukemia at any time during the performance period – exclusions are identified using the codes listed in the 2018 Chemotherapy Measure Data Dictionary on sheet “S.11 Denominator Exclusion – Leukemia.” If a patient has a claim with any of the diagnosis codes within the code set, at any point during the performance period, they are excluded from the cohort.

Rationale: Patients with leukemia are excluded due to the high toxicity of treatment and recurrence of disease so that admissions do not reflect poorly managed outpatient care for this population. Patients with leukemia have an expected admission rate due to relapse, so including leukemia patients in the cohort could be conceptualized as a planned admission, which does not align with the intent of the measure.

2) Patients who were not enrolled in Medicare FFS Parts A and B in the year prior to any outpatient chemotherapy treatment during the performance period. The Medicare Enrollment database is used to determine if a patient was enrolled in Medicare FFS Parts A and B in the year prior to the first outpatient chemotherapy treatment during the performance period.

Rationale: We exclude these patients to ensure complete patient diagnosis data for the risk-adjustment models, which use the year prior to the chemotherapy treatment during the period to identify comorbidities.

3) Patients who do not have at least one outpatient chemotherapy treatment followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the procedure. The Medicare Enrollment database is used to determine if a patient was enrolled in Medicare FFS Parts A and B in the 30-days after a qualifying outpatient chemotherapy treatment during the performance period.

Rationale: We exclude these patients to ensure full data availability for outcome assessment.

4) Cases in which patients receive chemotherapy to treat conditions other than cancer. If a case includes a chemotherapy procedure code from the “S.11 Denominator Exclusion – ChemoNonCancer” code set, a diagnosis code from the “S.11 Denominator Exclusion - AutoImmuneDiags” code set, and no cancer diagnosis from the “S.9 Denominator-Cancer” code set in any position on the claim, the case is excluded from the cohort. Note that this is a case-level exclusion; as long as the patient has additional cases that meet inclusion criteria, they will remain in the cohort.

Rationale: We exclude these patients because cases where chemotherapy is administered for non-cancer conditions, such as treatment of auto-immune diseases, is not aligned with the measure’s intent. The measure is intended to assess the quality of care provided to cancer patients receiving outpatient chemotherapy.

#### RISK ADJUSTMENT

Statistical risk model

## STRATIFICATION

Not applicable. This measure is not stratified.

## TYPE SCORE

Rate/proportion better quality = lower score

## ALGORITHM

Calculation of the Observed Rate

Denominator

Steps to Identify Cohort

Step 1: Identify all Medicare Fee-for-Service (FFS) patients age 18 and older with a diagnosis of cancer receiving chemotherapy treatment in a hospital outpatient setting during the performance period.

Step 2: Remove all patients with a diagnosis of leukemia at any time during the performance period.

Step 3: Remove all chemotherapy cases that are not preceded by 12 months of Medicare FFS Parts A and B.

Step 4: Remove all chemotherapy cases that are not followed by continuous enrollment in Medicare FFS Parts A and B in the 30 days after the treatment.

Step 5: Remove all cases in which patients receive chemotherapy to treat a qualifying autoimmune condition, rather than to treat cancer. Note that this is a case-level exclusion; as long as the patient has additional cases that meet inclusion criteria, they will remain in the cohort.

Step 6: Identify the unique number of patient-level provider ID/Facility ID combinations for the remaining cases.

Step 7: The remaining unique patients the measure denominator (cohort) at each facility.

Numerator

Steps to Identify Qualifying Inpatient Hospital Admissions and ED Visits

Step 1: Identify the first qualifying outpatient chemotherapy administration for each patient in each facility. [Note: a patient may be included at multiple facilities.]

Step 2: Determine whether that outpatient chemotherapy treatment was followed by either an inpatient hospital admission or ED visit within 30 days with either:

- A primary diagnosis of anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis, or
- A primary diagnosis of cancer and a secondary diagnosis of anemia, dehydration, diarrhea, emesis, fever, nausea, neutropenia, pain, pneumonia, or sepsis

Step 3: Remove any qualifying inpatient admissions with an "always planned" diagnosis or procedure.

Step 4: If a patient had both a qualifying inpatient admission and an ED visit within 30 days, select the inpatient admission.

Step 5: If a patient multiple qualifying inpatient admissions, select the first one.

Step 6: Sum the number of patients in the cohort with an inpatient admission. This is the numerator for the inpatient admissions outcome.

Step 7. Sum the number of patients in the cohort who had an ED visit, but no inpatient admission. This is the numerator for the ED visit outcome.

#### Calculation of the Observed Performance Rate

Calculate the inpatient admissions observed rate by dividing the number of patients with an inpatient hospital admission by the total number of patients in the cohort for a given facility.

Calculate the ED visits observed rate by dividing the number of patients with an ED visit by the total number of patients in the cohort for a given facility.

#### Calculation of the Predicted and Expected Rates

The measure's two-level hierarchical logistic regression model accounts for the clustering of patients within hospitals and variation in sample size. The measure calculates the hospital-specific risk-adjusted rate as the ratio of a hospital's "predicted" number of outcomes to "expected" number of outcomes multiplied by the national observed outcome rate.

