



# NATIONAL QUALITY FORUM

Driving measurable health  
improvements together

## Memo

July 28, 2020

**To:** Consensus Standards Approval Committee (CSAC)

**From:** Cancer Project Team

**Re:** Cancer Fall 2019, Track 1 Measures

### COVID-19 Updates

With the recent COVID-19 global pandemic, many organizations needed to focus their attention on the public health crisis. To provide greater flexibility for stakeholders and continue the important work in quality measurement, the National Quality Forum (NQF) extended commenting periods and adjusted measure endorsement timelines for the Fall 2019 cycle.

Commenting periods for all measures evaluated in the Fall 2019 cycle were extended from 30 days to 60 days. Based on the comments received during this 60-day extended commenting period, measures entered one of two tracks:

#### **Track 1: Measures Continuing in Fall 2019 Cycle**

**Measures that did not receive public comments or only received comments in support of the Standing Committees' recommendations** will be reviewed by the CSAC on July 28–29.

- **Exceptions**

Exceptions were granted to measures if non-supportive comments received during the extended post-comment period were similar to those received during the pre-evaluation meeting period and were already adjudicated by the respective Standing Committees during the measure evaluation Fall 2019 meetings.

#### **Track 2: Measures Deferred to Spring 2020 Cycle**

**Fall 2019 measures requiring further action or discussion from a Standing Committee were deferred to the Spring 2020 cycle.** This includes measures where consensus was not reached or those that require a response to Member and public comments. Measures undergoing maintenance review retain endorsement during this time. Track 2 measures will be reviewed during the CSAC's meeting in November 2020.

During the CSAC meeting on July 28-29, the CSAC will review Fall 2019 measures assigned to Track 1. Evaluation summaries for measures in track 1 have been described in this memo and related Cancer draft report. A list of measures assigned to Track 2 can be found in the Executive Summary section of the Cancer draft report for tracking purposes and will be described further in a subsequent report. Measures in track 2 will be reviewed by the CSAC on November 17-18, 2020.

### CSAC Action Required

The CSAC will review recommendations from the Cancer, Track 1 project at its July 28 - 29, 2020 meeting and vote on whether to uphold the recommendations from the Committee.

<http://www.qualityforum.org>

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 2019, Track 1 Draft Report. The draft report includes measure evaluation details on all measures that followed Track 1. Measures that followed Track 2 will be reviewed during the CSAC's meeting in November. The complete draft report and supplemental materials are available on the project webpage.
2. This table lists seven comments received during the post-meeting comment period. [Comment Table](#). This table lists comments received during the post-meeting comment period.

## Background

Cancer is the second most common cause of death in the U.S., exceeded only by heart disease.<sup>1</sup> NCI estimated that in 2018, 1.7 million new cases of cancer would 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. NCI 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>

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 cancer care for patients and their families.

The Cancer Standing Committee oversees NQF's portfolio of Cancer measures that includes measures for hematology, breast cancer, colon cancer, prostate cancer, and other cancer measures. This portfolio contains 20 measures: 19 process measures, and 1 outcome and resource use measure. 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.

## Draft Report

The Cancer, Track 1 draft report presents the results of the evaluation of six measures considered under the Consensus Development Process (CDP). Six are recommended for endorsement.

The measures were evaluated against the 2019 version of the [measure evaluation criteria](#).

	Maintenance	New	Total
Measures under consideration	6	0	6
Measures recommended for endorsement	6	0	6

## CSAC Action Required

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

## Measures Recommended for Endorsement

- [NQF 0219](#) Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer (Commission on Cancer, American College of Surgeons)

Overall Suitability for Endorsement: Y-15; N-0

- [NQF 0220](#) Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer (Commission on Cancer, American College of Surgeons)

Overall Suitability for Endorsement: Y-16; N-0

- [NQF 0383](#) Oncology: Medical and Radiation - Plan of Care for Pain (ASCO)

Overall Suitability for Endorsement: Y-15; N-2

- [NQF 1858](#) Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy (ASCO)

Overall Suitability for Endorsement: Y-18; N-0

- [NQF 1859](#) RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy (ASCO)

Overall Suitability for Endorsement: Y-16; N-2

- [NQF 1860](#) Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies (ASCO)

Overall Suitability for Endorsement: Y-17; N-1

## Comments and Their Disposition

NQF received seven comments from two organizations (including one member organizations) and individuals pertaining to the draft report and to the measures under consideration.

A table of comments submitted during the comment period, with the NQF responses to each comment, is posted to the Cancer [project webpage](#).

## 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. One NQF member provided an expression of support. [Appendix C](#) details the expression of support.

## Removal of NQF Endorsement

Five measures previously endorsed by NQF have not been re-submitted, and endorsement has been

removed.

Measure	Measure Description	Reason for Removal of Endorsement
0377	Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow	Unknown
0378	Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy	Unknown
0386	Oncology: Cancer Stage Documented	Unknown
1853	Radical Prostatectomy Pathology Reporting	Unknown
1854	Barrett's Esophagus	Unknown

## 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.	No	

## **Appendix B: Measures Not Recommended for Endorsement**

Not applicable.

## Appendix C: NQF Member Expression of Support Results

One NQF member provided their expression of support. NQF members provided their expression of support for 6 measures under consideration. Results for each measure are provided below.

- **NQF 0219 Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer (Commission on Cancer, American College of Surgeons)**
- **NQF 0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer (Commission on Cancer, American College of Surgeons)**
- **NQF 0383 Oncology: Medical and Radiation - Plan of Care for Pain (ASCO)**
- **NQF 1858 Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy (ASCO)**
- **NQF 1859 RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy (ASCO)**
- **NQF 1860 Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies (ASCO)**

Member Council	Support	Do Not Support	Total
Consumer	0	0	0
Health Plan	0	0	0
Health Professional	0	0	0
Provider Organization	1	0	1
Public/Community Health Agency	0	0	0
Purchaser	0	0	0
QMRI	0	0	0
Supplier/Industry	0	0	0

## Appendix D: Details of Measure Evaluation

### 0219 Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer

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

**Description:** Percentage of female patients, age = 18 and <70 at diagnosis, who have their first diagnosis of cancer (epithelial malignancy), whose primary tumor is of the breast, had breast conserving surgery and was administered radiation therapy within 1 year (365 days) of diagnosis

**Numerator Statement:** Radiation therapy is administered within 1 year (365 days) of the date of diagnosis

**Denominator Statement:** Include if all of the following characteristics are identified:

Women

Age = 18 and <70 at time of diagnosis

Known or assumed to be first or only cancer diagnosis

Epithelial malignancy only

Invasive tumors

Primary tumors of the breast

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

Known to be alive within 1 year (365 days) of date of diagnosis

Receipt of breast conserving surgery

**Exclusions:** Exclude, if any of the following characteristics are identified:

Men

Under age 18 or over 69 at time of diagnosis

Second or subsequent cancer diagnosis

Tumor not originating in the breast

Non-epithelial malignancies, exclude rare tumors: 8940 - Mixed tumor, malignant, NOS; 8950 - Mullerian mixed tumor; 8980 - Carcinosarcoma; 8981 - Carcinosarcoma, embryonal

Non-invasive tumor

Stage 0, in situ tumor

Stage IV, metastatic tumor

None of 1st course therapy performed at reporting facility

Breast conserving surgery was not received

Died within 1 year (365 days) of diagnosis

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

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

**Level of Analysis:** Facility

**Setting of Care:** Inpatient/Hospital

**Type of Measure:** Process

**Data Source:** Registry Data

**Measure Steward:** Commission on Cancer, American College of Surgeons



**0219 Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer**

**STANDING COMMITTEE MEETING 02/26/2020**

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

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

1a. Evidence: **M-15; L-0; I-0**; 1b. Performance Gap: **H-2; M-12; L-1; I-0**

**Rationale:**

- The evidence for this measure is a National Comprehensive Cancer Network (NCCN) Practice Guideline. The developer has used this as the supporting guideline, and categories for evidence is Level 1.
- The performance data from the NCDB was provided from 2015. The developer explained that the lag in data collection existed because it takes longer to document receipt of adjuvant therapy.
- The data from 2008 and 2015 demonstrated improvement over time, 88.1% (2008) and 92.0% (2015), and disparities exist based on race and ethnicity, age, insurance status, income, educational level, facility type, and region of the country. The Committee agreed there is a continuing gap in performance that justifies ongoing performance measurement and reporting. The Committee was pleased that the NCDB used by the developer contained disparities data, including race/ethnicity data and insurance data, and encouraged other developers to take note.

**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-3; M-12; L-0; I-0**; 2b. Validity: **M-14; L-1; I-0**

**Rationale:**

- The measure is a process measure reported at the facility level, and the data elements are collected from a registry. The Committee agreed the data elements were clear and precise, and there were no concerns of threats to reliability of the measure.
- Validity testing was conducted at the data element level. Annually a review of a minimum of 10% of the annual caseload of the registry abstracts is performed to verify that abstracted data accuracy. Both the annual caseload reviews and the measure reporting system reviews are intended to ensure that reported performance rates are an accurate reflection of the care provided to patients at CoC-accredited programs.

**3. Feasibility: **H-9; M-6; L-0; I-0****

*(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/unintended consequences identified; 3d. Data collection strategy can be implemented)*

**Rationale:**

- This measure is currently reported to CoC-accredited programs through the NCDB using the Cancer Program Practice Profile Report (CP3R) web-based audit and feedback reporting tool by registrars submitting new and updated cases annually. In addition, this measure is also reported to 1,500 cancer programs participating in its "real clinical time" feedback reporting tool through its Rapid Quality Reporting System (RQRS) reported daily from registrars in regard to new and updated cases. Both of these reporting tools have been used in the cancer registry community and do not produce an undue burden on the data collection network.
- The Committee expressed concern about smaller hospitals that might not have a registry. The Committee did ask whether this measure was limited to NCDB hospitals. The developer clarified that a benefit of being part of the CoC is they report back to COC programs, but that the measure specifications can be applied to any registry data, regardless of whether it is from a reporting hospital.

**0219 Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer**
**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-12; M-3; L-0; I-0**

**Rationale:**

- This measure is in use within accountability programs including Public Reporting – Pennsylvania Health Care Quality Alliance (PHCQA); Quality Improvement and Benchmarking – CoC, NCDB; and Regulatory and Accreditation programs –CoC Standards.

**5. Related and Competing Measures**

- No related or competing measures noted.

**6. Standing Committee Recommendation for Endorsement: Y-15; N-0**
**7. Public and Member Comment**

- The Alliance of Dedicated Cancer Centers (ADCC) supports the Committee's recommendation for continued endorsement. Thank you for the opportunity to comment.

**8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X**
**9. Appeals**
**0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**
[Submission](#) | [Specifications](#)

**Description:** Percentage of female patients, age = 18 at diagnosis, who have their first diagnosis of cancer (epithelial malignancy), at AJCC T1cN0M0 or stage IB to IIIC, whose primary tumor is of the breast, and is progesterone or estrogen receptor positive with adjuvant hormonal therapy (recommended or administered) within 1 year (365 days) of diagnosis

**Numerator Statement:** Adjuvant hormonal therapy is administered within 1 year (365 days) of the date of diagnosis or it is recommended but not administered

**Denominator Statement:** Include if all of the following characteristics are identified:

Women

Age = 18 at time of diagnosis

Known or assumed to be first or only cancer diagnosis

Epithelial malignancy only

Invasive tumors

Primary tumors of the breast

AJCC T1cN0M0 or Stage IB – IIIC

Primary tumor is estrogen receptor positive or progesterone receptor positive

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

Known to be alive within 1 year (365 days) of date of diagnosis

Surgical procedure of the primary site

**Exclusions:** Exclude, if any of the following characteristics are identified:

Men

Under age 18 at time of diagnosis

Second or subsequent cancer diagnosis

Tumor not originating in the breast

**0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

Non-epithelial malignancies, exclude malignant phyllodes tumors; 8940 - Mixed tumor, malignant, NOS; 8950 - Mullerian mixed tumor; 8980 - Carcinosarcoma; 8981 - Carcinosarcoma, embryonal

Non-invasive tumors

Stage 0, in-situ tumor

Stage IV, metastatic tumor

Primary tumor is estrogen receptor negative and progesterone receptor negative

None of 1st course therapy performed at reporting facility

Died within 1 year (365 days) of diagnosis,

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

No surgical procedure of the primary site

Not AJCC T1cN0M0 or not AJCC stage IB-IIIC

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

**Level of Analysis:** Facility

**Setting of Care:** Inpatient/Hospital

**Type of Measure:** Process

**Data Source:** Registry Data

**Measure Steward:** Commission on Cancer, American College of Surgeons

**STANDING COMMITTEE MEETING 02/26/2020**

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

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

1a. Evidence: **M-18; L-0; I-0**; 1b. Performance Gap: **H-3; M-14; L-1; I-0**

**Rationale:**

- In the 2019 submission, the developer provided an updated link to the National Comprehensive Cancer Network Guidelines v2.2019 and grade of evidence (Level 1).
- The performance data from the NCDB was provided from 2015. The developer explained that the lag existed in data collection because it takes longer to document receipt of adjuvant therapy.
- The data from 2008 and 2015 demonstrated improvement over time, 78.8% (2008) and 92.7% (2015), and disparities exist based on race, ethnicity, age, insurance status, income, educational level, facility type, and region of the country. The Committee agreed there is a continuing gap in performance that justifies ongoing performance measurement and reporting. The Committee was pleased that the NCDB used by the developer contained disparities data, including race/ethnicity data and insurance data, and encouraged other developers to take note.

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

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

2a. Reliability: **H-2; M-16; L-0; I-0**; 2b. Validity: **H-5; M-12; L-0; I-0**

**Rationale:**

- The measure is a process measure reported at the facility level, and the data elements are collected from a registry. The Committee agreed the data elements were clear and precise, and there were no concerns of threats to reliability of the measure.
- Validity testing was conducted at the data element level. Annually a review of a minimum of 10% of the annual caseload of the registry abstracts is performed to verify that abstracted data accuracy. Both the annual caseload reviews and the measure reporting system reviews are intended to ensure that reported performance rates are an accurate reflection of the care provided to patients at CoC-accredited programs.

**0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

**3. Feasibility: H-9; M-7; L-0; I-0**

*(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/unintended consequences identified; 3d. Data collection strategy can be implemented)*

Rationale:

- This measure is currently reported to CoC-accredited programs through the NCDB using the CP3R web-based audit and feedback reporting tool by registrars submitting new and updated cases annually. In addition, this measure is also reported to 1,500 cancer programs participating in its “real clinical time” feedback reporting tool through its RQRS reported daily from registrars in regard to new and updated cases. Both of these reporting tools have been used in the cancer registry community and do not produce an undue burden on the data collection network.
- The Committee did not express any additional concerns with feasibility.

**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-16; No Pass-0** 4b. Usability: **H-10; M-6; L-0; I-0**

Rationale:

- This measure is in use within accountability programs including Public Reporting – PHCQA); Quality Improvement and Benchmarking – CoC, NCDB; and Regulatory and Accreditation programs – CoC Standards, Cancer Program Practice Profile Reports, Cancer Quality Improvement Program, Rapid Quality Reporting System

**5. Related and Competing Measures**

- This measure is related to NQF 0387e – Breast Cancer: Hormonal Therapy for Stage I (T1b) – IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer.
- No competing measures noted.

**6. Standing Committee Recommendation for Endorsement: Y-16; N-0**

**7. Public and Member Comment**

- The Alliance of Dedicated Cancer Centers (ADCC) supports the Committee’s recommendation for continued endorsement. Thank you for the opportunity to comment.

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

**9. Appeals**

**0383 Oncology: Medical and Radiation - Plan of Care for Pain**[Submission](#) | [Specifications](#)

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

**Numerator Statement:** Patient visits that include a documented plan of care\* to address pain.

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

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

**Exclusions:** None

**Adjustment/Stratification:** N/A, no risk stratification. No risk adjustment or risk stratification

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

**Setting of Care:** Outpatient Services

**Type of Measure:** Process

**Data Source:** Paper Medical Records, Registry Data

**Measure Steward:** American Society of Clinical Oncology

**STANDING COMMITTEE MEETING 02/26/2020****1. Importance to Measure and Report: The measure meets the Importance criteria**

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

1a. Evidence: **M-3; L-4; I-11**; Evidence Exception: **Y-16; N-2**; 1b. Performance Gap: **H-1; M-13; L-3; I-0**

**Rationale:**

- The developer provided updated evidence for this measure, citing the NCCN Clinical Practice Guidelines in Oncology, Adult Cancer Pain includes management of pain in both opioid-naïve and opioid tolerant patient.
- This guideline did not include an overview of the body of evidence used for recommendations specific to the overall management of pain, nor does it address specifically what the measure is evaluating, which is or developing a plan of care for pain.
- The Committee discussed the difference between a level 1 guideline and level 2A guideline, citing that level 1 evidence is specific to randomized control trials (RCT).
- The Committee discussed the guideline level of evidence (Level 2A), which is a lower level, but there was consensus among the Committee that the intervention was appropriate. The guideline also includes an in-depth discussion on the evidence, benefits, as well as harms of specific therapies and interventions.
- Patient advocates on the Standing Committee stressed the importance of the measure, as it signifies a step to make certain that pain is addressed.
- The Committee discussed the difference between a Level 1 guideline and Level 2A guideline, citing that Level 1 evidence is specific to RCT.
- The Committee, using their expertise, made the determination that the benefits of what is being measured (documented plan of care to address pain) outweighs any potential harm, and voted to pass the measure on evidence with exception.
- Performance gap data ranged from 75-89% from 2015 through 2017, showing an increase in performance. There was no performance data on disparities.

**0383 Oncology: Medical and Radiation - Plan of Care for Pain****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-1; M-13; L-3; I-0**; 2b. Validity: **H-1; M-14; L-2; I-0**Rationale:

- Reliability was measured as the ratio of signal to noise, and testing was performed using a beta-binomial model.
- The measure was revised for the 2019 submission to include two different populations (chemotherapy patient and radiation patients both undergoing active therapy and experiencing pain).
- The overall reliability score was 0.98, which suggests a high degree of reliability.
- The Committee did not express any concerns on reliability.
- The developer performed a correlation analysis with measure #0384 (Oncology: Medical and Radiation – Pain Intensity Quantified) due to the similarities in patient population and domain.
- This correlation analysis method demonstrated an association between patients with a diagnosis of cancer receiving chemotherapy or radiation therapy in which pain intensity is quantified, 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.
- The Committee had no concerns with validity testing and did not find any threats of validity.

**3. Feasibility: H-0; M-13; L-5; I-0**

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/unintended consequences identified; 3d. Data collection strategy can be implemented)

Rationale:

- The data elements of the measure are generated during the provision of care, and are collected through the EHR or through the use of keyword searches.
- The Committee noted the difficulty with extracting the information from an EHR without a designated field. Traditionally, the extraction is completed through audits.
- The Committee noted that it could be extremely difficult to obtain an accurate number of visits; however, one unforeseen benefit is that practices are improving their electronic infrastructure to accurately capture this documentation.

**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-18; No Pass-0** 4b. Usability: **H-1; M-13; L-3; I-1**

Rationale:

- This measure is currently used in accountability programs: MIPS, American Society of Clinical Oncology's Quality Oncology Practice Incentive (QOPI) and PPS-Exempt Cancer Hospital Quality Reporting (PCHQR).
- The Committee noted a potential danger with the usability of this measure as it relates to opioid-prescribing patterns. The concern is that patients may inaccurately report pain to receive opioid prescriptions. The Committee suggested that a future version of the measure might consider the distinction between pain in patients with an incurable cancer versus a curable cancer.
- Patient representatives on the Committee also noted the importance of providing better patient education about medications prescribed to them.

**5. Related and Competing Measures**

- This measure is related to NQF #0524: Pain Interventions Implemented During Short Term Episodes of Care and NQF #1628: Patients with Advanced Cancer Screened for Pain at outpatient visits.

This measure does not compete with any measures.

<b>0383 Oncology: Medical and Radiation - Plan of Care for Pain</b>
<b>6. Standing Committee Recommendation for Endorsement: Y-15; N-2</b> <u>Rationale</u> <ul style="list-style-type: none"> <li>During the Committee’s discussion on evidence, they voted to use the evidence exception option, determining that the benefits of what is being measured (documented plan of care to address pain) outweighs any potential harm.</li> <li>The Committee also discussed the pairing of this measure (0383) with measure 0384, and suggested to the developer that a composite measure be developed that would include both.</li> </ul>
<b>7. Public and Member Comment</b> <ul style="list-style-type: none"> <li>The Alliance of Dedicated Cancer Centers (ADCC) supports the Committee's recommendation for continued endorsement. We believe this measure is dependent upon the related measure, NQF #0384, also an endorsed measure. Please refer to our comments on NQF #0384 for a detailed explanation. Thank you for the opportunity to comment.</li> </ul>
<b>8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X</b>
<b>9. Appeals</b>

**1858 Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**
[Submission](#) | [Specifications](#)

**Description:** Percentage of female patients aged 18 and over with HER2/neu positive invasive breast cancer who are administered trastuzumab

**Numerator Statement:** Patients for whom trastuzumab is administered within 12 months of diagnosis

**Denominator Statement:** Female patients aged 18 and over with AJCC stage I (T1c) – III, HER2/neu positive breast cancer who receive chemotherapy

**Exclusions:** Denominator Exclusions:

- o Patient transfer to practice after initiation of chemotherapy

Denominator Exceptions:

- o Reason for not administering trastuzumab documented (e.g. patient declined, patient died, patient transferred, contraindication or other clinical exclusion, neoadjuvant chemotherapy or radiation therapy not complete)

**Adjustment/Stratification:** N/A, no risk stratification. No risk adjustment or stratification.

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

**Setting of Care:** Outpatient Services

**Type of Measure:** Process

**Data Source:** Paper Medical Records, Registry Data

**Measure Steward:** American Society of Clinical Oncology

**STANDING COMMITTEE MEETING 02/26/2020**
**1. Importance to Measure and Report: The measure meets the Importance criteria**

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

1a. Evidence: **H-12; M-5; L-0; I-0**; 1b. Performance Gap: **H-0; M-12; L-5; I-0**

**Rationale:**

- The developer provided updated evidence for this measure, an additional clinical practice guideline on breast cancer from NCCN. The guideline recommended HER2-targeted therapy in patients with HER2-positive tumors. Trastuzumab is humanized monoclonal antibody with specificity for the extracellular domain of HER2. The use of trastuzumab with chemotherapy was a category 1 recommendation in patients with HER2-positive tumors greater than 1 cm.
- The developer provided a systematic review of the evidence for the American Society of Clinical Oncology (ASCO) guideline, noting that a 2018 guideline update reaffirmed the recommendation of this measure. No new studies changed the conclusions reached by the 2018 guideline. In addition, a systematic review of the evidence for the Cancer Care Ontario (CCO) guideline, noting that updated guidelines continue to support the measure.
- The developer provided 2017 MIPS performance data and QPP that indicated the performance rate is 97.5%.
- The Committee expressed strong views on the importance of this measure and cited that gaps persist in the medical literature. The developer offered comments in response to the performance gap, citing that this measure focuses on the importance of making sure the patient testing records are received by the physician in a timely manner to administer therapy, and if this is lacking, it could be an indication of systems issues rather than a physician's lack of adherence to guidelines.