- **Predicted Rate:** The measure estimates the predicted number of outcomes for each hospital using the same patient mix, but an estimated hospital-specific intercept. It calculates the predicted number of outcomes for each hospital by summing the predicted probabilities for all patients in the hospital. The measure calculates the predicted probability for each patient through the hierarchical model, which applies the estimated regression coefficients to the observed patient characteristics and adds the hospital-specific intercept.
- **Expected Rate:** This rate estimates the expected number of outcomes for each hospital using the hospital's patient mix and the average hospital-specific intercept (that is, the average intercept among all hospitals in the sample). Operationally, the measure obtains the expected number of outcomes for each hospital by summing the expected probabilities of outcomes for all patients treated at the hospital. It calculates the expected probability of outcomes for each patient via the hierarchical model, which applies the estimated regression coefficients to the observed patient characteristics and adds the average of the hospital-specific intercept.

If a hospital's ratio of predicted to expected outcomes is less than 1, it indicates that the hospital is performing better than expected given its case mix. If a hospital's ratio of predicted to expected outcomes is greater than 1, it indicates that the hospital is performing worse than expected given its case mix. The risk factors included in the Inpatient Admission and ED Visit models are listed below.

#### Inpatient Admission Model Variables

The patient-level risk-adjustment variables are:

1. Age (continuous)
2. Sex (male)
3. Number of Outpatient Chemotherapy Treatments
4. Receipt of Concurrent Radiotherapy
5. Respiratory Disorder
6. Renal Disease
7. Diabetes
8. Other Injuries
9. Metabolic Disorder
10. Gastrointestinal Disorder
11. Psychiatric Disorder

12. Neurological Conditions
13. Cardiovascular Disease
14. Breast Cancer
15. Digestive Cancer
16. Respiratory Cancer
17. Lymphoma
18. Prostate Cancer
19. Secondary Cancer of Lymph Nodes
20. Secondary Cancer of Solid Tumors
21. Other Cancer

#### ED Visits Model Variables

The patient-level risk-adjustment variables are:

1. Age (years above 18, continuous)
2. Sex (male)
3. Number of Outpatient Chemotherapy Treatments
4. Receipt of Concurrent Radiotherapy
5. Respiratory Disorder
6. Other Injuries
7. Gastrointestinal Disorder
8. Psychiatric Disorder
9. Neurological Conditions
10. Cardiovascular Disease
11. Breast Cancer
12. Digestive Cancer
13. Respiratory Cancer
14. Secondary Cancer of Lymph Nodes
15. Secondary Cancer of Solid Tumors
16. Other Cancer

#### Calculation of the Risk-Adjusted Rates

The risk-standardized admissions rate (RSAR) is calculated as the ratio of the number of “predicted” qualifying inpatient admissions to the number of “expected” qualifying inpatient admissions multiplied by the national observed qualifying inpatient admission rate. Similarly, the risk-standardized ED visits rate (RSEDR) is calculated as the ratio of the number of “predicted” qualifying ED visits to the number of “expected” qualifying ED visits multiplied by the national observed qualifying ED visit rate.

For each rate, this approach is analogous to a ratio of “observed” to “expected” outcomes used in other types of statistical analyses. It conceptually allows for a comparison of a particular facility’s performance given its case mix to an average facility’s performance with the same case mix. Thus, a predicted/expected ratio of less than one indicates a lower-than-expected visit rate (or better quality), and a ratio of greater than one indicates a higher-than-expected visit rate (or worse quality). 144249



COPYRIGHT / DISCLAIMER

Not applicable.

## Appendix E1: Related and Competing Measures (tabular version)

### Comparison of 0384, 0209, 1637, 1634

NQF #	0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)	0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment (National Hospice and Palliative Care Organization)	1637 Hospice and Palliative Care -- Pain Assessment (University of North Carolina-Chapel Hill)	1634 Hospice and Palliative Care -- Pain Screening (University of North Carolina-Chapel Hill)
<b>Endorsement Activity</b>	Currently under review in cancer project	Last endorsed 2016	Last endorsed 2016	Last endorsed 2016
<b>Level of Analysis</b>	Clinician: Group/Practice, Individual	Facility	Clinician: Group/Practice, Facility	Clinician: Group/Practice, Facility
<b>Setting</b>	Outpatient	Home Care	Home Care, Inpatient/Hospital	Home Care, Inpatient/Hospital
<b>Data Source</b>	Claims, Paper Medical Records, Registry Data	Instrument-Based Data	Electronic Health Records, Other	Electronic Health Records, Other
<b>Measure Focus</b>	Pain intensity quantified	Comfortable level of pain within 48 hours of assessment	Comprehensive clinical assessment within 24 hours of screening positive for pain	Standardized quantitative tool used to screen for pain during the initial encounter or admission
<b>Target Population</b>	Cancer patients of all ages currently receiving chemotherapy or radiation	Patients with pain at initial assessment	Hospice or palliative care patients with pain on admission and/or initial encounter	Hospice or palliative care patients
<b>Numerator</b>	Patient visits in which pain intensity is quantified	Patients whose pain was brought to a comfortable level (as defined by patient) within 48 hours of initial assessment	Patients who received a comprehensive clinical assessment to determine the severity, etiology and impact of their pain within 24 hours of screening positive for pain	Patients who are screened for the presence or absence of pain (and if present, rating of its severity) using a standardized quantitative tool during the admission evaluation for hospice/initial encounter for palliative care

NQF #	0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)	0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment (National Hospice and Palliative Care Organization)	1637 Hospice and Palliative Care -- Pain Assessment (University of North Carolina-Chapel Hill)	1634 Hospice and Palliative Care -- Pain Screening (University of North Carolina-Chapel Hill)
<b>Denominator</b>	All patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy	Patients who replied "yes" when asked if they were uncomfortable because of pain at the initial assessment	Patients enrolled in hospice OR receiving specialty palliative care in an acute hospital setting who report pain when pain screening is done on the admission evaluation / initial encounter	Patients enrolled in hospice OR patients receiving specialty palliative care in an acute hospital setting
<b>Exclusions</b>	None	Patients who do not report being uncomfortable because of pain at initial assessment Patients under 18 years of age Patients who cannot self report pain Patients who are unable to understand the language of the person asking the initial and follow up questions	Patients with length of stay < 1 day in palliative care. Patients who screen negative for pain are excluded from the denominator	Patients with length of stay < 1 day in palliative care

## Comparison of 0384 and 1628

NQF #	0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)	1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits (RAND)
<b>Endorsement Activity</b>	Currently under review in cancer project	Last endorsed 2016 (scheduled to be reviewed by Geriatrics and Palliative Care in 2020)
<b>Level of Analysis</b>	Clinician: Group/Practice, Individual	Facility, Health Plan, Integrated Delivery System
<b>Setting</b>	Outpatient	Outpatient
<b>Data Source</b>	Claims, Paper Medical Records, Registry Data	Electronic Health Records, Paper Medical Records, Registry Data
<b>Measure Focus</b>	Pain intensity quantified	Standardized quantitative tool used to screen for pain
<b>Target Population</b>	Cancer patients of all ages currently receiving chemotherapy or radiation	Adult patients with advanced cancer
<b>Numerator</b>	Patient visits in which pain intensity is quantified	Outpatient visits from the denominator in which the patient was screened for pain (and if present, severity noted) with a quantitative standardized tool
<b>Denominator</b>	All patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy	Adult patients with advanced cancer who have at least 1 primary care or cancer-related/specialty outpatient visit
<b>Exclusions</b>	None	None (other than those patients noted in 2a1.7. who did not survive at least 30 days after cancer diagnosis)

## Comparison of 0384, 0383, 0420

NQF #	0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)	0383 Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (paired with 0384) (ASCO)	0420 Pain Assessment and Follow-Up (CMS)
<b>Endorsement Activity</b>	Currently under review in cancer project	Last endorsed 2012 (scheduled to be reviewed by Cancer in Fall 2019)	Last endorsed 2016 (scheduled to be reviewed by Geriatrics and Palliative Care in Fall 2019)
<b>Level of Analysis</b>	Clinician: Group/Practice, Individual	Clinician: Group/Practice, Individual	Clinician: Group/Practice, Individual
<b>Setting</b>	Outpatient	Outpatient	Outpatient
<b>Data Source</b>	Claims, Paper Medical Records, Registry Data	Claims, Electronic Health Records, Other, Paper Medical Records, Registry Data	Claims, Paper Medical Records
<b>Measure Focus</b>	Pain intensity quantified	Documented plan of care to address pain	Documented pain assessment using standardized tool(s) AND follow-up plan (when pain present)
<b>Target Population</b>	Cancer patients of all ages currently receiving chemotherapy or radiation	Cancer patients of all ages currently receiving chemotherapy or radiation therapy who have pain	Patients 18 and older
<b>Numerator</b>	Patient visits in which pain intensity is quantified	Patient visits that included a documented plan of care to address pain	Patient visits with a documented pain assessment using a standardized tool(s) AND documentation of a follow-up plan when pain is present
<b>Denominator</b>	All patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy	All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain	All visits for patients aged 18 years and older

NQF #	0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)	0383 Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (paired with 0384) (ASCO)	0420 Pain Assessment and Follow-Up (CMS)
Exclusions	None	None	1)Pain assessment NOT documented as being performed, documentation the patient is not eligible for a pain assessment using a standardized tool 2) Not Eligible – A patient is not eligible if one or more of the following reason(s) is documented: Severe mental and/or physical incapacity where the person is unable to express himself/herself in a manner understood by others. For example, cases where pain cannot be accurately assessed through use of nationally recognized standardized pain assessment tools. Patient is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the patient’s health status.