## 1858 Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy

### 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-1; M-13; L-3; I-0**; 2b. Validity: **H-14; M-3; L-0; I-0**Rationale:

- The developer computed signal-to-noise scores to address precision of measurement (measure score) and used a beta-binomial model. The reported mean reliability was 0.9657, which is considered high. A reliability of zero implies that the variability in the measure is attributed to measurement error, while a reliability closer to 1 implies that the variability is attributable to real differences in facility performance. A 0.70-0.80 reliability is considered an acceptable threshold; 0.80-0.90 is considered high reliability; and 0.90-1.00 is considered very high.
- It was noted during the preliminary analysis of the measure that testing is at the facility level but indicated that level of analysis is group/practice. The developer clarified that there was a misunderstanding in the terminology between facility and group/practice, but the testing was conducted at the facility level.
- The developer conducted a Pearson correlation analysis to determine the association between performance scores of the shared providers. The correlation was 0.711, indicating a strong, positive correlation between performance scores of the shared providers.
- There was concern raised by one committee member about a statement in the denominator exclusions that state: Reason for not administering trastuzumab documented (e.g., patient declined, patient died, patient transferred, contraindication or other clinical exclusion, neoadjuvant chemotherapy or radiation therapy not complete). Specifically, the concern was that this statement gave the impression that physicians can give any reason at all for not administering Trastuzumab and be excluded from the denominator. The Committee urged the developer to think about this exclusion as they are developing a new measure.

### 3. Feasibility: **H-10; M-7; L-0; I-0**

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/unintended consequences identified; 3d. Data collection strategy can be implemented)

Rationale:

- The measure data elements are documented during routine care; however, they are either documented in a narrative note, an order (i.e., pain medication, referral), or in an electronic way depending on EHR build. It was noted by the Committee that this may be burdensome, as it may require chart abstractions. The developer reports that they are in the process of assessing feasibility of developing an eCQM.

### 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-17; No Pass-1** 4b. Usability: **H-2; M-15; L-0; I-1**

Rationale:

- This measure is currently used in accountability programs including MIPS, Quality Oncology Practice Initiative (QOPI), Core Quality Measure Collaborative's (CQMC) Medical Oncology Core Measure Set.
- The developer reported a high performance rate of 97.51% in the 2017 QPP Data Results. The 2019 MIPS benchmarking data for quality improvement is 450.

### 5. Related and Competing Measures

- This measure related to NQF 1855 Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines and NQF 1857 HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies
- No competing measures noted.

### 6. Standing Committee Recommendation for Endorsement: **Y-18; N-0**

<b>1858 Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy</b>
<b>7. Public and Member Comment</b> <ul style="list-style-type: none"> <li>The Alliance of Dedicated Cancer Centers (ADCC) supports the Committee’s recommendation for continued endorsement. Thank you for the opportunity to comment.</li> </ul>
<b>8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X</b>
<b>9. Appeals</b>

### 1859 RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy

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

**Description:** Percentage of adult patients (aged 18 and over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed

**Numerator Statement:** RAS (KRAS and NRAS) gene mutation testing performed prior to initiation of anti-EGFR monoclonal antibody therapy

**Denominator Statement:** Adult patients with metastatic colorectal cancer who receive anti-EGFR monoclonal antibody therapy

**Exclusions:** None

**Adjustment/Stratification:** N/A. No risk adjustment or stratification.

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

**Setting of Care:** Outpatient Services

**Type of Measure:** Process

**Data Source:** Paper Medical Records, Registry Data

**Measure Steward:** American Society of Clinical Oncology

#### STANDING COMMITTEE MEETING 02/26/2020

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

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

1a. Evidence: **H-4; M-13; L-1; I-0**; 1b. Performance Gap: **H-7; M-10; L-1; I-0**

##### Rationale:

- The developer provided updated evidence for this measure. A recommendation from the ASCO): Colorectal carcinoma patients being considered for anti-EGFR therapy must receive RAS mutational testing. Mutational analysis should include KRAS and NRAS codons 12, 13 of exon 2; 59, 61 of exon 3; and 117 and 146 of exon 4 ("expanded" or "extended" RAS).
- The grade of evidence for the ASCO recommendation was expert consensus opinion. The developer noted the limitations, such as limited strength of evidence, intermediate-to-low quality of evidence, and balance of benefits and harms, values, or costs.
- The updated evidence also included a clinical practice guideline: NCCN guideline on colon cancer: All patients with metastatic colorectal cancer should have tumor tissue genotyped for RAS (KRAS and NRAS) and BRAF mutations individually or as part of an NGS panel. The developer noted that the NCCN guidelines do not present evidence used for the recommendation specific to RAS mutation status; however, evidence is provided on the benefits and harms of EGFR inhibitors. This was noted as a challenge for the developer, considering the length of time it takes to develop new guidelines as well as working within the confines of what is available
- The Committee discussed specifically the evidence presented to support gene mutation testing, citing that the information presented seems to be indirect evidence to support the measure.
- The developer clarified that the intent of the measure is to focus on two components: 1) patients receiving the drug who have the RAS mutation; and 2) patients who are RAS mutant and are receiving this drug and whether it is causing harm (e.g., immediate toxicity related to cost and survivorship).
- A performance gap from the analysis of 2017 MIPS performance registry data was provided. The data is presented per practice with a mean of 76%. No disparities data was presented. However, the developer cited a 2017 Surveillance, Epidemiology, and End Results (SEER) study that found overall proportion of KRAS testing was only 22.7% among the sample population, with variation by geographic region and patient characteristics, indicating disparities in KRAS testing.

## 1859 RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy

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

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

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

#### Rationale:

- The developer computed signal-to-noise scores to address precision of measurement (measure score) and used a beta-binomial model. A reliability of zero implies that the variability in the measure is attributed to measurement error, while a reliability of 1 implies that the variability is attributable to real differences in facility performance. The developers reported a mean reliability of 0.8908, which is considered very high.
- It was noted during the preliminary analysis of the measure that testing was at the facility level, but it was indicated that level of analysis is group/practice. The developer clarified that there was a misunderstanding in the terminology between facility and group/practice, but the testing was conducted at the facility level. Facility-level reliability testing was found to be a mean of 0.9465, which is associated with a high level of reliability.
- Empirical validity testing of the measure score was provided. The developer performed a Pearson correlation analysis to determine the association between the performance scores of the shared providers, and those scores were interpreted in the following way: >0.40 correlation coefficient = strong correlation; 0.20-0.40 correlation coefficient = moderate correlation; <0.20 correlation coefficient = weak coefficient. The correlation was 0.49, indicating a positive correlation between performance scores of the shared providers.
- The Committee expressed a concern with the accuracy of the testing, citing it was critically important because there are a large number of RAS mutations that exist, and this measure may not be granular enough to capture the most appropriate clinical information.

### 3. Feasibility: **H-1; M-17; L-0; I-0**

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/unintended consequences identified; 3d. Data collection strategy can be implemented)

#### Rationale:

- The measure data elements are documented during routine care; however, they are either documented in a narrative note, an order (i.e., pain medication, referral), or in an electronic way depending on EHR build. It was noted by the Committee that this may be burdensome, as it may require chart abstractions. The developer reports that they are in the process of assessing feasibility of developing an eCQM.

### 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-18; No Pass-0** 4b. Usability: **H-4; M-12; L-1; I-1**

#### Rationale:

- The measure is currently used in several accountability programs, which include MIPS; Quality Oncology Practice Initiative (QOPI); and Core Quality Measure Collaborative's (CQMC) Medical Oncology Core Measure Set.
- The developer reported a high performance rate for usability of the measure. Approximately 54% of practices are performing at 100%; however, multiple practices are still operating at 0%. Mean performance is at 76%, indicating room for improvement. The MIPS 2017 performance data does not include RAS testing guideline changes made in 2018. The developer anticipates a greater performance gap to be made due to this guideline update.
- The Committee agreed with the use and usability of the measure.

**1859 RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**
**5. Related and Competing Measures**

- This measure is related to NQF 1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies.
- No competing measures presented

**6. Standing Committee Recommendation for Endorsement: Y-16; N-2**
**7. Public and Member Comment**

- The Alliance of Dedicated Cancer Centers (ADCC) supports the Committee's recommendation for continued endorsement. Thank you for the opportunity to comment.
- The College of American Pathologists (CAP) fully supports measure 1859, RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy, for renewal of endorsement by NQF. This measure is consistent with best clinical practice as recommended by the CAP with respect to RAS (KRAS and NRAS) testing in metastatic colorectal carcinoma. Endorsement of this measure recognizes the importance of accurate and complete biomarker testing to guide patient management and supports the continuity of care from diagnostic clinicians to oncologists to patients. This measure, which was already successfully implemented, has been updated to comply with the most recent guidelines and therefore represents the most stringent biomarker testing requirements and will likely show a significant gap in performance. Based on the clinical significance, scientific validity, and demonstrated feasibility, measure 1859 should be re-endorsed.

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

## 1860 Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies

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

**Description:** Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies

**Numerator Statement:** Anti-EGFR monoclonal antibody therapy not received

**Denominator Statement:** Adult patients with metastatic colorectal cancer who have a RAS (KRAS or NRAS) gene mutation

**Exclusions:** None

**Adjustment/Stratification:** N/A. No risk adjustment or stratification.

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

**Setting of Care:** Outpatient Services

**Type of Measure:** Process

**Data Source:** Paper Medical Records, Registry Data

**Measure Steward:** American Society of Clinical Oncology

### STANDING COMMITTEE MEETING 02/26/2020

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

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

1a. Evidence: **H-11; M-6; L-0; I-0**; 1b. Performance Gap: **H-15; M-3; L-0; I-0**

#### Rationale:

- The developer provided an overview of the evidence to support this measure, citing that the focus of the measure is halting the use of anti-EGFR monoclonal antibody (MoAb) therapies in patients who will not derive any benefit.
- The body of evidence provided for this measure addressed the relationship between RAS status in patients with metastatic colorectal cancer who underwent anti-EGFR MoAb therapy, specifically cetuximab or panitumumab, and the outcomes of tumor response, progression-free survival, and overall survival. Patients with and without KRAS or NRAS mutations to exons 2, 3, or 4 who underwent anti-EGFR MoAb therapy were evaluated with respect to these outcomes in both single-arm and randomized trials. Additionally, this measure is directly supported by recommendations in American Society for Clinical Pathology, College of American Pathologists, Association for Molecular Pathology, American Society of Clinical Oncology, and NCCN clinical practice guidelines.
- The Committee generally agreed that sufficient evidence was provided for this measure, and acknowledged that the discussion of measure 1859 on evidence would apply to this measure as well. It was noted that measure 1860 was a companion measure to 1859—the difference being that treatment is not administered for a patient who is positive for the KRASG mutation.
- The developer provided 2017 MIPS performance from registry data provided from CMS. The 2017 data was from 158 providers representing 43 practices and 495 individual patients. The majority (approximately 76.7%) of practices perform at 100% with a mean performance of 91%. The mean performance rate of 91% is statistically significant from 100%, suggesting that room for improvement remains across practices.

## 1860 Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies

### 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-10; M-8; L-0; I-0**; 2b. Validity: **H-12; M-6; L-0; I-0**

#### Rationale:

- The measure developer noted changes to the measure specifications since the last endorsement, including an expansion to RAS mutational testing based on a guideline update to include NRAS as well as KRAS. In addition to testing for mutations in KRAS exon 2 (codons 12 and 13) as recommended previously, before treatment with anti-EGFR antibody therapy, patients with metastatic colorectal cancer should have their tumor tested for mutations in: KRAS exons 3 (codons 59 and 61) and 4 (codons 117 and 146), NRAS exons 2 (codons 12 and 13), 3 (codons 59 and 61), and 4 (codons 117 and 146)
- Additionally, the developer noted that an exclusion was removed for patient transfer to practice after initiation of chemotherapy and receipt of anti-EGFR monoclonal antibody therapy as part of a clinical trial protocol.
- Reliability of the computed measure score was measured as the ratio of signal to noise. The signal in this case is the proportion of the variability in measured performance that can be explained by real differences in physician performance, and the noise is the total variability in measured performance.
- The Committee asked about patient retest and whether a former test for NGS tumors would be applicable for this measure. This led to a further discussion on payment with this measure. Since Medicaid will only pay for one test for each NGS tumor, there is the potential risk of financial burden for this measure, as the patient may not be able to afford sufficient testing.
- A correlation analysis was completed to conduct empirical validity testing using 2017 MIPS data. KRAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy (QI #451/ NQF#1859) was chosen as a suitable candidate for correlation analysis due to the similarities in patient population and domain.
- This measure has a strong positive correlation with another evidence-based process of care, as the correlation coefficient observed was 0.49.

### 3. Feasibility: **H-1; M-17; L-0; I-0**

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/unintended consequences identified; 3d. Data collection strategy can be implemented)

#### Rationale:

- When discussing feasibility, the Committee noted that the data to support this measure is not structured in the EHR and requires abstraction, and they questioned why this measure was not an eCQM, which may improve feasibility. The developer informed the Committee that not all EHRs are able to accommodate this, but as the technology becomes more widely available, they intend for the measure to move in that direction.

### 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-17; No Pass-1** 4b. Usability: **H-2; M-15; L-1; I-0**

#### Rationale:

- The measure is currently used in accountability programs including Payment Program MIPS; ASCO Qualified Clinical Data Registry; Quality Improvement (external benchmarking to organizations); Quality Oncology Practice Initiative (QOPI®); Quality Improvement (Internal to the specific organization); Quality Oncology Practice Initiative (QOPI®)
- The performance results of the measure show that 76% of the practices report at 100%, so there is still room for improved performance.

**1860 Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies****5. Related and Competing Measures**

- This measure is related to NQF 1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody treatment.
- No competing measures noted.

**6. Standing Committee Recommendation for Endorsement: Y-17; N-1****7. Public and Member Comment**

- The Alliance of Dedicated Cancer Centers (ADCC) supports the Committee's recommendation for continued endorsement. Thank you for the opportunity to comment.

**8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X****9. Appeals**





**NATIONAL  
QUALITY FORUM**

Driving measurable health  
improvements together

<http://www.qualityforum.org>

# Cancer Fall 2019 Review Cycle

CSAC Review and Endorsement

*July 28-29, 2020*

# Standing Committee Recommendations

- Nine measures reviewed for Fall 2019
  - ▣ None of the measures were reviewed by the Scientific Methods Panel
- Six measures recommended for endorsement
  - ▣ 0219 Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer
  - ▣ 0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB– Stage III hormone receptor positive breast cancer
  - ▣ 0383 Oncology: Medical and Radiation – Plan of Care for Pain
  - ▣ 1858 Trastuzumab administered to patients for AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER 2) positive breast cancer who receive adjuvant chemotherapy
  - ▣ 1859 RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy
  - ▣ 1860 Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies



## Standing Committee Recommendations

- Three measures deferred to Spring 2020 due to COVID-19 extended commenting periods
  - ▣ 0223 Adjuvant chemotherapy is recommended, or administered within 4 months (120 days) of diagnosis for patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer
  - ▣ 0384e Oncology: Medical and Radiation - Pain Intensity Quantified
  - ▣ 0384 Oncology: Medical and Radiation – Pain Intensity Quantified



## Public and Member Comment and Member Expressions of Support

- Seven comments received
  - ▣ All supportive of the measures under review
- One NQF member expressed support for the measures



## Timeline and Next Steps

Process Step	Timeline
CSAC Endorsement Meeting	July 28 - 29, 2020
Appeals Period	August 3 – September 1, 2020



## Questions?

- Project team:
  - ▣ Nicole Williams, Director
  - ▣ Tamara Funk, Manager
  - ▣ Teja Vemuganti, Analyst
  - ▣ Mike DiVecchia, Project Manager
- Project webpage: <http://www.qualityforum.org/Cancer.aspx>
- Project email address: [cancerem@qualityforum.org](mailto:cancerem@qualityforum.org)

**THANK YOU.**

**NATIONAL QUALITY FORUM**

<http://www.qualityforum.org>

# Cancer, Fall 2019 Cycle, Track 1: CDP Report

Draft Report For CSAC Review: July 28-29, 2020 This report is funded by the Department of Health and Human Services under contract HHSM-500-2017-00060I Task Order HHSM-500-T0001

<http://www.qualityforum.org>



## Contents

<b>Executive Summary</b> .....	<b>4</b>
<b>Introduction</b> .....	<b>5</b>
<b>NQF Portfolio of Performance Measures for Cancer Conditions</b> .....	<b>5</b>
Table 1. NQF Cancer Portfolio of Measures.....	5
<b>Cancer Measure Evaluation</b> .....	<b>6</b>
Table 2. Cancer Measure Evaluation Summary – Track 1.....	6
Comments Received Prior to Committee Evaluation .....	6
Comments Received After Committee Evaluation .....	6
Summary of Measure Evaluation: Fall 2019 Measures, Track 1 .....	7
<b>References</b> .....	<b>13</b>
<b>Appendix A: Details of Measure Evaluation</b> .....	<b>14</b>
Track 1 – Measures Recommended.....	14
0219 Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer .....	14
0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer .....	17
0383 Oncology: Medical and Radiation - Plan of Care for Pain .....	20
1858 Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy .....	23
1859 RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy .....	26
1860 Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies .....	29
<b>Appendix B: Cancer Portfolio—Use in Federal Programs</b> .....	<b>32</b>
<b>Appendix C: Cancer Standing Committee and NQF Staff</b> .....	<b>34</b>
<b>Appendix D: Measure Specifications (Tabular)</b> .....	<b>37</b>
0219 Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer .....	37
0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer .....	1
0383 Oncology: Medical and Radiation - Plan of Care for Pain .....	3
1858 Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy .....	1

1859 RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy .....	1
1860 Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies .....	1
<b>Appendix D: Measure Specifications (Narrative) .....</b>	<b>1</b>
0219 Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer .....	1
0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer .....	4
0383 Oncology: Medical and Radiation - Plan of Care for Pain .....	8
1858 Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy .....	12
1859 RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy .....	15
1860 Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies .....	17
<b>Appendix E1: Related and Competing Measures (Tabular).....</b>	<b>20</b>
<b>Appendix E2: Related and Competing Measures (Narrative).....</b>	<b>47</b>
<b>Appendix F: Pre-Evaluation Comments .....</b>	<b>82</b>

## 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 (NCI) estimated that in 2018 1.7 million new cases of cancer would be diagnosed in the United States and over 600,000 people will die from the disease.<sup>2</sup> 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 a significant economic impact on patients, their families, and society. The NCI 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 cancer treatment (including surgery, chemotherapy, and radiation therapy).

Due to circumstances around the COVID-19 global pandemic, commenting periods for all measures evaluated in the Fall 2019 cycle were extended from 30 days to 60 days. Based on the comments received during this 60-day extended commenting period, measures entered into one of two tracks:

Track 1: measures continuing its review in Fall 2019 Cycle:

Recommended for Endorsement:

- **NQF 0219** Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer
- **NQF 0220** Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer
- **NQF 0383** Oncology: Medical and Radiation - Plan of Care for Pain
- **NQF 1858** Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy
- **NQF 1859** RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy
- **NQF 1860** Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies

Track 2: measures deferred to Spring 2020 Cycle:

- **NQF 0223** Adjuvant chemotherapy is recommended, or administered within 4 months (120 days) of diagnosis for patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer
- **NQF 0384** Oncology: Medical and Radiation - Pain Intensity Quantified
- **NQF 0384e** Oncology: Medical and Radiation - Pain Intensity Quantified

This report contains details of the evaluation of measures assigned to *Track 1* and are continuing in the Fall 2019 cycle. The detailed evaluation summary of measures assigned to *Track 2* and deferred to the Spring 2020 cycle will be included in a subsequent report. Brief summaries of the Fall 2019 *Track 1* measures currently under review are included in the body of the report; detailed summaries of the Committee’s discussion and ratings of the criteria for each measure are in [Appendix A](#).

## Introduction

Cancer is the second most common cause of death in the U.S., exceeded only by heart disease.<sup>1</sup> NCI estimated that in 2018, 1.7 million new cases of cancer would 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. NCI 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>

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, pharmacists, 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 cancer 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 hematology, breast cancer, colon cancer, prostate cancer, and other cancer measures. This portfolio contains 20 measures: 19 process measures, and 1 outcome and resource use measure (see table below).

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

	Process/Structure	Outcome
<b>Breast Cancer</b>	9	0
<b>Colon Cancer</b>	5	0
<b>Hematology</b>	0	0
<b>Lung/Thoracic Cancer</b>	0	0
<b>Prostate Cancer</b>	2	0
<b>Other Cancer Measures</b>	3	1
<b>Total</b>	19	1

Additional measures related to cancer care are assigned to the Geriatrics and Palliative Care, Surgery, All Cause Admissions and Readmissions 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

On February 26, 2020, the Cancer Standing Committee evaluated nine measures undergoing maintenance review against NQF's [standard measure evaluation criteria](#). Six measures were assigned to *Track 1* and are continuing in the Fall 2019 cycle. The detailed evaluation summary of the three measures assigned to *Track 2* and deferred to the Spring 2020 cycle will be included in a subsequent report.