## Comparison of 3490 and 3188

NQF #	3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy (CMS)	3188 30 Day Unplanned Readmissions for Cancer Patients (Seattle Cancer Care Alliance)
<b>Endorsement Activity</b>	Currently under review in cancer project	Endorsed in Readmissions Project (July 2017)
<b>Level of Analysis</b>	Facility	Facility
<b>Setting</b>	Outpatient Services	Inpatient; Hospital
<b>Data Source</b>	Claims; Enrollment Data	Claims
<b>Measure Focus</b>	One or more inpatient admissions and/or ED visits (for any of the 10 potentially preventable conditions) within 30 days of chemotherapy treatment	Unplanned emergency/urgent readmissions to a short-term acute care hospital within 30 days of discharge
<b>Target Population</b>	Medicare FFS cancer patients 18 and over receiving outpatient chemotherapy treatment who received chemotherapy at least once at the reporting hospital	Medicare FFS patients 18 and over discharged from an acute care hospital with a discharge diagnosis of malignant cancer
<b>Numerator</b>	Calculate two mutually exclusive outcomes: (1) one or more inpatient admissions and (2) one or more ED visits – for any of the 10 potentially preventable conditions – within 30 days of chemotherapy treatment. To be counted as an outcome, the qualifying diagnosis on the admission or ED visit claim must be (1) the principal diagnosis or (2) a secondary diagnosis accompanied by a principal diagnosis of cancer.	The numerator includes all eligible unplanned readmissions to any short-term acute care hospital—defined as admission to a PPS-Exempt Cancer Hospital (PCH), a short-term acute care Prospective Payment (PPS) hospital, or Critical Access Hospital (CAH)—within 30 days of the discharge date from an index admission that is included in the measure denominator.
<b>Denominator</b>	Medicare Fee-for-Service (FFS) patients, aged 18 years and older at the start of the performance period, with a diagnosis of any cancer (except leukemia), who received at least one outpatient chemotherapy treatment at the reporting hospital during the performance period.	Inpatient admissions for all adult Fee-for-Service Medicare beneficiaries where the patient is discharged from a short-term acute care hospital (PCH, short-term acute care PPS hospital, or CAH) with a principal or secondary diagnosis (i.e., not admitting diagnosis) of malignant cancer within the defined measurement period.

NQF #	3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy (CMS)	3188 30 Day Unplanned Readmissions for Cancer Patients (Seattle Cancer Care Alliance)
<b>Exclusions</b>	<ol style="list-style-type: none"> <li>1) Diagnosis of leukemia at any time during the performance period</li> <li>2) Not enrolled in Medicare FFS Parts A and B in the year prior to the any outpatient chemotherapy treatment during the performance period</li> <li>3) Not enrolled in Medicare FFS Parts A and B for the 30 days following any chemotherapy treatment</li> <li>4) Cases in which patients receive chemotherapy to treat conditions other than cancer</li> </ol>	<ol style="list-style-type: none"> <li>1) Less than 18 years of age</li> <li>2) Patients who died during the index admission</li> <li>3) Patients discharged AMA</li> <li>4) Patients transferred to another acute care hospital during the index admission</li> <li>5) Patients discharged with a planned readmission;</li> <li>6) Patients having missing or incomplete data</li> <li>7) Patients not admitted to an inpatient bed</li> </ol>



## Appendix E2: Related and Competing Measures (narrative version)

### Comparison of 0384, 0209, 1637, 1634

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

0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment (National Hospice and Palliative Care Organization)

1637 Hospice and Palliative Care -- Pain Assessment (University of North Carolina-Chapel Hill)

1634 Hospice and Palliative Care -- Pain Screening (University of North Carolina-Chapel Hill)

#### *Endorsement Activity*

##### **0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Currently under review in cancer project

##### **0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment (National Hospice and Palliative Care Organization)**

Last endorsed 2016

##### **1637 Hospice and Palliative Care -- Pain Assessment (University of North Carolina-Chapel Hill)**

Last endorsed 2016

##### **1634 Hospice and Palliative Care -- Pain Screening (University of North Carolina-Chapel Hill)**

Last endorsed 2016

#### *Level of Analysis*

##### **0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Clinician: Group/Practice, Individual

##### **0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment (National Hospice and Palliative Care Organization)**

Facility

##### **1637 Hospice and Palliative Care -- Pain Assessment (University of North Carolina-Chapel Hill)**

Clinician: Group/Practice, Facility

##### **1634 Hospice and Palliative Care -- Pain Screening (University of North Carolina-Chapel Hill)**

Clinician: Group/Practice, Facility

#### *Setting*

##### **0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Outpatient

##### **0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment (National Hospice and Palliative Care Organization)**

Home Care

##### **1637 Hospice and Palliative Care -- Pain Assessment (University of North Carolina-Chapel Hill)**

Home Care, Inpatient/Hospital

**1634 Hospice and Palliative Care -- Pain Screening (University of North Carolina-Chapel Hill)**  
Home Care, Inpatient/Hospital

*Data Source*

**0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**  
Claims, Paper Medical Records, Registry Data

**0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment (National Hospice and Palliative Care Organization)**  
Instrument-Based Data

**1637 Hospice and Palliative Care -- Pain Assessment (University of North Carolina-Chapel Hill)**  
Electronic Health Records, Other

**1634 Hospice and Palliative Care -- Pain Screening (University of North Carolina-Chapel Hill)**  
Electronic Health Records, Other

*Measure Focus*

**0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**  
Pain intensity quantified

**0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment (National Hospice and Palliative Care Organization)**  
Comfortable level of pain within 48 hours of assessment

**1637 Hospice and Palliative Care -- Pain Assessment (University of North Carolina-Chapel Hill)**  
Comprehensive clinical assessment within 24 hours of screening positive for pain

**1634 Hospice and Palliative Care -- Pain Screening (University of North Carolina-Chapel Hill)**  
Standardized quantitative tool used to screen for pain during the initial encounter or admission

*Target Population*

**0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**  
Cancer patients of all ages currently receiving chemotherapy or radiation

**0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment (National Hospice and Palliative Care Organization)**  
Patients with pain at initial assessment

**1637 Hospice and Palliative Care -- Pain Assessment (University of North Carolina-Chapel Hill)**  
Hospice or palliative care patients with pain on admission and/or initial encounter

**1634 Hospice and Palliative Care -- Pain Screening (University of North Carolina-Chapel Hill)**  
Hospice or palliative care patients

*Numerator*

**0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**  
Patient visits in which pain intensity is quantified

**0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment (National Hospice and Palliative Care Organization)**

Patients whose pain was brought to a comfortable level (as defined by patient) within 48 hours of initial assessment

**1637 Hospice and Palliative Care -- Pain Assessment (University of North Carolina-Chapel Hill)**

Patients who received a comprehensive clinical assessment to determine the severity, etiology and impact of their pain within 24 hours of screening positive for pain

**1634 Hospice and Palliative Care -- Pain Screening (University of North Carolina-Chapel Hill)**

Patients who are screened for the presence or absence of pain (and if present, rating of its severity) using a standardized quantitative tool during the admission evaluation for hospice/initial encounter for palliative care

*Denominator*

**0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

All patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy

**0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment (National Hospice and Palliative Care Organization)**

Patients who replied "yes" when asked if they were uncomfortable because of pain at the initial assessment

**1637 Hospice and Palliative Care -- Pain Assessment (University of North Carolina-Chapel Hill)**

Patients enrolled in hospice OR receiving specialty palliative care in an acute hospital setting who report pain when pain screening is done on the admission evaluation / initial encounter

**1634 Hospice and Palliative Care -- Pain Screening (University of North Carolina-Chapel Hill)**

Patients enrolled in hospice OR patients receiving specialty palliative care in an acute hospital setting

*Exclusions*

**0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

None

**0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment (National Hospice and Palliative Care Organization)**

Patients who do not report being uncomfortable because of pain at initial assessment

Patients under 18 years of age

Patients who cannot self report pain

Patients who are unable to understand the language of the person asking the initial and follow up questions

**1637 Hospice and Palliative Care -- Pain Assessment (University of North Carolina-Chapel Hill)**

Patients with length of stay

< 1 day in palliative care. Patients who screen negative for pain are excluded from the denominator

**1634 Hospice and Palliative Care -- Pain Screening (University of North Carolina-Chapel Hill)**

Patients with length of stay

< 1 day in palliative care

## Comparison of 0384 and 1628

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

1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits (RAND)

### *Endorsement Activity*

**0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Currently under review in cancer project

**1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits (RAND)**

Last endorsed 2016 (scheduled to be reviewed by Geriatrics and Palliative Care in 2020)

### *Level of Analysis*

**0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Clinician: Group/Practice, Individual

**1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits (RAND)**

Facility, Health Plan, Integrated Delivery System

### *Setting*

**0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Outpatient

**1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits (RAND)**

Outpatient

### *Data Source*

**0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Claims, Paper Medical Records, Registry Data

**1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits (RAND)**

Electronic Health Records, Paper Medical Records, Registry Data

### *Measure Focus*

**0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Pain intensity quantified

**1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits (RAND)**

Standardized quantitative tool used to screen for pain

### *Target Population*

**0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Cancer patients of all ages currently receiving chemotherapy or radiation

**1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits (RAND)**

Adult patients with advanced cancer

### *Numerator*

#### **0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Patient visits in which pain intensity is quantified

#### **1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits (RAND)**

Outpatient visits from the denominator in which the patient was screened for pain (and if present, severity noted) with a quantitative standardized tool

### *Denominator*

#### **0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

All patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy

#### **1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits (RAND)**

Adult patients with advanced cancer who have at least 1 primary care or cancer-related/specialty outpatient visit

### *Exclusions*

#### **0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

None

#### **1628 Patients with Advanced Cancer Screened for Pain at Outpatient Visits (RAND)**

None (other than those patients noted in 2a1.7. who did not survive at least 30 days after cancer diagnosis)

## Comparison of 0384, 0383, 0420

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

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

0420 Pain Assessment and Follow-Up (CMS)

### *Endorsement Activity*

#### **0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Currently under review in cancer project

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

Last endorsed 2012 (scheduled to be reviewed by Cancer in Fall 2019)

#### **0420 Pain Assessment and Follow-Up (CMS)**

Last endorsed 2016 (scheduled to be reviewed by Geriatrics and Palliative Care in Fall 2019)