**Table 2. Cancer Measure Evaluation Summary – Track 1**

	Maintenance	New	Total
Measures under consideration	6	0	6
Measures recommended for endorsement	6	0	6

## 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, 2019 and closed on May 28, 2020. No comments were submitted and shared with the Committee prior to the measure evaluation meeting ([Appendix F](#)).

## Comments Received After Committee Evaluation

With the recent COVID-19 global pandemic, many organizations needed to focus their attention on the public health crisis. To provide greater flexibility for stakeholders and continue the important work in quality measurement, the National Quality Forum (NQF) extended commenting periods and adjusted measure endorsement timelines for the Fall 2019 cycle.

Commenting periods for all measures evaluated in the Fall 2019 cycle were extended from 30 days to 60 days. Based on the comments received during this 60-day extended commenting period, measures entered one of two tracks:

### **Track 1: Measures Continuing in Fall 2019 Cycle**

**Measures that did not receive public comments or only received comments in support of the Standing Committees' recommendations** will move forward to the CSAC for review and discussion during its meeting on July 28-29.

- **Exceptions**

Exceptions were granted to measures if non-supportive comments received during the extended post-comment period were similar to those received during the pre-evaluation meeting period and have already been adjudicated by the respective Standing Committees during the measure evaluation Fall 2019 meetings.

### **Track 2: Measures Deferred to Spring 2020 Cycle**

**Fall 2019 measures requiring further action or discussion from a Standing Committee were deferred to the Spring 2020 cycle.** This includes measures where consensus was not reached or those that require a response to public comments received. Measures undergoing maintenance review will retain endorsement during that time.

During the Fall 2019 CSAC meeting on July 28-29, the Consensus Standards Approval Committee (CSAC) will review all measures assigned to Track 1. A list of measures assigned to Track 2 can be found in the Executive Summary section of this report for tracking purposes, but these measures will be reviewed by CSAC on November 17 and 18, 2020.

The extended public commenting period with NQF member support closed on May 28, 2020. Following the Committee's evaluation of the measures under consideration, NQF received seven comments from two organizations (including two member organizations) and individuals pertaining to the draft report and to the measures under consideration. All comments for each measure under consideration have been summarized in [Appendix A](#).

Throughout the extended 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. One NQF member provided their expression of support.

## **Summary of Measure Evaluation: Fall 2019 Measures, Track 1**

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](#).

### **0219 Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer (Commission on Cancer, American College of Surgeons): Recommended**

**Description:** Percentage of female patients, age = 18 and <70 at diagnosis, who have their first diagnosis of cancer (epithelial malignancy), whose primary tumor is of the breast, had breast conserving surgery and was administered radiation therapy within 1 year (365 days) of diagnosis; **Measure Type:** Process; **Level of Analysis:** Facility; **Setting of Care:** Inpatient/Hospital; **Data Source:** Registry Data

The Committee recommended the measure for continued endorsement. The measure captures the percentage of female patients, age = 18 and <70 at diagnosis, who have their first diagnosis of cancer (epithelial malignancy), whose primary tumor is of the breast, had breast conserving surgery and was administered radiation therapy within 1 year of diagnosis.

The Committee expressed no concerns about evidence since it had not changed since the last review. The Committee noted that significant progress in performance has been made since the last review, but a performance gap still warrants a performance measure in this area. Disparities related to race/ethnicity and insurance status persist. The Committee had no concerns with reliability. In addition, the Committee did not have any concerns with the measure's validity.

Concerning feasibility, the Committee noted that this data is regularly generated by any facility with a cancer registry. The Committee inquired about whether this measure was limited to National Cancer Database (NCDB) hospitals. The developer clarified that a benefit of being part of the Commission on Cancer (CoC) is they report back to CoC programs, but that the measure specifications can be applied to any registry data, regardless of whether it is from a reporting hospital. The Committee had no further questions on feasibility.

The Committee also had no issues with the use of this measure, as it is currently publicly reported and used in a number of accountability programs. They also had no concerns about the usability of this measure, and noted being able to see improvement, as the measure is having an effect.

**0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer (Commission on Cancer, American College of Surgeons): Recommended**

**Description:** Percentage of female patients, age = 18 at diagnosis, who have their first diagnosis of cancer (epithelial malignancy), at AJCC T1cN0M0 or stage IB to IIIC, whose primary tumor is of the breast, and is progesterone or estrogen receptor positive with adjuvant hormonal therapy (recommended or administered) within 1 year (365 days) of diagnosis; **Measure Type:** Process; **Level of Analysis:** Facility; **Setting of Care:** Inpatient/Hospital; **Data Source:** Registry Data

The Committee recommended the measure for continued endorsement. The measure captures the percentage of female patients, age = 18 at diagnosis, who have their first diagnosis of cancer (epithelial malignancy), at AJCC T1cN0M0 or stage IB to IIIC, whose primary tumor is of the breast, and is progesterone or estrogen receptor positive with adjuvant hormonal therapy within one year of diagnosis.

The Committee agreed that there has been no change in evidence since the last evaluation. Although the performance data from the NCDB is from 2015, the Committee accepted the developer's justification that a lag exists in data collection, because it takes longer to document receipt of adjuvant therapy. Committee members noted that although the performance gap is fairly narrow, the data from 2008 and 2015 demonstrate improvement over time, and disparities exist based on race and ethnicity, age, insurance status, income, educational level, facility type, and region of the country. The Committee agreed there is continuing gap in performance that justifies ongoing performance measurement and reporting. The Committee was pleased that the NCDB used by the developer contained disparities data, including race/ethnicity data and insurance data.

The Committee did not have any concerns with the reliability or validity of this measure. The Committee agreed that the measure remains feasible for CoC-accredited hospitals, though it may not be as feasible

for non-CoC-accredited centers. The Committee had no concerns with the use or usability of this measure, as it is currently used in accountability programs.

### **0383 Oncology: Medical and Radiation - Plan of Care for Pain (American Society of Clinical Oncology): Recommended**

**Description:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain; **Measure Type:** Process; **Level of Analysis:** Clinician:Group/Practice; **Setting of Care:** Outpatient Services; **Data Source:** Paper Medical Records, Registry Data

The Committee recommended the measure for continued endorsement. This measure captures the percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.

The Committee agreed that there was clear evidence for the importance of addressing pain and having a plan of care, but that the evidence provided does not directly relate to the measure as stated. To meet NQF's standard measure criteria, a process measure must include a systematic assessment and grading of the quality and consistency of the body of evidence that the measured process leads to a desired health outcome. According to NQF measure criteria, if a measure does not include a systematic review of the evidence, the Committee may choose to consider it as having an exception to evidence requirement. The Committee acknowledged that, commonly, Level 1 guidelines are related to randomized control trials (RCTs), but it would be unethical to have an RCT for patients who are experiencing pain, so the highest level of guideline rating is 2A (weak recommendation; benefits closely balanced with risks and burdens). The Committee agreed that the information presented to support evidence did not show that the measured process leads to a desired health outcome, and therefore the measure was rated insufficient on evidence. The Committee then voted to pass the measure on evidence with exception. The Committee determined there is consensus of expert opinion that the benefits of what is being measured (documented plan of care to address pain) outweighs any potential harm.

For performance gap, the Committee noted that the developer provided data from the literature demonstrating that patients with cancer receive disparate treatment across groupings.

The Committee also had no concerns about the reliability or validity of the measure. During the discussion on feasibility, the Committee noted the difficulty with extracting the information from an EHR, since there is no designated field. Traditionally the extraction is completed through audits. Another member noted that this has been a challenging measure to measure consistently. The Committee noted that it could be extremely difficult to obtain an accurate number of visits; however, one unforeseen benefit is that practices are improving their electronic infrastructure to accurately capture this documentation. However, the Committee overall agreed that the measure was feasible to report and passed it on feasibility.



This measure is currently being publicly reported in the Merit-Based Incentive Payment System (MIPS) and in the Prospective Payment System-exempt Cancer Hospital Quality Reporting (PCHQR) program, and the Committee expressed no concerns about the use of the measure. When discussing usability, the Committee noted the dangers of opioid prescribing patterns associated with this measure and suggested that a future version of the measure might consider the distinction between pain in patients with an incurable cancer versus a curable cancer. Patient representatives on the Committee also noted the importance of providing better patient education about medications prescribed to them.

The Committee also discussed whether there was a way to create a unified measure between 0383 and 0384 as a composite measure. The developer clarified that this is an area of interest but might be procedurally challenging, as these measures return for maintenance and are related but no longer paired, and there is no current data for testing on such a composite.

**1858 Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy (American Society of Clinical Oncology): Recommended**

**Description:** Percentage of female patients aged 18 and over with HER2/neu positive invasive breast cancer who are administered trastuzumab; **Measure Type:** Process; **Level of Analysis:** Clinician: Group/Practice; **Setting of Care:** Outpatient Services; **Data Source:** Paper Medical Records, Registry Data

The Committee recommended the measure for continued endorsement. The Committee noted that this measure represents a standard of cancer care measure that remains relevant for measurement. Several Committee members expressed concern about the performance rate of 97.5% in the 2017 Quality Payment Program (QPP). While there is a high performance rate in the program, the Committee noted persist gaps in the medical literature and the importance for this measure. The developer offered that this measure focuses on the importance of ensuring records connect in order to get the necessary information to the physician in a timely manner, and if this is lacking, it could be an indication of a larger systems issue rather than a physician's lack of adherence to guidelines.

The Committee discussed the age range for the measure, noting that the measure should consider an upper bound in which treatment would stop. The developer noted that another measure is in development that will specify an age cutoff for treatment. The Committee discussed the lack of data on minority populations, noting concerns that the performance rates may mask underlying disparities.

The developer computed a signal-to-noise ratio to test the reliability of the measure score using a beta-binomial model. A Committee member raised concern regarding exclusions in the measure denominator. Specifically, the Committee member noted the denominator exclusion: *Reason for not administering trastuzumab documented (e.g., patient declined, patient died, patient transferred, contraindication or other clinical exclusion, neoadjuvant chemotherapy or radiation therapy not complete)*. The Committee member noted this exclusion is broad and may lead to the inappropriate exclusion of patients from the denominator and encouraged the developer to revisit this exclusion in future updates.

The Committee reviewed and discussed the remaining evaluation criterion—feasibility, use, and usability, and did not express any concerns.

**1859 RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy (American Society of Clinical Oncology): Recommended**

**Description:** Percentage of adult patients (aged 18 and over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed; **Measure Type:** Process; **Level of Analysis:** Clinician Group/Practice; **Setting of Care:** Outpatient Services; **Data Source:** Paper Medical Records, Registry Data

The Committee recommended the measure for continued endorsement. The measure captures the percentage of adult patients (aged 18 and over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed.

The Committee reviewed the updated evidence; specifically, the guidelines used to support it—an American Society of Clinical Oncology recommendation and National Comprehensive Cancer Network guideline on colon cancer. One Committee member mentioned that the evidence provided by the developer seems to be in direct support of this measure since it is focused on whether a test was performed. The developer responded, citing that there is a need for this testing, and the current evidence supports those with a KRAS gene mutation receiving anti-epidermal growth factor receptor monoclonal antibody therapy, and patients without a KRAS gene mutation are actually harmed by this treatment. This led to the development of a second measure (#1860) to address this difference. There was overall consensus among the Committee that data showed a persistent performance gap.

During the discussion of validity, the Committee expressed a concern with the numerator of the measure regarding whether RAS gene mutation testing was performed. The measure is capturing a process that may not be sufficiently granular enough to ensure that the molecular test identifies the important mutations for the treatment of colon cancer. While the Committee agreed that the issue of the granularity of the measurement is a challenge, the measure still addresses an important quality goal in the treatment of cancer.

The Committee agreed that since this measure is reported, the measure is feasible. The Committee also agreed that use and usability are not issues for this measure.

**1860 Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies (American Society of Clinical Oncology): Recommended**

**Description:** Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies; **Measure Type:** Process; **Level of Analysis:** Clinician: Group/Practice; **Setting of Care:** Outpatient Services; **Data Source:** Paper Medical Records, Registry Data

The Committee recommended the measure for continued endorsement. This measure captures the percentage of patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies.

The Committee generally agreed that sufficient evidence was provided for this measure, and the discussion of measure #1859 on evidence would apply to this measure as well. It was acknowledged that this measure was a companion measure to 1859, the difference being that treatment is not administered for a patient who is positive for the KRASG mutation. The Committee agreed that there is a performance gap with the current performance, at 91%. During the discussion on reliability, one Committee member asked about patient re-test and whether a former test for a next-generation sequencing (NGS) tumor would be applicable for this measure. The Committee discussed the probability of Medicaid covering the cost for more than one test for each NGS tumor and the potential risk of financial burden for a patient. The Committee did not express any significant concerns or comments on validity.

When discussing feasibility, the Committee noted that the data to support this measure is not structured in the electronic health record (EHR) and requires abstraction, and also questioned why this measure was not an eCQM, which may improve feasibility. The developer informed the Committee that not all EHRs are able to accommodate this, but as the technology becomes more widely available, they intend for the measure to move in that direction. It was noted by the Committee that this measure is currently used in various accountability programs and the benefits outweigh the harms.

## References

- 1 Economic Impact of Cancer. <https://www.cancer.org/cancer/cancer-basics/economic-impact-of-cancer.html>. Last accessed March 2020.
- 2 Cancer Statistics. National Cancer Institute. <https://www.cancer.gov/about-cancer/understanding/statistics>. Published April 2, 2015. Last accessed March 2020.
- 3 Cancer Facts & Figures 2016 | American Cancer Society. <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2016.html>. Last accessed March 2020.
- 4 Cancer Prevalence and Cost of Care Projections. <https://costprojections.cancer.gov/>. Last accessed March 2020.

## Appendix A: Details of Measure Evaluation

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

### Track 1 – Measures Recommended

#### 0219 Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer

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

**Description:** Percentage of female patients, age = 18 and <70 at diagnosis, who have their first diagnosis of cancer (epithelial malignancy), whose primary tumor is of the breast, had breast conserving surgery and was administered radiation therapy within 1 year (365 days) of diagnosis

**Numerator Statement:** Radiation therapy is administered within 1 year (365 days) of the date of diagnosis

**Denominator Statement:** Include if all of the following characteristics are identified:

Women

Age = 18 and <70 at time of diagnosis

Known or assumed to be first or only cancer diagnosis

Epithelial malignancy only

Invasive tumors

Primary tumors of the breast

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

Known to be alive within 1 year (365 days) of date of diagnosis

Receipt of breast conserving surgery

**Exclusions:** Exclude, if any of the following characteristics are identified:

Men

Under age 18 or over 69 at time of diagnosis

Second or subsequent cancer diagnosis

Tumor not originating in the breast

Non-epithelial malignancies, exclude rare tumors: 8940 - Mixed tumor, malignant, NOS; 8950 - Mullerian mixed tumor; 8980 - Carcinosarcoma; 8981 - Carcinosarcoma, embryonal

Non-invasive tumor

Stage 0, in situ tumor

Stage IV, metastatic tumor

None of 1st course therapy performed at reporting facility

Breast conserving surgery was not received

Died within 1 year (365 days) of diagnosis

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

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

**Level of Analysis:** Facility

**Setting of Care:** Inpatient/Hospital

**Type of Measure:** Process

**Data Source:** Registry Data

**Measure Steward:** Commission on Cancer, American College of Surgeons

**0219 Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer**

**STANDING COMMITTEE MEETING 02/26/2020**

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

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

1a. Evidence: **M-15; L-0; I-0**; 1b. Performance Gap: **H-2; M-12; L-1; I-0**

**Rationale:**

- The evidence for this measure is a National Comprehensive Cancer Network (NCCN) Practice Guideline. The developer has used this as the supporting guideline, and categories for evidence is Level 1.
- The performance data from the NCDB was provided from 2015. The developer explained that the lag in data collection existed because it takes longer to document receipt of adjuvant therapy.
- The data from 2008 and 2015 demonstrated improvement over time, 88.1% (2008) and 92.0% (2015), and disparities exist based on race and ethnicity, age, insurance status, income, educational level, facility type, and region of the country. The Committee agreed there is a continuing gap in performance that justifies ongoing performance measurement and reporting. The Committee was pleased that the NCDB used by the developer contained disparities data, including race/ethnicity data and insurance data, and encouraged other developers to take note.

**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-3; M-12; L-0; I-0**; 2b. Validity: **M-14; L-1; I-0**

**Rationale:**

- The measure is a process measure reported at the facility level, and the data elements are collected from a registry. The Committee agreed the data elements were clear and precise, and there were no concerns of threats to reliability of the measure.
- Validity testing was conducted at the data element level. Annually a review of a minimum of 10% of the annual caseload of the registry abstracts is performed to verify that abstracted data accuracy. Both the annual caseload reviews and the measure reporting system reviews are intended to ensure that reported performance rates are an accurate reflection of the care provided to patients at CoC-accredited programs.

**3. Feasibility: **H-9; M-6; L-0; I-0****

*(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/unintended consequences identified; 3d. Data collection strategy can be implemented)*

**Rationale:**

- This measure is currently reported to CoC-accredited programs through the NCDB using the Cancer Program Practice Profile Report (CP3R) web-based audit and feedback reporting tool by registrars submitting new and updated cases annually. In addition, this measure is also reported to 1,500 cancer programs participating in its “real clinical time” feedback reporting tool through its Rapid Quality Reporting System (RQRS) reported daily from registrars in regard to new and updated cases. Both of these reporting tools have been used in the cancer registry community and do not produce an undue burden on the data collection network.
- The Committee expressed concern about smaller hospitals that might not have a registry. The Committee did ask whether this measure was limited to NCDB hospitals. The developer clarified that a benefit of being part of the CoC is they report back to COC programs, but that the measure specifications can be applied to any registry data, regardless of whether it is from a reporting hospital.

**0219 Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer**

**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-12; M-3; L-0; I-0**

Rationale:

- This measure is in use within accountability programs including Public Reporting – Pennsylvania Health Care Quality Alliance (PHCQA); Quality Improvement and Benchmarking – CoC, NCDB; and Regulatory and Accreditation programs –CoC Standards.

**5. Related and Competing Measures**

- No related or competing measures noted.

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

**7. Public and Member Comment**

- The Alliance of Dedicated Cancer Centers (ADCC) supports the Committee’s recommendation for continued endorsement. Thank you for the opportunity to comment.

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

**9. Appeals**

**0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

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

**Description:** Percentage of female patients, age = 18 at diagnosis, who have their first diagnosis of cancer (epithelial malignancy), at AJCC T1cN0M0 or stage IB to IIIC, whose primary tumor is of the breast, and is progesterone or estrogen receptor positive with adjuvant hormonal therapy (recommended or administered) within 1 year (365 days) of diagnosis

**Numerator Statement:** Adjuvant hormonal therapy is administered within 1 year (365 days) of the date of diagnosis or it is recommended but not administered

**Denominator Statement:** Include if all of the following characteristics are identified:

Women

Age = 18 at time of diagnosis

Known or assumed to be first or only cancer diagnosis

Epithelial malignancy only

Invasive tumors

Primary tumors of the breast

AJCC T1cN0M0 or Stage IB – IIIC

Primary tumor is estrogen receptor positive or progesterone receptor positive

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

Known to be alive within 1 year (365 days) of date of diagnosis

Surgical procedure of the primary site

**Exclusions:** Exclude, if any of the following characteristics are identified:

Men

Under age 18 at time of diagnosis

Second or subsequent cancer diagnosis

Tumor not originating in the breast

Non-epithelial malignancies, exclude malignant phyllodes tumors; 8940 - Mixed tumor, malignant, NOS; 8950 - Mullerian mixed tumor; 8980 - Carcinosarcoma; 8981 - Carcinosarcoma, embryonal

Non-invasive tumors

Stage 0, in-situ tumor

Stage IV, metastatic tumor

Primary tumor is estrogen receptor negative and progesterone receptor negative

None of 1st course therapy performed at reporting facility

Died within 1 year (365 days) of diagnosis,

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

No surgical procedure of the primary site

Not AJCC T1cN0M0 or not AJCC stage IB-IIIC

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

**Level of Analysis:** Facility

**Setting of Care:** Inpatient/Hospital

**Type of Measure:** Process

**Data Source:** Registry Data

**Measure Steward:** Commission on Cancer, American College of Surgeons



**0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

**STANDING COMMITTEE MEETING 02/26/2020**

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

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

1a. Evidence: **M-18; L-0; I-0**; 1b. Performance Gap: **H-3; M-14; L-1; I-0**

**Rationale:**

- In the 2019 submission, the developer provided an updated link to the National Comprehensive Cancer Network Guidelines v2.2019 and grade of evidence (Level 1).
- The performance data from the NCDB was provided from 2015. The developer explained that the lag existed in data collection because it takes longer to document receipt of adjuvant therapy.
- The data from 2008 and 2015 demonstrated improvement over time, 78.8% (2008) and 92.7% (2015), and disparities exist based on race, ethnicity, age, insurance status, income, educational level, facility type, and region of the country. The Committee agreed there is a continuing gap in performance that justifies ongoing performance measurement and reporting. The Committee was pleased that the NCDB used by the developer contained disparities data, including race/ethnicity data and insurance data, and encouraged other developers to take note.

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

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

2a. Reliability: **H-2; M-16; L-0; I-0**; 2b. Validity: **H-5; M-12; L-0; I-0****Rationale:**

- The measure is a process measure reported at the facility level, and the data elements are collected from a registry. The Committee agreed the data elements were clear and precise, and there were no concerns of threats to reliability of the measure.
- Validity testing was conducted at the data element level. Annually a review of a minimum of 10% of the annual caseload of the registry abstracts is performed to verify that abstracted data accuracy. Both the annual caseload reviews and the measure reporting system reviews are intended to ensure that reported performance rates are an accurate reflection of the care provided to patients at CoC-accredited programs.

**3. Feasibility: **H-9; M-7; L-0; I-0****

*(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/unintended consequences identified; 3d. Data collection strategy can be implemented)*

**Rationale:**

- This measure is currently reported to CoC-accredited programs through the NCDB using the CP3R web-based audit and feedback reporting tool by registrars submitting new and updated cases annually. In addition, this measure is also reported to 1,500 cancer programs participating in its “real clinical time” feedback reporting tool through its RQRS reported daily from registrars in regard to new and updated cases. Both of these reporting tools have been used in the cancer registry community and do not produce an undue burden on the data collection network.
- The Committee did not express any additional concerns with feasibility.