### *Level of Analysis*

#### **0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Clinician: Group/Practice, Individual

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

Clinician: Group/Practice, Individual

#### **0420 Pain Assessment and Follow-Up (CMS)**

Clinician: Group/Practice, Individual

### *Setting*

#### **0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Outpatient

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

Outpatient

#### **0420 Pain Assessment and Follow-Up (CMS)**

Outpatient

### *Data Source*

#### **0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Claims, Paper Medical Records, Registry Data

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

Claims, Electronic Health Records, Other, Paper Medical Records, Registry Data

**0420 Pain Assessment and Follow-Up (CMS)**

Claims, Paper Medical Records

*Measure Focus*

**0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Pain intensity quantified

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

Documented plan of care to address pain

**0420 Pain Assessment and Follow-Up (CMS)**

Documented pain assessment using standardized tool(s) AND follow-up plan (when pain present)

*Target Population*

**0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Cancer patients of all ages currently receiving chemotherapy or radiation

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

Cancer patients of all ages currently receiving chemotherapy or radiation therapy who have pain

**0420 Pain Assessment and Follow-Up (CMS)**

Patients 18 and older

*Numerator*

**0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

Patient visits in which pain intensity is quantified

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

Patient visits that included a documented plan of care to address pain

**0420 Pain Assessment and Follow-Up (CMS)**

Patient visits with a documented pain assessment using a standardized tool(s) AND documentation of a follow-up plan when pain is present

*Denominator*

**0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

All patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy

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

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



#### **0420 Pain Assessment and Follow-Up (CMS)**

All visits for patients aged 18 years and older

#### *Exclusions*

#### **0384 Oncology: Medical and Radiation - Pain Intensity Quantified (paired with 0383) (PCPI)**

None

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

None

#### **0420 Pain Assessment and Follow-Up (CMS)**

1) Pain assessment NOT documented as being performed, documentation the patient is not eligible for a pain assessment using a standardized tool 2) Not Eligible – A patient is not eligible if one or more of the following reason(s) is documented: Severe mental and/or physical incapacity where the person is unable to express himself/herself in a manner understood by others. For example, cases where pain cannot be accurately assessed through use of nationally recognized standardized pain assessment tools. Patient is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the patient's health status.

## Comparison of 3490 and 3188

3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy (CMS)

3188 30 Day Unplanned Readmissions for Cancer Patients (Seattle Cancer Care Alliance)

### *Endorsement Activity*

#### **3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy (CMS)**

Currently under review in cancer project

#### **3188 30 Day Unplanned Readmissions for Cancer Patients (Seattle Cancer Care Alliance)**

Endorsed in Readmissions Project (July 2017)

### *Level of Analysis*

#### **3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy (CMS)**

Facility

#### **3188 30 Day Unplanned Readmissions for Cancer Patients (Seattle Cancer Care Alliance)**

Facility

### *Setting*

#### **3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy (CMS)**

Outpatient Services

#### **3188 30 Day Unplanned Readmissions for Cancer Patients (Seattle Cancer Care Alliance)**

Inpatient; Hospital

### *Data Source*

#### **3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy (CMS)**

Claims; Enrollment Data

#### **3188 30 Day Unplanned Readmissions for Cancer Patients (Seattle Cancer Care Alliance)**

Claims

### *Measure Focus*

#### **3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy (CMS)**

One or more inpatient admissions and/or ED visits (for any of the 10 potentially preventable conditions) within 30 days of chemotherapy treatment

#### **3188 30 Day Unplanned Readmissions for Cancer Patients (Seattle Cancer Care Alliance)**

Unplanned emergency/urgent readmissions to a short-term acute care hospital within 30 days of discharge

## *Target Population*

### **3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy (CMS)**

Medicare FFS cancer patients 18 and over receiving outpatient chemotherapy treatment who received chemotherapy at least once at the reporting hospital

### **3188 30 Day Unplanned Readmissions for Cancer Patients (Seattle Cancer Care Alliance)**

Medicare FFS patients 18 and over discharged from an acute care hospital with a discharge diagnosis of malignant cancer

## *Numerator*

### **3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy (CMS)**

Calculate two mutually exclusive outcomes: (1) one or more inpatient admissions and (2) one or more ED visits – for any of the 10 potentially preventable conditions – within 30 days of chemotherapy treatment. To be counted as an outcome, the qualifying diagnosis on the admission or ED visit claim must be (1) the principal diagnosis or (2) a secondary diagnosis accompanied by a principal diagnosis of cancer.

### **3188 30 Day Unplanned Readmissions for Cancer Patients (Seattle Cancer Care Alliance)**

The numerator includes all eligible unplanned readmissions to any short-term acute care hospital—defined as admission to a PPS-Exempt Cancer Hospital (PCH), a short-term acute care Prospective Payment (PPS) hospital, or Critical Access Hospital (CAH)—within 30 days of the discharge date from an index admission that is included in the measure denominator.

## *Denominator*

### **3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy (CMS)**

Medicare Fee-for-Service (FFS) patients, aged 18 years and older at the start of the performance period, with a diagnosis of any cancer (except leukemia), who received at least one outpatient chemotherapy treatment at the reporting hospital during the performance period.

### **3188 30 Day Unplanned Readmissions for Cancer Patients (Seattle Cancer Care Alliance)**

Inpatient admissions for all adult Fee-for-Service Medicare beneficiaries where the patient is discharged from a short-term acute care hospital (PCH, short-term acute care PPS hospital, or CAH) with a principal or secondary diagnosis (i.e., not admitting diagnosis) of malignant cancer within the defined measurement period.

## *Exclusions*

### **3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy (CMS)**

- 1) Diagnosis of leukemia at any time during the performance period
- 2) Not enrolled in Medicare FFS Parts A and B in the year prior to the any outpatient chemotherapy treatment during the performance period

- 3) Not enrolled in Medicare FFS Parts A and B for the 30 days following any chemotherapy treatment
- 4) Cases in which patients receive chemotherapy to treat conditions other than cancer

**3188 30 Day Unplanned Readmissions for Cancer Patients (Seattle Cancer Care Alliance)**

- 1) Less than 18 years of age
- 2) Patients who died during the index admission
- 3) Patients discharged AMA
- 4) Patients transferred to another acute care hospital during the index admission
- 5) Patients discharged with a planned readmission;
- 6) Patients having missing or incomplete data
- 7) Patients not admitted to an inpatient bed

## Appendix F: Pre-Evaluation Comments

Comments received as of January 30, 2018

### 3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy

Submitted by Dr. Claudia A. Salzberg, PhD, Federation of American Hospitals

The Federation of American Hospitals (FAH) appreciates the opportunity to comment on this measure prior to the Standing Committee's evaluation. While FAH agrees with the potential for this measure to support quality improvement efforts, we have several concerns regarding the measure and its intended use for accountability purposes.

The FAH questions why an assessment of similarity (some kind of analysis of variance or inter-class reliability) between the two groups (PPS-exempt cancer hospitals and non-cancer hospitals) was not made. For example, the risk-standardized admissions rate was 0.3116 lower for non-cancer hospitals and the risk-standardized emergency department visit rate was 0.3932 less than the PPS-exempt cancer hospitals at the 25<sup>th</sup> percentile. It is not clear whether these differences indicate whether there are group level effects that impact the measure. FAH understands it is important to account for the effects of clusters and whether there are differences in the repeatability of the measure. A difference which may suggest whether additional review is needed to determine if further refinements should be made to the measure to enable similar findings across the two distinct groups.

In addition, the FAH was disappointed to see that the risk adjustment model continues to include the identification and testing of social risk factors as supplementary. Given that this is a new measure, it provided an opportunity for the measure developer to include these factors within the testing of the model rather than the previous approach of "adding on" factors after the model is developed. This type of approach would assist hospitals and others in understanding how their inclusion could impact the model and provide additional information for groups examining this issue such as the NQF and Office of the Assistant Secretary for Planning and Evaluation.

As a result, the FAH does not believe that this measure is not appropriate for use for accountability purposes and lacks sufficient information on the social risk factors in the risk adjustment approach. FAH does not support endorsement of this measure at this time. The FAH thanks you for the opportunity to comment.

### 3490 Admission and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy

Submitted by Mr. Thomas W. Ross, Alliance of Dedicated Cancer Centers

The Alliance of Dedicated Cancer Centers (ADCC) represents the premier cancer centers in the nation, all of whom participate in the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Unlike other hospitals that care for patients suffering from any condition, the Dedicated Cancer Centers treat cancer patients exclusively. Much of the progress in understanding cancer's biology and successful

treatment methods is directly attributable to the work of ADCC members. Our institutions are at the forefront of innovative treatment options in precision medicine, immunotherapies, and other state of the art diagnostic and patient care technologies. The Dedicated Cancer Centers are committed to delivering the highest standard of cancer care and share the Centers for Medicare & Medicaid Services' (CMS) focus on cancer care delivery that is safe, effective, high-quality, and patient-centered. We are committed to achieving the best outcomes for our patients through novel therapies and excellent care delivery. Our members serve as regional, national, and international resources in developing the most effective and efficient ways to treat cancer patients.

We had provided extensive comment to the measure developer after the official dry run of this measure was conducted in Fall 2017. Furthermore, several members of the Expert Work Group (EWG) formed to respond to the findings of this dry run were from ADCC member institutions. This resulted in the updated measure specifications that are currently being reviewed in this review cycle by the NQF. Unfortunately, as the measure steward has disclosed in the materials submitted, these updated measure specifications were not used to produce the most recent measure results that CMS shared with the PCHQR program participants. Thus, we are limited in our ability to comment on the proposed updated specifications. According to the measure developer, it is anticipated that the ADCC members will receive data using the revised specifications in the Summer of 2019.

With that caveat in mind, we offer the following input pertaining to this measure based upon a review of the new technical specifications, and a review of the data received in the Fall of 2019 from CMS.

#### Denominator Validation of Patients Who Received Chemotherapy:

- Past analysis revealed that for 5-7% of patients included in the denominator, the date of administration of the outpatient chemotherapy could not be confirmed. This issue was identified in the latest round of Facility-Specific Reports (FSRs) as well. If the updated specifications include removal of the ICD-10 code Z51.11, that may reduce the number of cases in which patients who did not actually receive chemotherapy are included in the denominator, as will the exclusion of cases with AHQR CCS codes for bone marrow transplant and chemotherapy.
- We continue to identify cases in which patients received biologic response modifiers and hormonal or supportive care agents but no chemotherapy, and strongly recommend chemotherapy specifications be further updated to exclude medications such as BCG, degarelix, goserelin, mesna, leuprolide and histrelin.