**0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

**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-16; No Pass-0** 4b. Usability: **H-10; M-6; L-0; I-0**

Rationale:

- This measure is in use within accountability programs including Public Reporting – PHCQA); Quality Improvement and Benchmarking – CoC, NCDB; and Regulatory and Accreditation programs – CoC Standards, Cancer Program Practice Profile Reports, Cancer Quality Improvement Program, Rapid Quality Reporting System

**5. Related and Competing Measures**

- This measure is related to NQF 0387e – Breast Cancer: Hormonal Therapy for Stage I (T1b) – IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer.
- No competing measures noted.

**6. Standing Committee Recommendation for Endorsement: Y-16; N-0**

**7. Public and Member Comment**

- The Alliance of Dedicated Cancer Centers (ADCC) supports the Committee’s recommendation for continued endorsement. Thank you for the opportunity to comment.

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

**9. Appeals**

## 0383 Oncology: Medical and Radiation - Plan of Care for Pain

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

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

**Numerator Statement:** Patient visits that include a documented plan of care\* to address pain.

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

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

**Exclusions:** None

**Adjustment/Stratification:** N/A, no risk stratification. No risk adjustment or risk stratification

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

**Setting of Care:** Outpatient Services

**Type of Measure:** Process

**Data Source:** Paper Medical Records, Registry Data

**Measure Steward:** American Society of Clinical Oncology

### STANDING COMMITTEE MEETING 02/26/2020

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

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

1a. Evidence: **M-3; L-4; I-11**; Evidence Exception: **Y-16; N-2**; 1b. Performance Gap: **H-1; M-13; L-3; I-0**

#### Rationale:

- The developer provided updated evidence for this measure, citing the NCCN Clinical Practice Guidelines in Oncology, Adult Cancer Pain includes management of pain in both opioid-naïve and opioid tolerant patient.
- This guideline did not include an overview of the body of evidence used for recommendations specific to the overall management of pain, nor does it address specifically what the measure is evaluating, which is or developing a plan of care for pain.
- The Committee discussed the difference between a level 1 guideline and level 2A guideline, citing that level 1 evidence is specific to randomized control trials (RCT).
- The Committee discussed the guideline level of evidence (Level 2A), which is a lower level, but there was consensus among the Committee that the intervention was appropriate. The guideline also includes an in-depth discussion on the evidence, benefits, as well as and harms of specific therapies and interventions.
- Patient advocates on the Standing Committee stressed the importance of the measure, as it signifies a step to make certain that pain is addressed.
- The Committee discussed the difference between a Level 1 guideline and Level 2A guideline, citing that Level 1 evidence is specific to RCT.
- The Committee, using their expertise, made the determination that the benefits of what is being measured (documented plan of care to address pain) outweighs any potential harm, and voted to pass the measure on evidence with exception.
- Performance gap data ranged from 75-89% from 2015 through 2017, showing an increase in performance. There was no performance data on disparities.

## 0383 Oncology: Medical and Radiation - Plan of Care for Pain

### 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-1; M-13; L-3; I-0**; 2b. Validity: **H-1; M-14; L-2; I-0**Rationale:

- Reliability was measured as the ratio of signal to noise, and testing was performed using a beta-binomial model.
- The measure was revised for the 2019 submission to include two different populations (chemotherapy patient and radiation patients both undergoing active therapy and experiencing pain).
- The overall reliability score was 0.98, which suggests a high degree of reliability.
- The Committee did not express any concerns on reliability.
- The developer performed a correlation analysis with measure #0384 (Oncology: Medical and Radiation – Pain Intensity Quantified) due to the similarities in patient population and domain.
- This correlation analysis method demonstrated an association between patients with a diagnosis of cancer receiving chemotherapy or radiation therapy in which pain intensity is quantified, 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.
- The Committee had no concerns with validity testing and did not find any threats of validity.

### 3. Feasibility: **H-0; M-13; L-5; I-0**

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/unintended consequences identified; 3d. Data collection strategy can be implemented)

Rationale:

- The data elements of the measure are generated during the provision of care, and are collected through the EHR or through the use of keyword searches.
- The Committee noted the difficulty with extracting the information from an EHR without a designated field. Traditionally, the extraction is completed through audits.
- The Committee noted that it could be extremely difficult to obtain an accurate number of visits; however, one unforeseen benefit is that practices are improving their electronic infrastructure to accurately capture this documentation.

### 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-18; No Pass-0** 4b. Usability: **H-1; M-13; L-3; I-1**

Rationale:

- This measure is currently used in accountability programs: MIPS, American Society of Clinical Oncology's Quality Oncology Practice Incentive (QOPI) and PPS-Exempt Cancer Hospital Quality Reporting (PCHQR).
- The Committee noted a potential danger with the usability of this measure as it relates to opioid-prescribing patterns. The concern is that patients may inaccurately report pain to receive opioid prescriptions. The Committee suggested that a future version of the measure might consider the distinction between pain in patients with an incurable cancer versus a curable cancer.
- Patient representatives on the Committee also noted the importance of providing better patient education about medications prescribed to them.

### 5. Related and Competing Measures

- This measure is related to NQF #0524: Pain Interventions Implemented During Short Term Episodes of Care and NQF #1628: Patients with Advanced Cancer Screened for Pain at outpatient visits.

This measure does not compete with any measures.

## **0383 Oncology: Medical and Radiation - Plan of Care for Pain**

### **6. Standing Committee Recommendation for Endorsement: Y-15; N-2**

#### Rationale

- During the Committee's discussion on evidence, they voted to use the evidence exception option, determining that the benefits of what is being measured (documented plan of care to address pain) outweighs any potential harm.
- The Committee also discussed the pairing of this measure (0383) with measure 0384, and suggested to the developer that a composite measure be developed that would include both.

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

- The Alliance of Dedicated Cancer Centers (ADCC) supports the Committee's recommendation for continued endorsement. We believe this measure is dependent upon the related measure, NQF #0384, also an endorsed measure. Please refer to our comments on NQF #0384 for a detailed explanation. Thank you for the opportunity to comment.

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

### **9. Appeals**

**1858 Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

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

**Description:** Percentage of female patients aged 18 and over with HER2/neu positive invasive breast cancer who are administered trastuzumab

**Numerator Statement:** Patients for whom trastuzumab is administered within 12 months of diagnosis

**Denominator Statement:** Female patients aged 18 and over with AJCC stage I (T1c) – III, HER2/neu positive breast cancer who receive chemotherapy

**Exclusions:** Denominator Exclusions:

- o Patient transfer to practice after initiation of chemotherapy

Denominator Exceptions:

- o Reason for not administering trastuzumab documented (e.g. patient declined, patient died, patient transferred, contraindication or other clinical exclusion, neoadjuvant chemotherapy or radiation therapy not complete)

**Adjustment/Stratification:** N/A, no risk stratification. No risk adjustment or stratification.

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

**Setting of Care:** Outpatient Services

**Type of Measure:** Process

**Data Source:** Paper Medical Records, Registry Data

**Measure Steward:** American Society of Clinical Oncology

**STANDING COMMITTEE MEETING 02/26/2020**

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

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

1a. Evidence: **H-12; M-5; L-0; I-0**; 1b. Performance Gap: **H-0; M-12; L-5; I-0**

Rationale:

- The developer provided updated evidence for this measure, an additional clinical practice guideline on breast cancer from NCCN. The guideline recommended HER2-targeted therapy in patients with HER2-positive tumors. Trastuzumab is humanized monoclonal antibody with specificity for the extracellular domain of HER2. The use of trastuzumab with chemotherapy was a category 1 recommendation in patients with HER2-positive tumors greater than 1 cm.
- The developer provided a systematic review of the evidence for the American Society of Clinical Oncology (ASCO) guideline, noting that a 2018 guideline update reaffirmed the recommendation of this measure. No new studies changed the conclusions reached by the 2018 guideline. In addition, a systematic review of the evidence for the Cancer Care Ontario (CCO) guideline, noting that updated guidelines continue to support the measure.
- The developer provided 2017 MIPS performance data and QPP that indicated the performance rate is 97.5%.
- The Committee expressed strong views on the importance of this measure and cited that gaps persist in the medical literature. The developer offered comments in response to the performance gap, citing that this measure focuses on the importance of making sure the patient testing records are received by the physician in a timely manner to administer therapy, and if this is lacking, it could be an indication of systems issues rather than a physician's lack of adherence to guidelines.

**1858 Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

**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-1; M-13; L-3; I-0**; 2b. Validity: **H-14; M-3; L-0; I-0**Rationale:

- The developer computed signal-to-noise scores to address precision of measurement (measure score) and used a beta-binomial model. The reported mean reliability was 0.9657, which is considered high. A reliability of zero implies that the variability in the measure is attributed to measurement error, while a reliability closer to 1 implies that the variability is attributable to real differences in facility performance. A 0.70-0.80 reliability is considered an acceptable threshold; 0.80-0.90 is considered high reliability; and 0.90-1.00 is considered very high.
- It was noted during the preliminary analysis of the measure that testing is at the facility level but indicated that level of analysis is group/practice. The developer clarified that there was a misunderstanding in the terminology between facility and group/practice, but the testing was conducted at the facility level.
- The developer conducted a Pearson correlation analysis to determine the association between performance scores of the shared providers. The correlation was 0.711, indicating a strong, positive correlation between performance scores of the shared providers.
- There was concern raised by one committee member about a statement in the denominator exclusions that state: Reason for not administering trastuzumab documented (e.g., patient declined, patient died, patient transferred, contraindication or other clinical exclusion, neoadjuvant chemotherapy or radiation therapy not complete). Specifically, the concern was that this statement gave the impression that physicians can give any reason at all for not administering Trastuzumab and be excluded from the denominator. The Committee urged the developer to think about this exclusion as they are developing a new measure.

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

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/unintended consequences identified; 3d. Data collection strategy can be implemented)

Rationale:

- The measure data elements are documented during routine care; however, they are either documented in a narrative note, an order (i.e., pain medication, referral), or in an electronic way depending on EHR build. It was noted by the Committee that this may be burdensome, as it may require chart abstractions. The developer reports that they are in the process of assessing feasibility of developing an eCQM.

**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-17; No Pass-1** 4b. Usability: **H-2; M-15; L-0; I-1**

Rationale:

- This measure is currently used in accountability programs including MIPS, Quality Oncology Practice Initiative (QOPI), Core Quality Measure Collaborative's (CQMC) Medical Oncology Core Measure Set.
- The developer reported a high performance rate of 97.51% in the 2017 QPP Data Results. The 2019 MIPS benchmarking data for quality improvement is 450.

**5. Related and Competing Measures**

- This measure related to NQF 1855 Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines and NQF 1857 HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies
- No competing measures noted.

**1858 Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

**6. Standing Committee Recommendation for Endorsement: Y-18; N-0**

**7. Public and Member Comment**

- The Alliance of Dedicated Cancer Centers (ADCC) supports the Committee’s recommendation for continued endorsement. Thank you for the opportunity to comment.

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

**9. Appeals**



## 1859 RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy

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

**Description:** Percentage of adult patients (aged 18 and over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed

**Numerator Statement:** RAS (KRAS and NRAS) gene mutation testing performed prior to initiation of anti-EGFR monoclonal antibody therapy

**Denominator Statement:** Adult patients with metastatic colorectal cancer who receive anti-EGFR monoclonal antibody therapy

**Exclusions:** None

**Adjustment/Stratification:** N/A. No risk adjustment or stratification.

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

**Setting of Care:** Outpatient Services

**Type of Measure:** Process

**Data Source:** Paper Medical Records, Registry Data

**Measure Steward:** American Society of Clinical Oncology

### STANDING COMMITTEE MEETING 02/26/2020

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

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

1a. Evidence: **H-4; M-13; L-1; I-0**; 1b. Performance Gap: **H-7; M-10; L-1; I-0**

#### Rationale:

- The developer provided updated evidence for this measure. A recommendation from the ASCO): Colorectal carcinoma patients being considered for anti-EGFR therapy must receive RAS mutational testing. Mutational analysis should include KRAS and NRAS codons 12, 13 of exon 2; 59, 61 of exon 3; and 117 and 146 of exon 4 ("expanded" or "extended" RAS).
- The grade of evidence for the ASCO recommendation was expert consensus opinion. The developer noted the limitations, such as limited strength of evidence, intermediate-to-low quality of evidence, and balance of benefits and harms, values, or costs.
- The updated evidence also included a clinical practice guideline: NCCN guideline on colon cancer: All patients with metastatic colorectal cancer should have tumor tissue genotyped for RAS (KRAS and NRAS) and BRAF mutations individually or as part of an NGS panel. The developer noted that the NCCN guidelines do not present evidence used for the recommendation specific to RAS mutation status; however, evidence is provided on the benefits and harms of EGFR inhibitors. This was noted as a challenge for the developer, considering the length of time it takes to develop new guidelines as well as working within the confines of what is available
- The Committee discussed specifically the evidence presented to support gene mutation testing, citing that the information presented seems to be indirect evidence to support the measure.
- The developer clarified that the intent of the measure is to focus on two components: 1) patients receiving the drug who have the RAS mutation; and 2) patients who are RAS mutant and are receiving this drug and whether it is causing harm (e.g., immediate toxicity related to cost and survivorship).
- A performance gap from the analysis of 2017 MIPS performance registry data was provided. The data is presented per practice with a mean of 76%. No disparities data was presented. However, the developer cited a 2017 Surveillance, Epidemiology, and End Results (SEER) study that found overall proportion of KRAS testing was only 22.7% among the sample population, with variation by geographic region and patient characteristics, indicating disparities in KRAS testing.

## 1859 RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy

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

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

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

- The developer computed signal-to-noise scores to address precision of measurement (measure score) and used a beta-binomial model. A reliability of zero implies that the variability in the measure is attributed to measurement error, while a reliability of 1 implies that the variability is attributable to real differences in facility performance. The developers reported a mean reliability of 0.8908, which is considered very high.
- It was noted during the preliminary analysis of the measure that testing was at the facility level, but it was indicated that level of analysis is group/practice. The developer clarified that there was a misunderstanding in the terminology between facility and group/practice, but the testing was conducted at the facility level. Facility-level reliability testing was found to be a mean of 0.9465, which is associated with a high level of reliability.
- Empirical validity testing of the measure score was provided. The developer performed a Pearson correlation analysis to determine the association between the performance scores of the shared providers, and those scores were interpreted in the following way: >0.40 correlation coefficient = strong correlation; 0.20-0.40 correlation coefficient = moderate correlation; <0.20 correlation coefficient = weak coefficient. The correlation was 0.49, indicating a positive correlation between performance scores of the shared providers.
- The Committee expressed a concern with the accuracy of the testing, citing it was critically important because there are a large number of RAS mutations that exist, and this measure may not be granular enough to capture the most appropriate clinical information.

### 3. Feasibility: **H-1; M-17; L-0; I-0**

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/unintended consequences identified; 3d. Data collection strategy can be implemented)

Rationale:

- The measure data elements are documented during routine care; however, they are either documented in a narrative note, an order (i.e., pain medication, referral), or in an electronic way depending on EHR build. It was noted by the Committee that this may be burdensome, as it may require chart abstractions. The developer reports that they are in the process of assessing feasibility of developing an eCQM.

### 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-18; No Pass-0** 4b. Usability: **H-4; M-12; L-1; I-1**

Rationale:

- The measure is currently used in several accountability programs, which include MIPS; Quality Oncology Practice Initiative (QOPI); and Core Quality Measure Collaborative's (CQMC) Medical Oncology Core Measure Set.
- The developer reported a high performance rate for usability of the measure. Approximately 54% of practices are performing at 100%; however, multiple practices are still operating at 0%. Mean performance is at 76%, indicating room for improvement. The MIPS 2017 performance data does not include RAS testing guideline changes made in 2018. The developer anticipates a greater performance gap to be made due to this guideline update.
- The Committee agreed with the use and usability of the measure.

**1859 RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

**5. Related and Competing Measures**

- This measure is related to NQF 1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies.
- No competing measures presented

**6. Standing Committee Recommendation for Endorsement: Y-16; N-2**

**7. Public and Member Comment**

- The Alliance of Dedicated Cancer Centers (ADCC) supports the Committee’s recommendation for continued endorsement. Thank you for the opportunity to comment.
- The College of American Pathologists (CAP) fully supports measure 1859, RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy, for renewal of endorsement by NQF. This measure is consistent with best clinical practice as recommended by the CAP with respect to RAS (KRAS and NRAS) testing in metastatic colorectal carcinoma. Endorsement of this measure recognizes the importance of accurate and complete biomarker testing to guide patient management and supports the continuity of care from diagnostic clinicians to oncologists to patients. This measure, which was already successfully implemented, has been updated to comply with the most recent guidelines and therefore represents the most stringent biomarker testing requirements and will likely show a significant gap in performance. Based on the clinical significance, scientific validity, and demonstrated feasibility, measure 1859 should be re-endorsed.

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

**9. Appeals**

## 1860 Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies

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

**Description:** Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies

**Numerator Statement:** Anti-EGFR monoclonal antibody therapy not received

**Denominator Statement:** Adult patients with metastatic colorectal cancer who have a RAS (KRAS or NRAS) gene mutation

**Exclusions:** None

**Adjustment/Stratification:** N/A. No risk adjustment or stratification.

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

**Setting of Care:** Outpatient Services

**Type of Measure:** Process

**Data Source:** Paper Medical Records, Registry Data

**Measure Steward:** American Society of Clinical Oncology

### STANDING COMMITTEE MEETING 02/26/2020

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

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

1a. Evidence: **H-11; M-6; L-0; I-0**; 1b. Performance Gap: **H-15; M-3; L-0; I-0**

#### Rationale:

- The developer provided an overview of the evidence to support this measure, citing that the focus of the measure is halting the use of anti-EGFR monoclonal antibody (MoAb) therapies in patients who will not derive any benefit.
- The body of evidence provided for this measure addressed the relationship between RAS status in patients with metastatic colorectal cancer who underwent anti-EGFR MoAb therapy, specifically cetuximab or panitumumab, and the outcomes of tumor response, progression-free survival, and overall survival. Patients with and without KRAS or NRAS mutations to exons 2, 3, or 4 who underwent anti-EGFR MoAb therapy were evaluated with respect to these outcomes in both single-arm and randomized trials. Additionally, this measure is directly supported by recommendations in American Society for Clinical Pathology, College of American Pathologists, Association for Molecular Pathology, American Society of Clinical Oncology, and NCCN clinical practice guidelines.
- The Committee generally agreed that sufficient evidence was provided for this measure, and acknowledged that the discussion of measure 1859 on evidence would apply to this measure as well. It was noted that measure 1860 was a companion measure to 1859—the difference being that treatment is not administered for a patient who is positive for the KRASG mutation.
- The developer provided 2017 MIPS performance from registry data provided from CMS. The 2017 data was from 158 providers representing 43 practices and 495 individual patients. The majority (approximately 76.7%) of practices perform at 100% with a mean performance of 91%. The mean performance rate of 91% is statistically significant from 100%, suggesting that room for improvement remains across practices.

## 1860 Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies

### 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-10; M-8; L-0; I-0**; 2b. Validity: **H-12; M-6; L-0; I-0**

#### Rationale:

- The measure developer noted changes to the measure specifications since the last endorsement, including an expansion to RAS mutational testing based on a guideline update to include NRAS as well as KRAS. In addition to testing for mutations in KRAS exon 2 (codons 12 and 13) as recommended previously, before treatment with anti-EGFR antibody therapy, patients with metastatic colorectal cancer should have their tumor tested for mutations in: KRAS exons 3 (codons 59 and 61) and 4 (codons 117 and 146), NRAS exons 2 (codons 12 and 13), 3 (codons 59 and 61), and 4 (codons 117 and 146)
- Additionally, the developer noted that an exclusion was removed for patient transfer to practice after initiation of chemotherapy and receipt of anti-EGFR monoclonal antibody therapy as part of a clinical trial protocol.
- Reliability of the computed measure score was measured as the ratio of signal to noise. The signal in this case is the proportion of the variability in measured performance that can be explained by real differences in physician performance, and the noise is the total variability in measured performance.
- The Committee asked about patient retest and whether a former test for NGS tumors would be applicable for this measure. This led to a further discussion on payment with this measure. Since Medicaid will only pay for one test for each NGS tumor, there is the potential risk of financial burden for this measure, as the patient may not be able to afford sufficient testing.
- A correlation analysis was completed to conduct empirical validity testing using 2017 MIPS data. KRAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy (QI #451/ NQF#1859) was chosen as a suitable candidate for correlation analysis due to the similarities in patient population and domain.
- This measure has a strong positive correlation with another evidence-based process of care, as the correlation coefficient observed was 0.49.

### 3. Feasibility: **H-1; M-17; L-0; I-0**

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/unintended consequences identified; 3d. Data collection strategy can be implemented)

#### Rationale:

- When discussing feasibility, the Committee noted that the data to support this measure is not structured in the EHR and requires abstraction, and they questioned why this measure was not an eCQM, which may improve feasibility. The developer informed the Committee that not all EHRs are able to accommodate this, but as the technology becomes more widely available, they intend for the measure to move in that direction.

## 1860 Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies

### 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-17; No Pass-1** 4b. Usability: **H-2; M-15; L-1; I-0**

#### Rationale:

- The measure is currently used in accountability programs including Payment Program MIPS; ASCO Qualified Clinical Data Registry; Quality Improvement (external benchmarking to organizations); Quality Oncology Practice Initiative (QOPI®); Quality Improvement (Internal to the specific organization); Quality Oncology Practice Initiative (QOPI®)
- The performance results of the measure show that 76% of the practices report at 100%, so there is still room for improved performance.

### 5. Related and Competing Measures

- This measure is related to NQF 1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody treatment.
- No competing measures noted.

### 6. Standing Committee Recommendation for Endorsement: Y-17; N-1

### 7. Public and Member Comment

- The Alliance of Dedicated Cancer Centers (ADCC) supports the Committee's recommendation for continued endorsement. Thank you for the opportunity to comment.