#### Numerator Validation

- Patients Whose Admission Was Planned, Not the Result of an Adverse Event Associated with Chemotherapy: We identified a number of cases in which patients who had planned admissions (such as surgery after neo-adjuvant therapy, stem cell transplantation, and CAR-T cell therapy) were included in the numerator. We anticipate the inclusion of the AHRQ CCS exclusion codes will reduce the number of cases in which planned admissions are included in the numerator. In addition, or alternatively, we also recommend the specifications take into account whether an admission is coded as "elective" (classification "3" on UB-04) to further reduce the number of planned admissions included erroneously in the numerator.

- **Patients Admitted for Reasons Other Than Adverse Events from Chemotherapy:** Several of the Dedicated Cancer Centers conducted chart and/or clinical reviews to ascertain whether potentially preventable diagnoses were reasonably attributable to the chemotherapy. These Centers identified multiple instances in which the potentially preventable diagnosis, particularly pain, was attributed to factors other than chemotherapy, such as disease progression including pericardial effusion, bladder rupture, or cord compression. One solution to better capture symptoms related to prior chemotherapy administration is to incorporate Present on Admission (POA) codes. We proposed this update in our comments to the proposed Final Rule and we understand the measure developer was receptive to this recommendation. Nevertheless, we were disappointed to learn that these updated specifications do not consider whether the qualifying symptoms are present on admission.
- As noted in the CMS Measure Dry Run Facility Specific Report (FSR) User Guide for Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy document released in August 2017, the goal of the measures is to stimulate efforts “to improve the quality of care delivered to patients undergoing chemotherapy in the hospital outpatient department (HOPD).” Therefore, attribution of these adverse events to the chemotherapy is a critical component of the measure. This point is reinforced under question #22 in the CMS Measure Dry Run Frequently Asked Questions (FAQs) for Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy document released in August 2017, which states “...relating the time frame to a specific chemotherapy administration supports the idea that the admission stems from the management of side effects of treatment and ongoing care, rather than progression of the disease or other unrelated events.” Furthermore, question #33 notes that “facilities that provide outpatient chemotherapy should proactively implement appropriate care to minimize the need for acute hospital care for these adverse events. Guidelines from the American Society of Clinical Oncology, National Comprehensive Cancer Network...and other professional societies recommend evidence-based interventions to prevent and treat common side effects and complications of chemotherapy.” In light of the intent of these measures, we strongly recommend that the measures be further refined to capture accurately side effects and complications of the outpatient chemotherapy accurately, and distinguish from the effects of the cancer in general.
- Another potential to consider to reduce the excessive noise of adverse events that are not under the control of the clinical team caring for the patient receiving outpatient chemotherapy would be to exclude those patients with metastatic disease. Patients with metastatic disease have more advanced and/or aggressive disease and may in fact present with adverse events not associated with the outpatient chemotherapy.
- Existing code sets are limited in their ability to identify adverse events resulting from chemotherapy. Although the add-on adverse effect chemotherapy code T451X5A can be used to indicate instances in which a condition is chemotherapy-related, it is not possible to identify which specific condition occurred as a result of the chemotherapy when multiple conditions are listed. Given the current lack of specificity of codes available, the ADCC submitted a suggestion for a more durable and sustainable solution in their July 2017 letter to the ICD-10 Coordination and Maintenance Committee, recommending that additional ICD-10-CM diagnosis codes be created that specifically identify diagnoses related to chemotherapy to improve CMS quality measure reporting.

#### Limitations to Risk Adjustment:

Although numerous factors are taken into consideration in the risk adjustment model for this measure, basic cancer-specific factors, such as the cytotoxicity of chemotherapy regimens and disease stage of

patients, are not included. The absence of these factors in the risk adjustment is concerning within the context of the PCHQR Program; this absence poses a particularly serious limitation in the risk adjustment method used in the Hospital Outpatient Quality Reporting Program, given the variation in patient populations across the hospitals included in that program. In the absence of adequate risk adjustment, public reporting of these measures in both Programs could lead to inaccurate benchmark comparisons. An example of this are myeloma and lymphoma patients, who oftentimes have aggressive conditioning regimens.

We thank you for this opportunity to comment. While we are supportive of the intent of this measure to reduce potentially preventable harm and associated costs, at this time we cannot support endorsement. We strongly recommend further testing of the improved measure specifications in the cancer-hospital setting. We also strongly encourage adding the requirement that the adverse events be POA to be included in the numerator and the exclusions for planned readmissions be expanded to include all elective admissions. We also ask that consideration be given to the exclusion of patients with metastatic disease. As currently tested, there are too many “false positives” attributed to the numerator, making productive performance improvement efforts difficult. We are happy to continue to offer supportive guidance to CMS and their partners in the further refinement of this measure.



National Quality Forum  
1030 15th St NW, Suite 800  
Washington, DC 20005  
<http://www.qualityforum.org>

ISBN  
©2019 National Quality Forum