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

### 9. Appeals

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

NQF #	Title	Federal Programs: Finalized or Implemented as of February 25, 2019
0220	Adjuvant Hormonal Therapy	N/A
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)
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 (Implemented)
0384	Oncology: Medical and Radiation - Pain Intensity Quantified	MIPS Program (Implemented), Medicaid Promoting Interoperability Program for Eligible Professionals (Implemented)
0385	Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients	N/A
0385e	Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients	N/A
0387	Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer	N/A
0387e	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	N/A
0389e	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	MIPS Program (Implemented), Medicaid Promoting Interoperability Program for Eligible Professionals (Implemented)
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 (Implemented)
0508	Diagnostic Imaging: Inappropriate Use of “Probably Benign” Assessment Category in Screening Mammograms	Merit-Based Incentive Payment System (MIPS) Program (Implemented)
0509	Diagnostic Imaging: Reminder System for Screening Mammograms	Merit-Based Incentive Payment System (MIPS) Program (Implemented)
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	Hospital Compare (Implemented)

<sup>1</sup> Per CMS Measures Inventory Tool as of March 11, 2020

NQF #	Title	Federal Programs: Finalized or Implemented as of February 25, 2019
1857	HER2 Negative or Undocumented Breast Cancer Patients Spared Treatment with HER2-Targeted Therapies	N/A
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 (Implemented)
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 (Implemented)
1878	HER2 Testing for Overexpression or Gene Amplification in Patients with Breast Cancer	N/A
2930	Febrile Neutropenia Risk Assessment Prior to Chemotherapy	N/A



## 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

**Afsaneh Barzi, MD, PhD**

Associate Professor, USC – Norris Cancer Center  
Los Angeles, California

**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 (*Inactive*)**

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

**Wenora Johnson**

Research Advocate, Fight Colorectal Cancer  
Joliet, Illinois

### NATIONAL QUALITY FORUM

NQF REVIEW DRAFT—Comments due by Month DD, YYYY by 6:00 PM ET.

**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

**Denise Morse, MBA**

Director of Quality and Value Analytics, City of Hope Cancer Center  
Duarte, California

**Benjamin Movsas, MD**

Henry Ford Health System  
Detroit, Michigan

**Beverly Reigle, PhD, RN (*Inactive*)**

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

**Kathleen Giblin, RN**

Acting Senior Vice President, Quality Measurement

**Apryl Clark, MHSA**

Acting Vice President, Quality Measurement

**Nicole Williams, MPH**

Director

**Kathryn Goodwin, MS**  
Senior Project Manager

**Tamara Funk, MPH**  
Project Manager

**Hannah Bui, MPH**  
Project Analyst

## Appendix D: Measure Specifications (Tabular)

	<b>0219 Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer</b>
Steward	Commission on Cancer, American College of Surgeons
Description	Percentage of female patients, age = 18 and < 70 at diagnosis, who have their first diagnosis of cancer (epithelial malignancy), whose primary tumor is of the breast, had breast conserving surgery and was administered radiation therapy within 1 year (365 days) of diagnosis
Type	Process
Data Source	Registry Data Hospital cancer registry data, reported to the American College of Surgeons' Commission on Cancer, National Cancer Database
Level	Facility
Setting	Inpatient/Hospital
Numerator Statement	Radiation therapy is administered within 1 year (365 days) of the date of diagnosis
Numerator Details	Radiation treatment is administered (phase I radiation treatment modality [NAACCR Item# 1506] = 01-16, or phase I radiation treatment modality [NAACCR Item# 1506] = 99 AND phase I radiation primary treatment volume [NAACCR Item# 1504] = 40, 41), AND date radiation therapy started [NAACCR Item# 1210] <=365 days following date of initial diagnosis [NAACCR Item# 390]
Denominator Statement	Include if all of the following characteristics are identified: Women Age = 18 and < 70 at time of diagnosis Known or assumed to be first or only cancer diagnosis Epithelial malignancy only Invasive tumors Primary tumors of the breast All or part of 1st course of treatment performed at the reporting facility Known to be alive within 1 year (365 days) of date of diagnosis Receipt of breast conserving surgery
Denominator Details	Sex [NAACCR Item# 220] = 2 Age at diagnosis [NAACCR Item# 230] = 018 and < 070 Known or assumed to be first or only cancer diagnosis [NAACCR Item# 560] = 00, 01 Stageable epithelial tumor ICD-O codes in the AJCC 8th Edition staging manual [NAACCR Item# 522] = 8022, 8032, 8035, 8041, 8070, 8200, 8201, 8211, 8246, 8290, 8314, 8315, 8410, 8430, 8480, 8500, 8502, 8503, 8504, 8507, 8509, 8510, 8513, 8520, 8525, 8530, 8540, 8550, 8570, 8571, 8572, 8574, 8575, 8982, 8983, 8000, 8010, 8140, 8255, 8401, 8501, 8521, 8522, 8523, 8524, 8541, 8543 Invasive tumor behavior [NAACCR Item# 523] = 3 Primary tumors of the breast [NAACCR Item# 400] = C50.0, C50.1, C50.2, C50.3, C50.4, C50.5, C50.6, C50.8, C50.9 AJCC clinical stage group [NAACCR Item# 1004] ? 0, 4 when AJCC pathologic stage group [NAACCR Item# 1014] = 88, 99 AJCC pathologic stage group [NAACCR Item# 1014] ? 0, 4 AJCC clinical M [NAACCR Item#1003] ? cM1, pM1 AJCC pathologic M [NAACCR Item#1013] ? cM1, pM1

	<b>0219 Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer</b>
	<p>All or part of 1st course of treatment performed at the reporting facility [NAACCR Item# 610] = 10-22</p> <p>Known to be alive within 1 year (365 days) of date of diagnosis: vital status [NAACCR Item# 1760] = 1 AND date of last contact or death [NAACCR Item# 1750] – date of initial diagnosis [NAACCR Item# 390] &gt; 365</p> <p>Surgical Procedure of the Primary Site (breast conserving surgery) [NAACCR Item# 1290] = 20–24</p>
Exclusions	<p>Exclude, if any of the following characteristics are identified:</p> <p>Men</p> <p>Under age 18 or over 69 at time of diagnosis</p> <p>Second or subsequent cancer diagnosis</p> <p>Tumor not originating in the breast</p> <p>Non-epithelial malignancies, exclude rare tumors: 8940 - Mixed tumor, malignant, NOS; 8950 - Mullerian mixed tumor; 8980 - Carcinosarcoma; 8981 - Carcinosarcoma, embryonal</p> <p>Non-invasive tumor</p> <p>Stage 0, in-situ tumor</p> <p>Stage IV, metastatic tumor</p> <p>None of 1st course therapy performed at reporting facility</p> <p>Breast conserving surgery was not received</p> <p>Died within 1 year (365 days) of diagnosis</p> <p>Patient enrolled in a clinical trial that directly impacts delivery of the standard of care</p>
Exclusion details	See pages 3-8: <a href="https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx">https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx</a>
Risk Adjustment	No risk adjustment or risk stratification
Stratification	No stratification applied
Type Score	Rate/proportion    better quality = higher score
Algorithm	See pages 3-8: <a href="https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx">https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx</a> 108891  138615  141025  134906  141015
Copyright / Disclaimer	

	<b>0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer</b>
Steward	Commission on Cancer, American College of Surgeons
Description	Percentage of female patients, age = 18 at diagnosis, who have their first diagnosis of cancer (epithelial malignancy), at AJCC T1cN0M0 or stage IB to IIIC, whose primary tumor is of the breast, and is progesterone or estrogen receptor positive with adjuvant hormonal therapy (recommended or administered) within 1 year (365 days) of diagnosis
Type	Process
Data Source	Registry Data Hospital cancer registry data, reported to the American College of Surgeons' Commission on Cancer, National Cancer Database
Level	Facility
Setting	Inpatient/Hospital
Numerator Statement	Adjuvant hormonal therapy is administered within 1 year (365 days) of the date of diagnosis or it is recommended but not administered
Numerator Details	Hormone Therapy recommended and not received [NAACCR Item# 1400]=82, 85, 86, 87 (82:not recommended/ administered because it was contraindicated due to patient risk factors, 85:not administered because the patient died prior to planned or recommended therapy, 86:It was recommended by the patient's physician, but was not administered as part of first-course therapy. No reason was stated in the patient record, 87: it was recommended by the patient's physician, but this treatment was refused by the patient, the patient's family member, or the patient's guardian. The refusal was noted in the patient record) or Hormone Therapy administered [NAACCR Item# 1400] = 01 AND date hormone therapy started [NAACCR Item# 1230] <=365 days following date of initial diagnosis [NAACCR Item# 390]
Denominator Statement	Include if all of the following characteristics are identified: Women Age = 18 at time of diagnosis Known or assumed to be first or only cancer diagnosis Epithelial malignancy only Invasive tumors Primary tumors of the breast AJCC T1cN0M0 or Stage IB – IIIC Primary tumor is estrogen receptor positive or progesterone receptor positive All or part of 1st course of treatment performed at the reporting facility Known to be alive within 1 year (365 days) of date of diagnosis Surgical procedure of the primary site
Denominator Details	Sex [NAACCR Item# 220] = 2 Age [NAACCR Item# 230] = 018 Known or assumed to be first or only cancer diagnosis [NAACCR Item# 560] = 00, 01 Stageable epithelial tumor ICD-O codes in the AJCC 8th Edition staging manual [NAACCR Item# 522] = 8022, 8032, 8035, 8041, 8070, 8200, 8201, 8211, 8246, 8290, 8314, 8315, 8410, 8430, 8480, 8500, 8502, 8503, 8504, 8507, 8509, 8510, 8513, 8520, 8525, 8530, 8540, 8550, 8570, 8571, 8572, 8574, 8575, 8982, 8983, 8000, 8010, 8140, 8255, 8401, 8501, 8521, 8522, 8523, 8524, 8541, 8543

	<b>0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer</b>
	<p>Invasive tumor behavior [NAACCR Item# 523] = 3</p> <p>Primary tumors of the breast [NAACCR Item# 400] = C50.0, C50.1, C50.2, C50.3, C50.4, C50.5, C50.6, C50.8, C50.9</p> <p>AJCC T1cN0M0 or Stage IB – IIIC:</p> <p>AJCC pathologic N [NAACCR Item# 1012] = (cN0, pN0, pN0(i+), pN0(mol+)) AND tumor size summary [NAACCR Item# 756] = 011-989</p> <p>or</p> <p>AJCC pathologic N [NAACCR Item# 1012] = (cN1, cN1mi, cN2, cN2a, cN2b, cN3, cN3a, cN3b, cN3c, pN1, pN1mi, pN1a, pN1b, pN1c, pN2, pN2a, pN2b, pN3, pN3a, pN3b, pN3c)</p> <p>AJCC clinical stage group [NAACCR Item# 1004] ? 0, 4 when AJCC pathologic stage group [NAACCR Item# 1014] = 88, 99</p> <p>AJCC pathologic stage group [NAACCR Item# 1014] ? 0, 4</p> <p>AJCC clinical M [NAACCR Item# 1003] ? cM1, pM1</p> <p>AJCC pathologic M [NAACCR Item# 1013] ? cM1, pM1</p> <p>Hormone receptor positive:</p> <p>SSDI ER positive [NAACCR Item# 3826] = 001-100, R10-R99</p> <p>or</p> <p>SSDI PR positive [NAACCR Item# 3914] = 001-100, R10-R99</p> <p>All or part of 1st course of treatment performed at the reporting facility [NAACCR Item# 610] = 10-22</p> <p>Known to be alive within 1 year (365 days) of date of diagnosis: vital status [NAACCR Item# 1760] = 1 and date of last contact or death [NAACCR Item# 1750] – date of initial diagnosis [NAACCR Item# 390] &gt; 365</p> <p>Surgical Procedure of the Primary Site [NAACCR Item# 1290] = 20–90</p>
Exclusions	<p>Exclude, if any of the following characteristics are identified:</p> <p>Men</p> <p>Under age 18 at time of diagnosis</p> <p>Second or subsequent cancer diagnosis</p> <p>Tumor not originating in the breast</p> <p>Non-epithelial malignancies, exclude malignant phyllodes tumors; 8940 - Mixed tumor, malignant, NOS; 8950 - Mullerian mixed tumor; 8980 - Carcinosarcoma; 8981 - Carcinosarcoma, embryonal</p> <p>Non-invasive tumors</p> <p>Stage 0, in-situ tumor</p> <p>Stage IV, metastatic tumor</p> <p>Primary tumor is estrogen receptor negative and progesterone receptor negative</p> <p>None of 1st course therapy performed at reporting facility</p> <p>Died within 1 year (365 days) of diagnosis,</p> <p>Patient enrolled in a clinical trial that directly impacts delivery of the standard of care</p> <p>No surgical procedure of the primary site</p> <p>Not AJCC T1cN0M0 or not AJCC stage IB-IIIC</p>
Exclusion details	<p>See pages 18-26: <a href="https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx">https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx</a></p>

	<b>0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer</b>
Risk Adjustment	No risk adjustment or risk stratification
Stratification	No stratification applied
Type Score	Rate/proportion better quality = higher score
Algorithm	See pages 18-26: <a href="https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx">https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx</a> 108891  138615  141025  134906  141015
Copyright / Disclaimer	

	<b>0383 Oncology: Medical and Radiation - Plan of Care for Pain</b>
Steward	American Society of Clinical Oncology
Description	Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.
Type	Process
Data Source	Paper Medical Records, Registry Data N/A, measure is not instrument-based
Level	Clinician : Group/Practice
Setting	Outpatient Services
Numerator Statement	Patient visits that include a documented plan of care* to address pain. *A documented plan of care may include: use of non-opioid analgesics, opioids, psychological support, patient and/or family education, referral to a pain clinic, or reassessment of pain at an appropriate time interval.
Numerator Details	Patient visits that included a documented plan of care to address pain. Time Period for Data Collection: At each visit within the measurement period for patients with a diagnosis of cancer and in which pain is present. Guidance: A documented outline of care for a positive pain assessment is required. May include: use of non-opioid analgesics, opioids, psychological support, patient and/or family education, referral to a pain clinic, or reassessment of pain at an appropriate time interval.
Denominator Statement	All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain
Denominator Details	Time Period for Data Collection: 12 consecutive months Denominator Criteria (Eligible Cases): For all eligible patient encounters when pain severity quantified and pain is present (e.g., CPT II: 1125F is submitted in the numerator for NQF 0384) for patients regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy. Guidance: This measure is an episode-of-care measure; the level of analysis for this measure is every visit for patients with a diagnosis of cancer who are also currently receiving chemotherapy or radiation therapy and a positive pain assessment during the measurement period. For patients receiving radiation therapy, pain intensity should be quantified at each radiation treatment management encounter. 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.



	<b>0383 Oncology: Medical and Radiation - Plan of Care for Pain</b>
	<p>All visits for patients, regardless of age AND Diagnosis of cancer AND Patient encounter during the performance period AND Patient reported pain was present AND Radiation treatment management encounter OR Face-to-face encounter with the physician while the patient is currently receiving chemotherapy</p>
Exclusions	None
Exclusion details	N/A, no denominator exclusion
Risk Adjustment	No risk adjustment or risk stratification
Stratification	N/A, no risk stratification
Type Score	Rate/proportion better quality = higher score
Algorithm	<p>This measure is comprised of two populations but is intended to result in one reporting rate. The reporting rate is the aggregate of Population 1 and Population 2, resulting in a single performance rate. For the purposes of this measure, the single performance rate can be calculated as follows:</p> $\text{Performance Rate} = (\text{Numerator 1} + \text{Numerator 2}) / (\text{Denominator 1} + \text{Denominator 2})$ <p>Calculation algorithm for Population 1: Patient visits for patients with a diagnosis of cancer currently receiving chemotherapy</p> <ol style="list-style-type: none"> <li>1. Find the patients who meet the initial population (i.e., the general group of patients that a set of performance measures is designed to address).</li> <li>2. From the patients within the initial population criteria, find the patients who qualify for the denominator (i.e., 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.</li> <li>3. From the patients within the denominator, find the patients who meet the numerator criteria (i.e., 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</li> </ol> <p>If the patient does not meet the numerator, this case represents a quality failure.</p> <p>Calculation algorithm for Population 2: Patient visits for patients with a diagnosis of cancer currently receiving radiation therapy</p> <ol style="list-style-type: none"> <li>1. Find the patients who meet the initial population (i.e., the general group of patients that a set of performance measures is designed to address).</li> <li>2. From the patients within the initial population criteria, find the patients who qualify for the denominator (i.e., 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.</li> <li>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</li> </ol>

	<b>0383 Oncology: Medical and Radiation - Plan of Care for Pain</b>
	<p>care occurs). Validate that the number of patients in the numerator is less than or equal to the number of patients in the denominator.</p> <p>If the patient does not meet the numerator, this case represents a quality failure. 139330   139677   146282   145869   108520   141015   146763   150216   131991</p>
Copyright / Disclaimer	<p>The Measure is not clinical guidelines, does not establish a standard of medical care, and has not been tested for all potential applications.</p> <p>The Measure, while copyrighted, can be reproduced and distributed, without modification, for noncommercial purposes, e.g., use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of the Measure into a product or service that is sold, licensed or distributed for commercial gain.</p> <p>Commercial uses of the Measure require a license agreement between the user and the American Society of Clinical Oncology (ASCO) and American Medical Association (AMA), [on behalf of the Physician Consortium for Performance Improvement® (PCPI®)] and prior written approval of ASCO, AMA, or PCPI. Neither ASCO, AMA, or PCPI, nor its members shall be responsible for any use of the Measures.</p> <p>The AMA's and PCPI's significant past efforts and contributions to the development and updating of the Measure is acknowledged. ASCO is solely responsible for the review and enhancement ("Maintenance") of the Measures as of January 2015.</p> <p>ASCO encourages use of the Measures by other health care professionals, where appropriate.</p> <p>THE MEASURES AND SPECIFICATIONS ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND.</p> <p>© 2020 American Medical Association and American Society of Clinical Oncology. All Rights Reserved.</p> <p>Limited proprietary coding is contained in the Measure specification for convenience. Users of the proprietary code sets should obtain all necessary licenses from the owners of these code sets. ASCO, AMA, , PCPI and its members disclaim all liability for use or accuracy of any Current Procedural Terminology (CPT®) or other coding contained in the specification.</p> <p>CPT® contained in the Measures specifications is copyright 2004-2019 American Medical Association. LOINC® copyright 2004-2018 Regenstrief Institute, Inc. SNOMED CLINICAL TERMS (SNOMED CT®) copyright 2004-2018 College of American Pathologists. All Rights Reserved.</p>

	<b>1858 Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy</b>
Steward	American Society of Clinical Oncology
Description	Percentage of female patients aged 18 and over with HER2/neu positive invasive breast cancer who are administered trastuzumab
Type	Process
Data Source	Paper Medical Records, Registry Data N/A, measure is not instrument-based.
Level	Clinician : Group/Practice
Setting	Outpatient Services
Numerator Statement	Patients for whom trastuzumab is administered within 12 months of diagnosis
Numerator Details	<p>Numerator:</p> <p>Trastuzumab administered within 12 months of diagnosis</p> <p>Numerator Options:</p> <p>Performance Met: Trastuzumab administered within 12 months of diagnosis</p> <p>OR</p> <p>Denominator Exception: Reason for not administering Trastuzumab documented (e. g. patient declined, patient died, patient transferred, contraindication or other clinical exclusion, neoadjuvant chemotherapy or radiation NOT complete)</p> <p>OR</p> <p>Performance Not Met: Trastuzumab not administered within 12 months of diagnosis</p>
Denominator Statement	Female patients aged 18 and over with AJCC stage I (T1c) – III, HER2/neu positive breast cancer who receive chemotherapy
Denominator Details	<p>Denominator Criteria (Eligible Cases):</p> <p>Female Patients aged = 18 years on date of encounter</p> <p>AND</p> <p>Diagnosis of breast cancer</p> <p>AND</p> <p>Patient encounter during performance period</p> <p>AND</p> <p>Two or more encounters at the reporting site AND</p> <p>Breast Adjuvant Chemotherapy administered:</p> <p>AND</p> <p>HER-2/neu positive:</p> <p>AND</p> <p>AJCC stage at breast cancer diagnosis = II or III: G9831</p> <p>OR</p> <p>AJCC stage at breast cancer diagnosis = I (IA or IB) and T-Stage at breast cancer diagnosis does NOT equal = T1, T1a, T1b</p> <p>AND NOT</p> <p>Denominator Exclusions:</p> <p>Patient transfer to practice after initiation of chemotherapy</p>
Exclusions	<p>Denominator Exclusions:</p> <ul style="list-style-type: none"> <li>o Patient transfer to practice after initiation of chemotherapy</li> </ul>

	<b>1858 Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy</b>
	Denominator Exceptions: o Reason for not administering trastuzumab documented (e.g. patient declined, patient died, patient transferred, contraindication or other clinical exclusion, neoadjuvant chemotherapy or radiation therapy not complete)
Exclusion details	Denominator Exclusions: Patient transfer to practice after initiation of chemotherapy
Risk Adjustment	No risk adjustment or risk stratification
Stratification	N/A, no risk stratification
Type Score	Rate/proportion better quality = higher score
Algorithm	This measure is a proportion with exclusions and exceptions; thus, the calculation algorithm is: Patients meeting the numerator + patients with valid exceptions/ (Patients in the denominator – Patients with valid exclusions) x 100 139255  139677  142086  142085  145869  108520  141015  146763  150216
Copyright / Disclaimer	<p>The Measure is not clinical guidelines, does not establish a standard of medical care, and has not been tested for all potential applications.</p> <p>The Measure, while copyrighted, can be reproduced and distributed, without modification, for noncommercial purposes, e.g., use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of the Measure into a product or service that is sold, licensed or distributed for commercial gain.</p> <p>Commercial uses of the Measure require a license agreement between the user and the American Society of Clinical Oncology (ASCO) and American Medical Association (AMA), [on behalf of the Physician Consortium for Performance Improvement® (PCPI®)] and prior written approval of ASCO, AMA, or PCPI. Neither ASCO, AMA, or PCPI, nor its members shall be responsible for any use of the Measures.</p> <p>The AMA's and PCPI's significant past efforts and contributions to the development and updating of the Measure is acknowledged. ASCO is solely responsible for the review and enhancement ("Maintenance") of the Measures as of January 2015.</p> <p>ASCO encourages use of the Measures by other health care professionals, where appropriate.</p> <p>THE MEASURES AND SPECIFICATIONS ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND.</p> <p>© 2020 American Medical Association and American Society of Clinical Oncology. All Rights Reserved.</p> <p>Limited proprietary coding is contained in the Measure specification for convenience. Users of the proprietary code sets should obtain all necessary licenses from the owners of these code sets. ASCO, AMA, , PCPI and its members disclaim all liability for use or accuracy of any Current Procedural Terminology (CPT®) or other coding contained in the specification.</p> <p>CPT® contained in the Measures specifications is copyright 2004-2019 American Medical Association. LOINC® copyright 2004-2018 Regenstrief Institute, Inc. SNOMED CLINICAL TERMS (SNOMED CT®) copyright 2004-2018 College of American Pathologists. All Rights Reserved.</p>

	<b>1859 RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy</b>
Steward	American Society of Clinical Oncology
Description	Percentage of adult patients (aged 18 and over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed
Type	Process
Data Source	Paper Medical Records, Registry Data N/A, measure is not instrument-based.
Level	Clinician : Group/Practice
Setting	Outpatient Services
Numerator Statement	RAS (KRAS and NRAS) gene mutation testing performed prior to initiation of anti-EGFR monoclonal antibody therapy
Numerator Details	<p>RAS gene mutation testing = RAS mutation detected OR RAS gene mutation testing = No RAS mutation detected (wildtype) AND RAS gene mutation testing date</p> <p>Numerator definitions: RAS mutation testing - RAS testing for this measure refers to assays that detect mutations in codons 12 and 13 of exon 2, codons 59 and 61 of exon 3 and codons 117 and 146 in exon 4 in KRAS or NRAS. Do not include results from mutations at other codons or assays for other alterations (e.g., BRAF, PI3K, PTEN genes). The College of American Pathologists (CAP) Perspectives on Emerging Technology (POET) Report on RAS mutation testing provides additional guidance on testing. If multiple RAS mutation tests have been performed, refer to the most recent test results. In the absence of any documentation regarding testing for the RAS gene mutation, select 'Test not ordered/no documentation.'</p> <p>Refer to the interpretive report for the RAS test. The report will indicate if a mutation within codons 12 and 13 of exon 2, codons 59 and 61 of exon 3 and codons 117 and 146 in exon 4 in KRAS or NRAS, where KRAS or NRAS gene was detected in the DNA extracted from the colon tumor specimen.</p>
Denominator Statement	Adult patients with metastatic colorectal cancer who receive anti-EGFR monoclonal antibody therapy
Denominator Details	<p>Age at diagnosis greater than or equal to 18 years AND 2 or more encounters at the reporting site AND Initial colon or rectal cancer diagnosis (153.x, 154.0, 154.0, 154.1, 154.8) AND Presence of metastatic disease documented AND Anti-EGFR monoclonal antibody therapy received</p> <p>Definitions</p>

	<b>1859 RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy</b>
	Encounter: new patient visit (CPT 99201-99205) or established patient (CPT 99211-99215), not consult (CPT 99241-99245) office consult or inpatient consult CPT 99251-99255)
Exclusions	None
Exclusion details	n/a
Risk Adjustment	No risk adjustment or risk stratification
Stratification	n/a
Type Score	Rate/proportion better quality = higher score
Algorithm	This measure is a proportion without exclusions. The calculation algorithm is: (Patients meeting the numerator/patients in the denominator) x 100 139255  145869  108520  141015  146763  150216  131991  139677
Copyright / Disclaimer	<p>The Measure is not clinical guidelines, does not establish a standard of medical care, and has not been tested for all potential applications.</p> <p>The Measure, while copyrighted, can be reproduced and distributed, without modification, for noncommercial purposes, e.g., use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of the Measure into a product or service that is sold, licensed or distributed for commercial gain.</p> <p>Commercial uses of the Measure require a license agreement between the user and the American Society of Clinical Oncology (ASCO) and prior written approval of ASCO. Neither ASCO nor its members shall be responsible for any use of the Measures.</p> <p>ASCO encourages use of the Measures by other health care professionals, where appropriate.</p> <p>THE MEASURES AND SPECIFICATIONS ARE PROVIDED “AS IS” WITHOUT WARRANTY OF ANY KIND.</p> <p>© 2020 American Society of Clinical Oncology. All Rights Reserved.</p> <p>Limited proprietary coding is contained in the Measure specification for convenience. Users of the proprietary code sets should obtain all necessary licenses from the owners of these code sets. ASCO and its members disclaim all liability for use or accuracy of any Current Procedural Terminology (CPT®) or other coding contained in the specification.</p> <p>CPT® contained in the Measures specifications is copyright 2004-2019 American Medical Association. LOINC® copyright 2004-2018 Regenstrief Institute, Inc. SNOMED CLINICAL TERMS (SNOMED CT®) copyright 2004-2018 College of American Pathologists. All Rights Reserved.</p>

	<b>1860 Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies</b>
Steward	American Society of Clinical Oncology
Description	Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies
Type	Process
Data Source	Paper Medical Records, Registry Data N/A, measure is not instrument-based.
Level	Clinician : Group/Practice
Setting	Outpatient Services
Numerator Statement	Anti-EGFR monoclonal antibody therapy not received
Numerator Details	Anti-EGFR monoclonal antibody therapy status = No Anti-EGFR monoclonal antibody therapy received
Denominator Statement	Adult patients with metastatic colorectal cancer who have a RAS (KRAS or NRAS) gene mutation
Denominator Details	<p>Age at diagnosis greater than or equal to 18 years</p> <p>AND</p> <p>2 or more encounters at the reporting site</p> <p>AND</p> <p>Initial colon or rectal cancer diagnosis (ICD-10 CM C18.0, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C18.9, C19, C20)</p> <p>AND</p> <p>Presence of metastatic disease documented</p> <p>AND</p> <p>RAS (KRAS or NRAS) gene mutation detected</p> <p>Definitions</p> <p>Encounter = new patient visit (CPT 99201 -99205) or established patient (CPT 99211-99215), not consult (CPT 99241-99245 office consult or inpatient consult CPT 99251-99255)</p> <p>RAS mutation testing - RAS testing for this measure refers to assays that detect mutations in codons 12 and 13 of exon 2, codons 59 and 61 of exon 3 and codons 117 and 146 in exon 4 in KRAS or NRAS. Do not include results from mutations at other codons or assays for other alterations (e.g., BRAF, PI3K, PTEN genes). The College of American Pathologists (CAP) Perspectives on Emerging Technology (POET) Report on RAS mutation testing provides additional guidance on testing.</p> <p>If multiple RAS mutation tests have been performed, refer to the most recent test results.</p>
Exclusions	None
Exclusion details	n/a
Risk Adjustment	No risk adjustment or risk stratification
Stratification	n/a
Type Score	Rate/proportion better quality = higher score
Algorithm	This measure is a proportion without exclusions. The calculation algorithm is: (Patients meeting the numerator/patients in the denominator) x 100 139255   145869   141015   146763   150216   131991   139677
Copyright / Disclaimer	The Measure is not clinical guidelines, does not establish a standard of medical care, and has not been tested for all potential applications.

	<p><b>1860 Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies</b></p>
	<p>The Measure, while copyrighted, can be reproduced and distributed, without modification, for noncommercial purposes, e.g., use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of the Measure into a product or service that is sold, licensed or distributed for commercial gain.</p> <p>Commercial uses of the Measure require a license agreement between the user and the American Society of Clinical Oncology (ASCO) and prior written approval of ASCO. Neither ASCO nor its members shall be responsible for any use of the Measures.</p> <p>ASCO encourages use of the Measures by other health care professionals, where appropriate.</p> <p>THE MEASURES AND SPECIFICATIONS ARE PROVIDED “AS IS” WITHOUT WARRANTY OF ANY KIND.</p> <p>© 2020 American Society of Clinical Oncology. All Rights Reserved.</p> <p>Limited proprietary coding is contained in the Measure specification for convenience. Users of the proprietary code sets should obtain all necessary licenses from the owners of these code sets. ASCO and its members disclaim all liability for use or accuracy of any Current Procedural Terminology (CPT®) or other coding contained in the specification.</p> <p>CPT® contained in the Measures specifications is copyright 2004-2019 American Medical Association. LOINC® copyright 2004-2018 Regenstrief Institute, Inc. SNOMED CLINICAL TERMS (SNOMED CT®) copyright 2004-2018 College of American Pathologists. All Rights Reserved.</p>





## Appendix D: Measure Specifications (Narrative)

---

### 0219 Radiation therapy is administered within 1 year (365 days) of diagnosis for women under age 70 receiving breast conserving surgery for breast cancer

#### STEWARD

Commission on Cancer, American College of Surgeons

#### DESCRIPTION

Percentage of female patients, age = 18 and < 70 at diagnosis, who have their first diagnosis of cancer (epithelial malignancy), whose primary tumor is of the breast, had breast conserving surgery and was administered radiation therapy within 1 year (365 days) of diagnosis

#### TYPE

Process

#### DATA SOURCE

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

#### LEVEL

Facility

#### SETTING

Inpatient/Hospital

#### NUMERATOR STATEMENT

Radiation therapy is administered within 1 year (365 days) of the date of diagnosis

#### NUMERATOR DETAILS

Radiation treatment is administered (phase I radiation treatment modality [NAACCR Item# 1506] = 01-16, or phase I radiation treatment modality [NAACCR Item# 1506] = 99 AND phase I radiation primary treatment volume [NAACCR Item# 1504] = 40, 41), AND date radiation therapy started [NAACCR Item# 1210] <=365 days following date of initial diagnosis [NAACCR Item# 390]

#### DENOMINATOR STATEMENT

Include if all of the following characteristics are identified:

Women

Age = 18 and < 70 at time of diagnosis

Known or assumed to be first or only cancer diagnosis

Epithelial malignancy only

Invasive tumors

#### NATIONAL QUALITY FORUM

NQF REVIEW DRAFT

Primary tumors of the breast

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

Known to be alive within 1 year (365 days) of date of diagnosis

Receipt of breast conserving surgery

#### DENOMINATOR DETAILS

Sex [NAACCR Item# 220] = 2

Age at diagnosis [NAACCR Item# 230] = 018 and < 070

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

Stageable epithelial tumor ICD-O codes in the AJCC 8th Edition staging manual [NAACCR Item# 522] = 8022, 8032, 8035, 8041, 8070, 8200, 8201, 8211, 8246, 8290, 8314, 8315, 8410, 8430, 8480, 8500, 8502, 8503, 8504, 8507, 8509, 8510, 8513, 8520, 8525, 8530, 8540, 8550, 8570, 8571, 8572, 8574, 8575, 8982, 8983, 8000, 8010, 8140, 8255, 8401, 8501, 8521, 8522, 8523, 8524, 8541, 8543

Invasive tumor behavior [NAACCR Item# 523] = 3

Primary tumors of the breast [NAACCR Item# 400] = C50.0, C50.1, C50.2, C50.3, C50.4, C50.5, C50.6, C50.8, C50.9

AJCC clinical stage group [NAACCR Item# 1004] ? 0, 4 when AJCC pathologic stage group [NAACCR Item# 1014] = 88, 99

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

AJCC clinical M [NAACCR Item#1003] ? cM1, pM1

AJCC pathologic M [NAACCR Item#1013] ? cM1, pM1

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

Known to be alive within 1 year (365 days) of date of diagnosis: vital status [NAACCR Item# 1760] = 1 AND date of last contact or death [NAACCR Item# 1750] – date of initial diagnosis [NAACCR Item# 390] > 365

Surgical Procedure of the Primary Site (breast conserving surgery) [NAACCR Item# 1290] = 20–24

#### EXCLUSIONS

Exclude, if any of the following characteristics are identified:

Men

Under age 18 or over 69 at time of diagnosis

Second or subsequent cancer diagnosis

Tumor not originating in the breast

Non-epithelial malignancies, exclude rare tumors: 8940 - Mixed tumor, malignant, NOS; 8950 - Mullerian mixed tumor; 8980 - Carcinosarcoma; 8981 - Carcinosarcoma, embryonal

Non-invasive tumor

Stage 0, in situ tumor

Stage IV, metastatic tumor

#### NATIONAL QUALITY FORUM

NQF REVIEW DRAFT

None of 1st course therapy performed at reporting facility  
Breast conserving surgery was not received  
Died within 1 year (365 days) of diagnosis  
Patient enrolled in a clinical trial that directly impacts delivery of the standard of care

#### EXCLUSION DETAILS

See pages 3-8: [https://www.facs.org/~media/files/quality\\_programs/cancer/ncdb/measure\\_specs\\_breast.ashx](https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx)

#### RISK ADJUSTMENT

No risk adjustment or risk stratification

#### STRATIFICATION

No stratification applied

#### TYPE SCORE

Rate/proportion better quality = higher score

#### ALGORITHM

See pages 3-8: [https://www.facs.org/~media/files/quality\\_programs/cancer/ncdb/measure\\_specs\\_breast.ashx](https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx)

#### COPYRIGHT / DISCLAIMER

---

**0220 Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

**STEWARD**

Commission on Cancer, American College of Surgeons

**DESCRIPTION**

Percentage of female patients, age = 18 at diagnosis, who have their first diagnosis of cancer (epithelial malignancy), at AJCC T1cN0M0 or stage IB to IIIC, whose primary tumor is of the breast, and is progesterone or estrogen receptor positive with adjuvant hormonal therapy (recommended or administered) within 1 year (365 days) of diagnosis

**TYPE**

Process

**DATA SOURCE**

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

**LEVEL**

Facility

**SETTING**

Inpatient/Hospital

**NUMERATOR STATEMENT**

Adjuvant hormonal therapy is administered within 1 year (365 days) of the date of diagnosis or it is recommended but not administered

**NUMERATOR DETAILS**

Hormone Therapy recommended and not received [NAACCR Item# 1400]=82, 85, 86, 87 (82:not recommended/ administered because it was contraindicated due to patient risk factors, 85:not administered because the patient died prior to planned or recommended therapy, 86:It was recommended by the patient's physician, but was not administered as part of first-course therapy. No reason was stated in the patient record, 87: it was recommended by the patient's physician, but this treatment was refused by the patient, the patient's family member, or the patient's guardian. The refusal was noted in the patient record)

or

Hormone Therapy administered [NAACCR Item# 1400] = 01 AND date hormone therapy started [NAACCR Item# 1230] <=365 days following date of initial diagnosis [NAACCR Item# 390]

**DENOMINATOR STATEMENT**

Include if all of the following characteristics are identified:

**NATIONAL QUALITY FORUM**

NQF REVIEW DRAFT

Women

Age = 18 at time of diagnosis

Known or assumed to be first or only cancer diagnosis

Epithelial malignancy only

Invasive tumors

Primary tumors of the breast

AJCC T1cN0M0 or Stage IB – IIIC

Primary tumor is estrogen receptor positive or progesterone receptor positive

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

Known to be alive within 1 year (365 days) of date of diagnosis

Surgical procedure of the primary site

#### DENOMINATOR DETAILS

Sex [NAACCR Item# 220] = 2

Age [NAACCR Item# 230] = 018

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

Stageable epithelial tumor ICD-O codes in the AJCC 8th Edition staging manual [NAACCR Item# 522] = 8022, 8032, 8035, 8041, 8070, 8200, 8201, 8211, 8246, 8290, 8314, 8315, 8410, 8430, 8480, 8500, 8502, 8503, 8504, 8507, 8509, 8510, 8513, 8520, 8525, 8530, 8540, 8550, 8570, 8571, 8572, 8574, 8575, 8982, 8983, 8000, 8010, 8140, 8255, 8401, 8501, 8521, 8522, 8523, 8524, 8541, 8543

Invasive tumor behavior [NAACCR Item# 523] = 3

Primary tumors of the breast [NAACCR Item# 400] = C50.0, C50.1, C50.2, C50.3, C50.4, C50.5, C50.6, C50.8, C50.9

AJCC T1cN0M0 or Stage IB – IIIC:

AJCC pathologic N [NAACCR Item# 1012] = (cN0, pN0, pN0(i+), pN0(mol+)) AND tumor size summary [NAACCR Item# 756] = 011-989

or

AJCC pathologic N [NAACCR Item# 1012] = (cN1, cN1mi, cN2, cN2a, cN2b, cN3, cN3a, cN3b, cN3c, pN1, pN1mi, pN1a, pN1b, pN1c, pN2, pN2a, pN2b, pN3, pN3a, pN3b, pN3c)

AJCC clinical stage group [NAACCR Item# 1004] ? 0, 4 when AJCC pathologic stage group [NAACCR Item# 1014] = 88, 99

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

AJCC clinical M [NAACCR Item# 1003] ? cM1, pM1

AJCC pathologic M [NAACCR Item# 1013] ? cM1, pM1

Hormone receptor positive:

SSDI ER positive [NAACCR Item# 3826] = 001-100, R10-R99

or

SSDI PR positive [NAACCR Item# 3914] = 001-100, R10-R99

#### NATIONAL QUALITY FORUM

NQF REVIEW DRAFT

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

Known to be alive within 1 year (365 days) of date of diagnosis: vital status [NAACCR Item# 1760] = 1 and date of last contact or death [NAACCR Item# 1750] – date of initial diagnosis [NAACCR Item# 390] > 365

Surgical Procedure of the Primary Site [NAACCR Item# 1290] = 20–90

## EXCLUSIONS

Exclude, if any of the following characteristics are identified:

Men

Under age 18 at time of diagnosis

Second or subsequent cancer diagnosis

Tumor not originating in the breast

Non-epithelial malignancies, exclude malignant phyllodes tumors; 8940 - Mixed tumor, malignant, NOS; 8950 - Mullerian mixed tumor; 8980 - Carcinosarcoma; 8981 - Carcinosarcoma, embryonal

Non-invasive tumors

Stage 0, in situ tumor

Stage IV, metastatic tumor

Primary tumor is estrogen receptor negative and progesterone receptor negative

None of 1st course therapy performed at reporting facility

Died within 1 year (365 days) of diagnosis,

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

No surgical procedure of the primary site

Not AJCC T1cN0M0 or not AJCC stage IB-IIIC

## EXCLUSION DETAILS

See pages 18-26: [https://www.facs.org/~media/files/quality\\_programs/cancer/ncdb/measure\\_specs\\_breast.ashx](https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx)

## RISK ADJUSTMENT

No risk adjustment or risk stratification

## STRATIFICATION

No stratification applied

## TYPE SCORE

Rate/proportion better quality = higher score

## ALGORITHM

See pages 18-26: [https://www.facs.org/~media/files/quality\\_programs/cancer/ncdb/measure\\_specs\\_breast.ashx](https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx)

## NATIONAL QUALITY FORUM

NQF REVIEW DRAFT

COPYRIGHT / DISCLAIMER



---

## 0383 Oncology: Medical and Radiation - Plan of Care for Pain

### STEWARD

American Society of Clinical Oncology

### DESCRIPTION

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

### TYPE

Process

### DATA SOURCE

Paper Medical Records, Registry Data N/A, measure is not instrument-based

### LEVEL

Clinician : Group/Practice

### SETTING

Outpatient Services

### NUMERATOR STATEMENT

Patient visits that include a documented plan of care\* to address pain.

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

### NUMERATOR DETAILS

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

Time Period for Data Collection: At each visit within the measurement period for patients with a diagnosis of cancer and in which pain is present.

Guidance: A documented outline of care for a positive pain assessment is required. May include: use of non-opioid analgesics, opioids, psychological support, patient and/or family education, referral to a pain clinic, or reassessment of pain at an appropriate time interval.

### DENOMINATOR STATEMENT

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

### DENOMINATOR DETAILS

Time Period for Data Collection: 12 consecutive months

Denominator Criteria (Eligible Cases):

## NATIONAL QUALITY FORUM

NQF REVIEW DRAFT

For all eligible patient encounters when pain severity quantified and pain is present (e.g., CPT II: 1125F is submitted in the numerator for NQF 0384) for patients regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy.

Guidance: This measure is an episode-of-care measure; the level of analysis for this measure is every visit for patients with a diagnosis of cancer who are also currently receiving chemotherapy or radiation therapy and a positive pain assessment during the measurement period. For patients receiving radiation therapy, pain intensity should be quantified at each radiation treatment management encounter. 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.

All visits for patients, regardless of age

AND

Diagnosis of cancer

AND

Patient encounter during the performance period

AND

Patient reported pain was present

AND

Radiation treatment management encounter

OR

Face-to-face encounter with the physician while the patient is currently receiving chemotherapy

#### EXCLUSIONS

None

#### EXCLUSION DETAILS

N/A, no denominator exclusion

#### RISK ADJUSTMENT

No risk adjustment or risk stratification

#### STRATIFICATION

N/A, no risk stratification

#### TYPE SCORE

Rate/proportion better quality = higher score

#### ALGORITHM

This measure is comprised of two populations but is intended to result in one reporting rate. The reporting rate is the aggregate of Population 1 and Population 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)

#### NATIONAL QUALITY FORUM

NQF REVIEW DRAFT

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

1. Find the patients who meet the initial population (i.e., 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 (i.e., 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 (i.e., 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 Population 2: Patient visits for patients with a diagnosis of cancer currently receiving radiation therapy

1. Find the patients who meet the initial population (i.e., 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 (i.e., 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.

#### **COPYRIGHT / DISCLAIMER**

The Measure is not clinical guidelines, does not establish a standard of medical care, and has not been tested for all potential applications.

The Measure, while copyrighted, can be reproduced and distributed, without modification, for noncommercial purposes, e.g., use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of the Measure into a product or service that is sold, licensed or distributed for commercial gain.

Commercial uses of the Measure require a license agreement between the user and the American Society of Clinical Oncology (ASCO) and American Medical Association (AMA), [on behalf of the Physician Consortium for Performance Improvement® (PCPI®)] and prior written approval of ASCO, AMA, or PCPI. Neither ASCO, AMA, or PCPI, nor its members shall be responsible for any use of the Measures.

The AMA's and PCPI's significant past efforts and contributions to the development and updating of the Measure is acknowledged. ASCO is solely responsible for the review and enhancement ("Maintenance") of the Measures as of January 2015.

ASCO encourages use of the Measures by other health care professionals, where appropriate. THE MEASURES AND SPECIFICATIONS ARE PROVIDED “AS IS” WITHOUT WARRANTY OF ANY KIND.

© 2020 American Medical Association and American Society of Clinical Oncology. All Rights Reserved.

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

CPT® contained in the Measures specifications is copyright 2004-2019 American Medical Association. LOINC® copyright 2004-2018 Regenstrief Institute, Inc. SNOMED CLINICAL TERMS (SNOMED CT®) copyright 2004-2018 College of American Pathologists. All Rights Reserved.

---

**1858 Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

**STEWARD**

American Society of Clinical Oncology

**DESCRIPTION**

Percentage of female patients aged 18 and over with HER2/neu positive invasive breast cancer who are administered trastuzumab

**TYPE**

Process

**DATA SOURCE**

Paper Medical Records, Registry Data N/A, measure is not instrument-based.

**LEVEL**

Clinician : Group/Practice

**SETTING**

Outpatient Services

**NUMERATOR STATEMENT**

Patients for whom trastuzumab is administered within 12 months of diagnosis

**NUMERATOR DETAILS**

Numerator:

Trastuzumab administered within 12 months of diagnosis

Numerator Options:

Performance Met: Trastuzumab administered within 12 months of diagnosis

OR

Denominator Exception: Reason for not administering Trastuzumab documented (e. g. patient declined, patient died, patient transferred, contraindication or other clinical exclusion, neoadjuvant chemotherapy or radiation NOT complete)

OR

Performance Not Met: Trastuzumab not administered within 12 months of diagnosis

**DENOMINATOR STATEMENT**

Female patients aged 18 and over with AJCC stage I (T1c) – III, HER2/neu positive breast cancer who receive chemotherapy

**DENOMINATOR DETAILS**

Denominator Criteria (Eligible Cases):

**NATIONAL QUALITY FORUM**

NQF REVIEW DRAFT

Female Patients aged = 18 years on date of encounter

AND

Diagnosis of breast cancer

AND

Patient encounter during performance period

AND

Two or more encounters at the reporting site AND

Breast Adjuvant Chemotherapy administered:

AND

HER-2/neu positive:

AND

AJCC stage at breast cancer diagnosis = II or III: G9831

OR

AJCC stage at breast cancer diagnosis = I (IA or IB) and T-Stage at breast cancer diagnosis does NOT equal = T1, T1a, T1b

AND NOT

Denominator Exclusions:

Patient transfer to practice after initiation of chemotherapy

#### EXCLUSIONS

Denominator Exclusions:

- o Patient transfer to practice after initiation of chemotherapy

Denominator Exceptions:

- o Reason for not administering trastuzumab documented (e.g. patient declined, patient died, patient transferred, contraindication or other clinical exclusion, neoadjuvant chemotherapy or radiation therapy not complete)

#### EXCLUSION DETAILS

Denominator Exclusions:

Patient transfer to practice after initiation of chemotherapy

#### RISK ADJUSTMENT

No risk adjustment or risk stratification

#### STRATIFICATION

N/A, no risk stratification

#### TYPE SCORE

Rate/proportion better quality = higher score

#### NATIONAL QUALITY FORUM

NQF REVIEW DRAFT

## ALGORITHM

This measure is a proportion with exclusions and exceptions; thus, the calculation algorithm is:  
$$\frac{\text{Patients meeting the numerator} + \text{patients with valid exceptions}}{(\text{Patients in the denominator} - \text{Patients with valid exclusions})} \times 100$$

## COPYRIGHT / DISCLAIMER

The Measure is not clinical guidelines, does not establish a standard of medical care, and has not been tested for all potential applications.

The Measure, while copyrighted, can be reproduced and distributed, without modification, for noncommercial purposes, e.g., use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of the Measure into a product or service that is sold, licensed or distributed for commercial gain.

Commercial uses of the Measure require a license agreement between the user and the American Society of Clinical Oncology (ASCO) and American Medical Association (AMA), [on behalf of the Physician Consortium for Performance Improvement® (PCPI®)] and prior written approval of ASCO, AMA, or PCPI. Neither ASCO, AMA, or PCPI, nor its members shall be responsible for any use of the Measures.

The AMA's and PCPI's significant past efforts and contributions to the development and updating of the Measure is acknowledged. ASCO is solely responsible for the review and enhancement ("Maintenance") of the Measures as of January 2015.

ASCO encourages use of the Measures by other health care professionals, where appropriate.

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

© 2020 American Medical Association and American Society of Clinical Oncology. All Rights Reserved.

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

CPT® contained in the Measures specifications is copyright 2004-2019 American Medical Association. LOINC® copyright 2004-2018 Regenstrief Institute, Inc. SNOMED CLINICAL TERMS (SNOMED CT®) copyright 2004-2018 College of American Pathologists. All Rights Reserved.

---

## 1859 RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy

### STEWARD

American Society of Clinical Oncology

### DESCRIPTION

Percentage of adult patients (aged 18 and over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed

### TYPE

Process

### DATA SOURCE

Paper Medical Records, Registry Data N/A, measure is not instrument-based.

### LEVEL

Clinician : Group/Practice

### SETTING

Outpatient Services

### NUMERATOR STATEMENT

RAS (KRAS and NRAS) gene mutation testing performed prior to initiation of anti-EGFR monoclonal antibody therapy

### NUMERATOR DETAILS

RAS gene mutation testing = RAS mutation detected

OR

RAS gene mutation testing = No RAS mutation detected (wildtype)

AND

RAS gene mutation testing date

Numerator definitions:

RAS mutation testing - RAS testing for this measure refers to assays that detect mutations in codons 12 and 13 of exon 2, codons 59 and 61 of exon 3 and codons 117 and 146 in exon 4 in KRAS or NRAS. Do not include results from mutations at other codons or assays for other alterations (e.g., BRAF, PI3K, PTEN genes). The College of American Pathologists (CAP) Perspectives on Emerging Technology (POET) Report on RAS mutation testing provides additional guidance on testing.

If multiple RAS mutation tests have been performed, refer to the most recent test results.

In the absence of any documentation regarding testing for the RAS gene mutation, select 'Test not ordered/no documentation.'

### NATIONAL QUALITY FORUM

NQF REVIEW DRAFT



Refer to the interpretive report for the RAS test. The report will indicate if a mutation within codons 12 and 13 of exon 2, codons 59 and 61 of exon 3 and codons 117 and 146 in exon 4 in KRAS or NRAS, where KRAS or NRAS gene was detected in the DNA extracted from the colon tumor specimen.

#### DENOMINATOR STATEMENT

Adult patients with metastatic colorectal cancer who receive anti-EGFR monoclonal antibody therapy

#### DENOMINATOR DETAILS

Age at diagnosis greater than or equal to 18 years

AND

2 or more encounters at the reporting site

AND

Initial colon or rectal cancer diagnosis (153.x, 154.0, 154.0, 154.1, 154.8)

AND

Presence of metastatic disease documented

AND

Anti-EGFR monoclonal antibody therapy received

Definitions

Encounter: new patient visit (CPT 99201-99205) or established patient (CPT 99211-99215), not consult (CPT 99241-99245) office consult or inpatient consult CPT 99251-99255)

#### EXCLUSIONS

None

#### EXCLUSION DETAILS

n/a

#### RISK ADJUSTMENT

No risk adjustment or risk stratification

#### STRATIFICATION

n/a

#### TYPE SCORE

Rate/proportion better quality = higher score

#### ALGORITHM

This measure is a proportion without exclusions. The calculation algorithm is: (Patients meeting the numerator/patients in the denominator) x 100

#### NATIONAL QUALITY FORUM

NQF REVIEW DRAFT

## COPYRIGHT / DISCLAIMER

The Measure is not clinical guidelines, does not establish a standard of medical care, and has not been tested for all potential applications.

The Measure, while copyrighted, can be reproduced and distributed, without modification, for noncommercial purposes, e.g., use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of the Measure into a product or service that is sold, licensed or distributed for commercial gain.

Commercial uses of the Measure require a license agreement between the user and the American Society of Clinical Oncology (ASCO) and prior written approval of ASCO. Neither ASCO nor its members shall be responsible for any use of the Measures.

ASCO encourages use of the Measures by other health care professionals, where appropriate.

THE MEASURES AND SPECIFICATIONS ARE PROVIDED “AS IS” WITHOUT WARRANTY OF ANY KIND.

© 2020 American Society of Clinical Oncology. All Rights Reserved.

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

CPT® contained in the Measures specifications is copyright 2004-2019 American Medical Association. LOINC® copyright 2004-2018 Regenstrief Institute, Inc. SNOMED CLINICAL TERMS (SNOMED CT®) copyright 2004-2018 College of American Pathologists. All Rights Reserved.

---

## 1860 Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies

### STEWARD

American Society of Clinical Oncology

### DESCRIPTION

Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies

### TYPE

Process

### DATA SOURCE

Paper Medical Records, Registry Data N/A, measure is not instrument-based.

### LEVEL

Clinician : Group/Practice

## NATIONAL QUALITY FORUM

NQF REVIEW DRAFT

## SETTING

Outpatient Services

## NUMERATOR STATEMENT

Anti-EGFR monoclonal antibody therapy not received

## NUMERATOR DETAILS

Anti-EGFR monoclonal antibody therapy status = No Anti-EGFR monoclonal antibody therapy received

## DENOMINATOR STATEMENT

Adult patients with metastatic colorectal cancer who have a RAS (KRAS or NRAS) gene mutation

## DENOMINATOR DETAILS

Age at diagnosis greater than or equal to 18 years

AND

2 or more encounters at the reporting site

AND

Initial colon or rectal cancer diagnosis (ICD-10 CM C18.0, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C18.9, C19, C20)

AND

Presence of metastatic disease documented

AND

RAS (KRAS or NRAS) gene mutation detected

Definitions

Encounter = new patient visit (CPT 99201 -99205) or established patient (CPT 99211-99215), not consult (CPT 99241-99245 office consult or inpatient consult CPT 99251-99255)

RAS mutation testing - RAS testing for this measure refers to assays that detect mutations in codons 12 and 13 of exon 2, codons 59 and 61 of exon 3 and codons 117 and 146 in exon 4 in KRAS or NRAS. Do not include results from mutations at other codons or assays for other alterations (e.g., BRAF, PI3K, PTEN genes). The College of American Pathologists (CAP) Perspectives on Emerging Technology (POET) Report on RAS mutation testing provides additional guidance on testing.

If multiple RAS mutation tests have been performed, refer to the most recent test results.

## EXCLUSIONS

None

## EXCLUSION DETAILS

n/a

## RISK ADJUSTMENT

No risk adjustment or risk stratification

## NATIONAL QUALITY FORUM

NQF REVIEW DRAFT

## STRATIFICATION

n/a

## TYPE SCORE

Rate/proportion better quality = higher score

## ALGORITHM

This measure is a proportion without exclusions. The calculation algorithm is: (Patients meeting the numerator/patients in the denominator) x 100

## COPYRIGHT / DISCLAIMER

The Measure is not clinical guidelines, does not establish a standard of medical care, and has not been tested for all potential applications.

The Measure, while copyrighted, can be reproduced and distributed, without modification, for noncommercial purposes, e.g., use by health care providers in connection with their practices. Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of the Measure into a product or service that is sold, licensed or distributed for commercial gain.

Commercial uses of the Measure require a license agreement between the user and the American Society of Clinical Oncology (ASCO) and prior written approval of ASCO. Neither ASCO nor its members shall be responsible for any use of the Measures.

ASCO encourages use of the Measures by other health care professionals, where appropriate.

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

© 2020 American Society of Clinical Oncology. All Rights Reserved.

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

CPT® contained in the Measures specifications is copyright 2004-2019 American Medical Association. LOINC® copyright 2004-2018 Regenstrief Institute, Inc. SNOMED CLINICAL TERMS (SNOMED CT®) copyright 2004-2018 College of American Pathologists. All Rights Reserved.

## Appendix E1: Related and Competing Measures (Tabular)

### Comparison of NQF #0220 and NQF #0387e

	0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer	0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer
Steward	Commission on Cancer, American College of Surgeons	PCPI Foundation
Description	Percentage of female patients, age = 18 at diagnosis, who have their first diagnosis of cancer (epithelial malignancy), at AJCC T1cN0M0 or stage IB to IIIC, whose primary tumor is of the breast, and is progesterone or estrogen receptor positive with adjuvant hormonal therapy (recommended or administered) within 1 year (365 days) of diagnosis	Percentage of female patients aged 18 years and older with Stage I (T1b) through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period
Type	Process	Process
Data Source	Registry Data Hospital cancer registry data, reported to the American College of Surgeons' Commission on Cancer, National Cancer Database Available at measure-specific web page URL identified in S.1 No data dictionary	Claims, Electronic Health Records, Paper Medical Records, Registry Data Not applicable. Zip file for data dictionary/code table to be sent separately (cannot be attached to 2a1.30). Attachment 0387_BreastCancer_v6_ValueSets_09282017.xls
Level	Facility	Clinician : Group/Practice, Clinician : Individual
Setting	Inpatient/Hospital	Other, Outpatient Services Oncology/Outpatient Clinic
Numerator Statement	Adjuvant hormonal therapy is administered within 1 year (365 days) of the date of diagnosis or it is recommended but not administered	Patients who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period
Numerator Details	Hormone Therapy recommended and not received [NAACCR Item# 1400]=82, 85, 86, 87 (82:not recommended/ administered because it was contraindicated due to patient risk factors, 85:not administered because the patient died prior to planned or recommended therapy, 86:It was recommended by the patient's physician, but was not administered as part of first-course therapy. No reason was stated in the patient record, 87: it was recommended by the patient's physician, but this	Time Period for Data Collection: At least once during the measurement period Definition: Prescribed - May include prescription given to the patient for tamoxifen or aromatase inhibitor (AI) at one or more visits in the 12-month period OR patient already taking tamoxifen or aromatase inhibitor (AI) as documented in the current medication list. For Claims/Registry: Report the CPT Category II code: 4179F - Tamoxifen or aromatase inhibitor (AI) prescribed For EHR: HQMF eQOM developed and is included in this submission.

	0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer	0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer
	treatment was refused by the patient, the patient's family member, or the patient's guardian. The refusal was noted in the patient record) or Hormone Therapy administered [NAACCR Item# 1400] = 01 AND date hormone therapy started [NAACCR Item# 1230] <=365 days following date of initial diagnosis [NAACCR Item# 390]	
Denominator Statement	Include if all of the following characteristics are identified: Women Age = 18 at time of diagnosis Known or assumed to be first or only cancer diagnosis Epithelial malignancy only Invasive tumors Primary tumors of the breast AJCC T1cN0M0 or Stage IB – IIIC Primary tumor is estrogen receptor positive or progesterone receptor positive All or part of 1st course of treatment performed at the reporting facility Known to be alive within 1 year (365 days) of date of diagnosis Surgical procedure of the primary site	All female patients aged 18 years and older with a diagnosis of breast cancer with Stage I (T1b) through IIIC, estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer
Denominator Details	Sex [NAACCR Item# 220] = 2 Age [NAACCR Item# 230] = 018 Known or assumed to be first or only cancer diagnosis [NAACCR Item# 560] = 00, 01 Stageable epithelial tumor ICD-O codes in the AJCC 8th Edition staging manual [NAACCR Item# 522] = 8022, 8032, 8035, 8041, 8070, 8200, 8201, 8211, 8246, 8290, 8314, 8315, 8410, 8430, 8480, 8500,	Time Period for Data Collection: 12 consecutive months For Claims/Registry: All female patients aged >= 18 years on date of encounter AND Diagnosis for breast cancer (ICD-10-CM): C50.011, C50.012, C50.019, C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.311, C50.312, C50.319, C50.411, C50.412, C50.419, C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, C50.812, C50.819, C50.911, C50.912, C50.919

	0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer	0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer
	<p>8502, 8503, 8504, 8507, 8509, 8510, 8513, 8520, 8525, 8530, 8540, 8550, 8570, 8571, 8572, 8574, 8575, 8982, 8983, 8000, 8010, 8140, 8255, 8401, 8501, 8521, 8522, 8523, 8524, 8541, 8543</p> <p>Invasive tumor behavior [NAACCR Item# 523] = 3</p> <p>Primary tumors of the breast [NAACCR Item# 400] = C50.0, C50.1, C50.2, C50.3, C50.4, C50.5, C50.6, C50.8, C50.9</p> <p>AJCC T1cN0M0 or Stage IB – IIIC:</p> <p>AJCC pathologic N [NAACCR Item# 1012] = (cN0, pN0, pN0(i+), pN0(mol+)) AND tumor size summary [NAACCR Item# 756] = 011-989</p> <p>or</p> <p>AJCC pathologic N [NAACCR Item# 1012] = (cN1, cN1mi, cN2, cN2a, cN2b, cN3, cN3a, cN3b, cN3c, pN1, pN1mi, pN1a, pN1b, pN1c, pN2, pN2a, pN2b, pN3, pN3a, pN3b, pN3c)</p> <p>AJCC clinical stage group [NAACCR Item# 1004] ? 0, 4 when AJCC pathologic stage group [NAACCR Item# 1014] = 88, 99</p> <p>AJCC pathologic stage group [NAACCR Item# 1014] ? 0, 4</p> <p>AJCC clinical M [NAACCR Item# 1003] ? cM1, pM1</p> <p>AJCC pathologic M [NAACCR Item# 1013] ? cM1, pM1</p> <p>Hormone receptor positive:</p> <p>SSDI ER positive [NAACCR Item# 3826] = 001-100, R10-R99</p> <p>or</p> <p>SSDI PR positive [NAACCR Item# 3914] = 001-100, R10-R99</p> <p>All or part of 1st course of treatment performed at the reporting facility [NAACCR Item# 610] = 10-22</p>	<p>AND</p> <p>Patient encounter during the reporting period (CPT): 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215</p> <p>WITHOUT</p> <p>Telehealth Modifier: GQ, GT, 95, Place of Service (POS) 2</p> <p>AND</p> <p>Quality Data Code (G-code) G9705: AJCC Breast Cancer Stage I: T1b (tumor &gt; 0.5 cm but &lt;= 1 cm in greatest dimension) documented OR</p> <p>CPT Category II code 3374F: AJCC Breast Cancer Stage I: T1c (tumor size &gt; 1 cm to 2 cm) documented OR</p> <p>CPT Category II code 3376F: AJCC Breast Cancer Stage II documented OR</p> <p>CPT Category II code 3378F: AJCC Breast Cancer Stage III documented</p> <p>AND</p> <p>CPT Category II code 3315F: Estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer</p> <p>For EHR:</p> <p>HQMF eCQM developed and is included in this submission.</p>

	0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer	0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer
	Known to be alive within 1 year (365 days) of date of diagnosis: vital status [NAACCR Item# 1760] = 1 and date of last contact or death [NAACCR Item# 1750] – date of initial diagnosis [NAACCR Item# 390] > 365 Surgical Procedure of the Primary Site [NAACCR Item# 1290] = 20–90	
Exclusions	<p>Exclude, if any of the following characteristics are identified:</p> <p>Men</p> <p>Under age 18 at time of diagnosis</p> <p>Second or subsequent cancer diagnosis</p> <p>Tumor not originating in the breast</p> <p>Non-epithelial malignancies, exclude malignant phyllodes tumors; 8940 - Mixed tumor, malignant, NOS; 8950 - Mullerian mixed tumor; 8980 - Carcinosarcoma; 8981 - Carcinosarcoma, embryonal</p> <p>Non-invasive tumors</p> <p>Stage 0, in situ tumor</p> <p>Stage IV, metastatic tumor</p> <p>Primary tumor is estrogen receptor negative and progesterone receptor negative</p> <p>None of 1st course therapy performed at reporting facility</p> <p>Died within 1 year (365 days) of diagnosis,</p> <p>Patient enrolled in a clinical trial that directly impacts delivery of the standard of care</p> <p>No surgical procedure of the primary site</p> <p>Not AJCC T1cN0M0 or not AJCC stage IB-IIIC</p>	<p>Documentation of medical reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient's disease has progressed to metastatic; patient is receiving a gonadotropin-releasing hormone analogue, patient has received oophorectomy, patient is receiving radiation or chemotherapy, patient's diagnosis date was &gt; 5 years from reporting date, patient's diagnosis date is within 120 days of the end of the 12-month reporting period, other medical reasons)</p> <p>Documentation of patient reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient refusal, other patient reasons)</p> <p>Documentation of system reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient is currently enrolled in a clinical trial, other system reasons)</p>
Exclusion Details	<p>See pages 18-26:</p> <p><a href="https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx">https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx</a></p>	<p>Time Period for Data Collection: At the time of the encounter</p> <p>Exceptions are used to remove a patient from the denominator of a performance measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons. The patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment,</p>



	0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer	0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer
		<p>individual patient characteristics, or patient preferences. The PCPI exception methodology uses three categories of reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For measure Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer, exceptions may include medical reason(s) (eg, patient’s disease has progressed to metastatic; patient is receiving a gonadotropin-releasing hormone analogue, patient has received oophorectomy, patient is receiving radiation or chemotherapy, patient’s diagnosis date was &gt; 5 years from reporting date, patient’s diagnosis date is within 120 days of the end of the 12-month reporting period, other medical reasons), patient reason(s) (eg, patient refusal, other patient reasons), or system reason(s) (eg, patient is currently enrolled in a clinical trial, other system reasons). Where examples of exceptions are included in the measure language, value sets for these examples are developed and included in the eCQM. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients’ medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician’s exceptions data to identify practice patterns and opportunities for quality improvement.</p> <p>Additional details by data source are as follows:</p> <p>For Claims/Registry:</p> <p>Documentation of medical reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient’s disease has progressed to metastatic; patient is receiving a gonadotropin-releasing hormone analogue, patient has received oophorectomy, patient is receiving radiation or chemotherapy, patient’s diagnosis date was &gt; 5 years from reporting date, patient’s diagnosis date is within 120 days of the end of the 12-month reporting period, other medical reasons): Append modifier to CPT Category II code: 4179F-1P</p> <p>Documentation of patient reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient refusal, other patient reasons): Append modifier to CPT Category II code: 4179F-2P</p> <p>Documentation of system reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient is currently enrolled in a clinical trial, other system reasons): Append modifier to CPT Category II code: 4179F-3P</p> <p>For EHR:</p>

	0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer	0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer
		HQMF eCQM developed and is included in this submission.
Risk Adjustment	No risk adjustment or risk stratification	No risk adjustment or risk stratification
Stratification	No stratification applied	Consistent with 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 and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = higher score	Rate/proportion better quality = higher score
Algorithm	See pages 18-26: <a href="https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx">https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx</a>	<p>To calculate performance rates:</p> <ol style="list-style-type: none"> <li>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).</li> <li>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.</li> <li>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</li> <li>4. From the patients who did not meet the numerator criteria, determine if the provider has documented that the patient meets any criteria for exception when denominator exceptions have been specified [for this measure: medical reason(s) (eg, patient's disease has progressed to metastatic; patient is receiving a gonadotropin-releasing hormone analogue, patient has received oophorectomy, patient is receiving radiation or chemotherapy, patient's diagnosis date was &gt; 5 years from reporting date, patient's diagnosis date is within 120 days of the end of the 12-month reporting period, other medical reasons), patient reason(s) (eg, patient refusal, other patient reasons), or system reason(s) (eg, patient is currently enrolled in a clinical trial, other system reasons)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. --Although the exception cases are removed from the denominator population for the performance calculation, the exception rate (ie, percentage with valid exceptions) should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.</li> </ol>

	0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer	0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer
		If the patient does not meet the numerator and a valid exception is not present, this case represents a quality failure.
Submission items	<p>5.1 Identified measures: 0387 : Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer</p> <p>5a.1 Are specs completely harmonized? No</p> <p>5a.2 If not completely harmonized, identify difference, rationale, impact: These measures are related but assess different levels of analysis and different data systems are used to determine eligibility and compliance.</p> <p>5b.1 If competing, why superior or rationale for additive value: 0387 assesses hormone therapy for patients with stage Ic through III hormone receptor positive cancer. 0387 assesses if hormone therapy was prescribed within a 12 month period while our measure (0220) assesses if hormone therapy was administered within one year of diagnosis or if it was recommended but not received based on patient refusal, medical co-morbidity or other valid reasons. 0220 also assesses compliance at the facility level while 0387 assesses individual physician or practice level performance. The two measures use different data sources as well. 0220 utilizes cancer registry coding.</p>	<p>5.1 Identified measures:</p> <p>5a.1 Are specs completely harmonized? No</p> <p>5a.2 If not completely harmonized, identify difference, rationale, impact: No related measures; See competing measures section below regarding the harmonization of measure specifications.</p> <p>5b.1 If competing, why superior or rationale for additive value: Measure 0220 is similarly limited to stage I through III breast cancer patients whose primary tumor is progesterone or estrogen receptor positive. Measure 0220 requires that the agents be considered or administered within 1 year of diagnosis while our measure looks at the receipt of adjuvant endocrine therapy over time, specifically whether the agents were prescribed once within a 12 month reporting period. Since the recommended treatment duration of adjuvant endocrine therapy is 5 years, our measure includes medical reason exceptions to allow physicians to exclude patients who have already received the agents for the recommended duration and for other medical reasons. Our measure assess performance at the individual physician level while measure 0220 was designed to assess performance at the facility level.</p>



## Comparison of NQF #0383, NQF #0420, and NQF #1628

	0383: Oncology: Medical and Radiation - Plan of Care for Pain	0420: Pain Assessment and Follow-Up	1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits
Steward	American Society of Clinical Oncology	Centers for Medicare & Medicaid Services	RAND Corporation
Description	Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present	Adult patients with advanced cancer who are screened for pain with a standardized quantitative tool at each outpatient visit
Type	Process	Process	Process
Data Source	Paper Medical Records, Registry Data N/A, measure is not instrument-based No data collection instrument provided Attachment 0383_NQF_PlanofCarePain_CodeSet_07312019.xlsx	Claims, Paper Medical Records The data source is the patient medical record. Medicare Part B claims data and registry data is provided for test purposes. No data collection instrument provided Attachment NQF_420_DataDic_1117.xlsx	Electronic Health Records, Paper Medical Records, Registry Data Patients were identified via the testing organizations' cancer registries. At one institution, outpatient pain vital sign scores were extracted electronically from the patient EHR. At other institutions, quantitative pain scores were collected via medical record abstraction. No data collection instrument provided No data dictionary
Level	Clinician : Group/Practice	Clinician : Group/Practice, Clinician : Individual	Facility, Health Plan, Integrated Delivery System
Setting	Outpatient Services	Outpatient Services	Outpatient Services
Numerator Statement	Patient visits that include a documented plan of care* to address pain. *A documented plan of care may include: use of non-opioid analgesics, opioids, psychological support, patient and/or family education, referral to a pain clinic, or reassessment of pain at an appropriate time interval.	Patient visits with a documented pain assessment using a standardized tool(s) AND documentation of a follow-up plan when pain is present	Outpatient visits from the denominator in which the patient was screened for pain (and if present, severity noted) with a quantitative standardized tool
Numerator Details	Patient visits that included a documented plan of care to address pain. Time Period for Data Collection: At each visit within the measurement period for patients	Definitions: Pain Assessment – Documentation of a clinical assessment for the presence or absence of pain using a standardized tool is required. A multi-dimensional clinical assessment of pain	Pain screening with a standardized quantitative tool during the primary care or cancer-related/specialty outpatient visit(s). Screening may be completed using verbal, numeric, visual analog, rating scales designed

	0383: Oncology: Medical and Radiation - Plan of Care for Pain	0420: Pain Assessment and Follow-Up	1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits
	<p>with a diagnosis of cancer and in which pain is present.</p> <p>Guidance: A documented outline of care for a positive pain assessment is required. May include: use of non-opioid analgesics, opioids, psychological support, patient and/or family education, referral to a pain clinic, or reassessment of pain at an appropriate time interval.</p>	<p>using a standardized tool may include characteristics of pain, such as: location, intensity, description, and onset/duration.</p> <p>Standardized Tool – An assessment tool that has been appropriately normed and validated for the population in which it is used.</p> <p>Examples of tools for pain assessment, include, but are not limited to: Brief Pain Inventory (BPI), Faces Pain Scale (FPS), McGill Pain Questionnaire (MPQ), Multidimensional Pain Inventory (MPI), Neuropathic Pain Scale (NPS), Numeric Rating Scale (NRS), Oswestry Disability Index (ODI), Roland Morris Disability Questionnaire (RMDQ), Verbal Descriptor Scale (VDS), Verbal Numeric Rating Scale (VNRS), Visual Analog Scale (VAS)), and Patient-Reported Outcomes Measurement Information System (PROMIS).</p> <p>Follow-Up Plan – A documented outline of care for a positive pain assessment is required. This must include a planned follow-up appointment or a referral, a notification to other care providers as applicable OR indicate the initial treatment plan is still in effect. These plans may include pharmacologic, behavioral, physical medicine and/or educational interventions.</p> <p>Not Eligible (Denominator Exception)– A patient is not eligible if one or more of the following reason(s) is documented:</p> <ul style="list-style-type: none"> <li>• 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</li> </ul>	<p>for use with nonverbal patients, or other standardized tools.</p>

	0383: Oncology: Medical and Radiation - Plan of Care for Pain	0420: Pain Assessment and Follow-Up	1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits
		<ul style="list-style-type: none"> <li>• 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</li> </ul> <p>NUMERATOR NOTE: The standardized tool used to assess the patient's pain must be documented in the medical record (exception: A provider may use a fraction such as 5/10 for Numeric Rating Scale without documenting this actual tool name when assessing pain for intensity).</p> <p>Numerator Quality-Data Coding Options: Pain Assessment Documented as Positive AND Follow-Up Plan Documented</p> <p>Performance Met: G8730: Pain assessment documented as positive using a standardized tool AND a follow-up plan is documented</p> <p>OR</p> <p>Pain Assessment Documented as Negative, No Follow-Up Plan Required</p> <p>Performance Met: G8731: Pain assessment using a standardized tool is documented as negative, no follow-up plan required</p> <p>OR</p> <p>Pain Assessment not Documented, Reason not Given</p> <p>Performance Not Met: G8732: No documentation of pain assessment, reason not given</p> <p>OR</p> <p>Pain Assessment Documented as Positive, Follow-Up Plan not Documented, Reason not Given</p> <p>Performance Not Met: G8509: Pain assessment documented as positive using a</p>	

	0383: Oncology: Medical and Radiation - Plan of Care for Pain	0420: Pain Assessment and Follow-Up	1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits
		standardized tool, follow-up plan not documented, reason not given	
Denominator Statement	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	Adult patients with advanced cancer who have at least 1 primary care or cancer-related/specialty outpatient visit
Denominator Details	<p>Time Period for Data Collection: 12 consecutive months</p> <p>Denominator Criteria (Eligible Cases):</p> <p>For all eligible patient encounters when pain severity quantified and pain is present (e.g., CPT II: 1125F is submitted in the numerator for NQF 0384) for patients regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy.</p> <p>Guidance: This measure is an episode-of-care measure; the level of analysis for this measure is every visit for patients with a diagnosis of cancer who are also currently receiving chemotherapy or radiation therapy and a positive pain assessment during the measurement period. For patients receiving radiation therapy, pain intensity should be quantified at each radiation treatment management encounter. 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.</p> <p>All visits for patients, regardless of age</p> <p>AND</p> <p>Diagnosis of cancer</p> <p>AND</p> <p>Patient encounter during the performance period</p> <p>AND</p>	<p>Denominator Criteria (Eligible Cases): Patients aged greater than or equal to 18 years on date of encounter AND Patient encounter during the reporting period (CPT or HCPCS): 90791, 90792, 92002, 92004, 92012, 92014, 92507, 92508, 92526, 96116, 96118, 96150, 96151, 97161, 97162, 97164, 97165, 97166, 97167, 97168, 97532, 98940, 98941, 98942, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, D7140, D7210, G0101, G0402, G0438, G0439 WITHOUT Telehealth Modifier: GQ, GT</p>	<p>Adult patients with Stage IV cancer who are alive 30 days or more after diagnosis and who have had at least 1 primary care visit or cancer-related/specialty outpatient visit.</p> <p>Cancer-related visit = any oncology (medical, surgical, radiation) visit, chemotherapy infusion</p>



	0383: Oncology: Medical and Radiation - Plan of Care for Pain	0420: Pain Assessment and Follow-Up	1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits
	<p>Patient reported pain was present AND Radiation treatment management encounter OR Face-to-face encounter with the physician while the patient is currently receiving chemotherapy</p>		
Exclusions	None	<p>Pain Assessment not Documented Patient not Eligible Denominator Exception: G8442: Pain assessment NOT documented as being performed, documentation the patient is not eligible for a pain assessment using a standardized tool 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</p>	None (other than those patients noted in 2a1.7. who did not survive at least 30 days after cancer diagnosis)
Exclusion Details	N/A, no denominator exclusion	<p>Pain Assessment not Documented Patient not Eligible Denominator Exception: G8442: Pain assessment NOT documented as being performed, documentation the patient is not eligible for a pain assessment using a standardized tool OR</p>	

	0383: Oncology: Medical and Radiation - Plan of Care for Pain	0420: Pain Assessment and Follow-Up	1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits
		<p>Pain Assessment Documented as Positive, Follow-Up Plan not Documented, Patient not Eligible</p> <p>Denominator Exception: G8939: Pain assessment documented as positive, follow-up plan not documented, documentation the patient is not eligible</p>	
Risk Adjustment	No risk adjustment or risk stratification	No risk adjustment or risk stratification	No risk adjustment or risk stratification
Stratification	N/A, no risk stratification	N/A	
Type Score	Rate/proportion better quality = higher score	Rate/proportion better quality = higher score	Rate/proportion better quality = higher score
Algorithm	<p>This measure is comprised of two populations but is intended to result in one reporting rate. The reporting rate is the aggregate of Population 1 and Population 2, resulting in a single performance rate. For the purposes of this measure, the single performance rate can be calculated as follows:</p> <p>Performance Rate = (Numerator 1 + Numerator 2)/ (Denominator 1 + Denominator 2)</p> <p>Calculation algorithm for Population 1: Patient visits for patients with a diagnosis of cancer currently receiving chemotherapy</p> <ol style="list-style-type: none"> <li>1. Find the patients who meet the initial population (i.e., the general group of patients that a set of performance measures is designed to address).</li> <li>2. From the patients within the initial population criteria, find the patients who qualify for the denominator (i.e., 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.</li> </ol>	<p>Satisfactory reporting criteria are met by valid submission of one of six G codes on claims that meet denominator criteria.</p> <p>A rate of quality performance is calculated by dividing the number of records with G codes indicating that the quality actions were performed or that the patient was not eligible by total number of valid G code submissions.</p> <p>THIS SECTION PROVIDES DEFINITIONS &amp; FORMULAS FOR THE NUMERATOR (A), TOTAL DENOMINATOR POPULATION (TDP), DENOMINATOR EXCEPTIONS (B) CALCULATION &amp; PERFORMANCE DENOMINATOR (PD) CALCULATION.</p> <p>NUMERATOR (A): HCPCS Clinical Quality Codes G8730, G8731</p> <p>TOTAL DENOMINATOR POPULATION (TDP): Patient aged 18 years and older on the date of the encounter of the 12-month reporting period, with denominator defined encounter codes &amp; Medicare Part B Claims reported HCPCS Clinical Quality Codes G8730, G8731, G8442, G8939, G8732, G8509</p> <p>DENONINATOR Exception(B): HCPCS Clinical Quality Code G8442, G8939</p>	<ol style="list-style-type: none"> <li>1. Identify patients at least 18 years of age with Stage IV cancer</li> <li>2. Identify patients who have had at least 1 primary care or cancer-related visit. Exclude patients who are not alive 30 or more days after diagnosis.</li> <li>3. For each applicable visit, determine if a screening for pain was performed using a quantitative standardized tool.</li> <li>4. Performance score = number of visits with standardized quantitative screening for pain/total number of outpatient visits</li> </ol>

	0383: Oncology: Medical and Radiation - Plan of Care for Pain	0420: Pain Assessment and Follow-Up	1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits
	<p>3. From the patients within the denominator, find the patients who meet the numerator criteria (i.e., 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.</p> <p>Calculation algorithm for Population 2: Patient visits for patients with a diagnosis of cancer currently receiving radiation therapy</p> <p>1. Find the patients who meet the initial population (i.e., the general group of patients that a set of performance measures is designed to address).</p> <p>2. From the patients within the initial population criteria, find the patients who qualify for the denominator (i.e., 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.</p> <p>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.</p>	<p>DENOMINATOR Exception CALCULATION: Denominator Exception (B): # of patients with valid exceptions # G8442+G8939 / # TDP</p> <p>PERFORMANCE DENOMINATOR CALCULATION: Performance Denominator (B): Patients meeting criteria for performance denominator calculation # A / (# TDP - # B)</p>	
Submission items	<p>5.1 Identified measures: 0420 : Pain Assessment and Follow-Up</p> <p>1628 : Patients with Advanced Cancer Screened for Pain at Outpatient Visits</p>	<p>5.1 Identified measures: 0676 : Percent of Residents Who Self-Report Moderate to Severe Pain (Short Stay)</p> <p>0677 : Percent of Residents Who Self-Report Moderate to Severe Pain (Long Stay)</p>	<p>5.1 Identified measures:</p> <p>5a.1 Are specs completely harmonized? Yes</p>

	0383: Oncology: Medical and Radiation - Plan of Care for Pain	0420: Pain Assessment and Follow-Up	1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits
	<p>5a.1 Are specs completely harmonized? Yes</p> <p>5a.2 If not completely harmonized, identify difference, rationale, impact: Measure #420 is broadly applicable to any patients 18 years of age and older using claims. Measure #383 is examines whether a plan of care is present and maintained for a population who frequently experience pain – a population in which adequate pain management is crucial. In addition, it uses registry data in addition to paper medical records. Measure #1628 targets only patients with Stage IV cancer. Our measure looks at any stage of cancer for purposes of managing pain for which chemotherapy or radiation may be appropriate.</p> <p>5b.1 If competing, why superior or rationale for additive value: An environmental scan did not identify competing measures.</p>	<p>0383 : Oncology: Medical and Radiation - Plan of Care for Pain</p> <p>1628 : Patients with Advanced Cancer Screened for Pain at Outpatient Visits</p> <p>1634 : Hospice and Palliative Care -- Pain Screening</p> <p>1637 : Hospice and Palliative Care -- Pain Assessment</p> <p>5a.1 Are specs completely harmonized? No</p> <p>5a.2 If not completely harmonized, identify difference, rationale, impact: Six related measures were identified that are not harmonized with NQF# 0420. The differences between these related measures and the submitted measure NQF# 0420 are listed below: 0383 - Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (paired with 0384 which is unrelated to and non-competing with 0420) - target population is specific to patients with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain; 0383 does not include the use of a standardized pain assessment tool. Both measures are process measures. Both measures have outpatient care setting. 0676 - Percent of Residents Who Self-Report Moderate to Severe Pain (Short-Stay) – target population is specific to short - stay residents whereas 0420 has a broader outpatient population; 0420 is NOT a self-report measure, it is an eligible provider report; 0676 does not include the use of a standardized pain assessment tool; 0676 does not include documentation of a follow-up plan if pain is</p>	<p>5a.2 If not completely harmonized, identify difference, rationale, impact:</p> <p>5b.1 If competing, why superior or rationale for additive value: This measure was part of the National Palliative Care Research Center (NPCRC) Key Palliative Measures Bundle during the original submission. At that time, a NPCRC cover letter and table of bundle measures for description of the selection and harmonization of the Key Palliative Measures Bundle was provided.</p> <p>Measures 0677, 0675, 0523, and 0524 apply to nursing home and home health care settings and are, therefore, not competing with the proposed measure.</p> <p>It is unclear exactly what the scope of measure 0420 is, however it appears to be directed at ancillary, non-physician professionals. It is unclear what "initiation of therapy" is referring to. The measure's endorsement is time limited (endorsed July 31, 2008)</p> <p>Measure 0384 (paired with 0383) also has a time-limited endorsement (endorsed July 31, 2008). This measure targets only patients who are currently receiving chemotherapy or radiation therapy, and by definition, excludes some patients with advanced cancer who are not receiving this type of treatment. The proposed measure targets patients with Stage IV cancer and includes more venues of care than the existing measure where it would be applied (primary care and all cancer-related outpatient visits). This is in keeping with the reality that pain and pain control becomes a central focus for patients with late-stage cancer, and regular pain assessment should</p>

	0383: Oncology: Medical and Radiation - Plan of Care for Pain	0420: Pain Assessment and Follow-Up	1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits
		<p>present; 0676 is an outcome measure whereas 0420 is a process measure. Care setting for 0676 is long term care/skilled nursing facilities whereas 0420 care setting is outpatient clinician office or outpatient rehabilitation. 0677 - Percent of Residents Who Self-Report Moderate to Severe Pain (Long-Stay) – target population is specific to long - stay residents whereas 0420 has a broader outpatient population; 0420 is NOT a self-report measure, it is an eligible provider report; 0677 does not include the use of a standardized pain assessment tool; 0677 does not include documentation of a follow-up plan if pain is present; 0677 is an outcome measure whereas 0420 is a process measure. Care setting for 0677 is long term care/skilled nursing facilities whereas 0420 care setting is outpatient clinician office or outpatient rehabilitation. 1628 - Patients with Advanced Cancer Screened for Pain at Outpatient Visits - target population is specific to patients with a diagnosis of advanced cancer; 1628 does not include a follow-up plan if pain is present; Both 1628 and 0420 are process measures; Both measures have outpatient care setting. 1634 - Hospice and Palliative Care -- Pain Screening: target population has no age parameters whereas 0420 has an age range (&gt; 18 yrs.); 1634 target population is specific to hospice and palliative care patients whereas 0420 is not diagnosis specific; 1634 does not include documentation of a follow-up plan if pain is present; Both 1634 and 0420 are process measures; Care setting for 1634 is restricted to Hospice/Hospital/Acute Care Facility, whereas 0420 care setting is outpatient</p>	<p>occur in multiple outpatient care settings. The developers propose that measure 0383 be limited to patients with Stage I-III cancer and endorse the proposed measure which targets Stage IV cancer patients.</p> <p>Proposed measure 1634: Hospice and Palliative Care - Pain Screening: Proposed measure 1634 targets patients with serious conditions who are entering hospice or hospital-based palliative care. The measure proposed here targets a sub-population (advanced cancer). However, the setting and timing of 1634 is hospice/palliative care admission and is a one-time screen. 1628 focuses on pain screening at all outpatient visits. Although the 2 measures focus on different venues of care (and 1 is a time measure and the other every visit), they are completely harmonized in content.</p>

	0383: Oncology: Medical and Radiation - Plan of Care for Pain	0420: Pain Assessment and Follow-Up	1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits
		<p>clinician office or outpatient rehabilitation. 1637 – Hospice and Palliative Care—Pain Assessment- target population has no age parameters whereas 0420 has an age range (&gt; 18 yrs.); 1637 target population is specific to hospice and palliative care patients whereas 0420 is not diagnosis specific; 1637 measure focus is clinical assessment within 24hrs of positive screening for pain; 0420 measure focus is performing a screening and a documented follow-up plan not just limited to a clinical assessment; Both are process measures; Care setting for 1637 is restricted to Hospice/Hospital/Acute Care Facility; whereas 0420 care setting is outpatient clinician office or outpatient rehabilitation.</p> <p>5b.1 If competing, why superior or rationale for additive value: There are no competing measures.</p>	

## Comparison of NQF #1858 and NQF #1857

	1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy	1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies
Steward	American Society of Clinical Oncology	American Society of Clinical Oncology
Description	Percentage of female patients aged 18 and over with HER2/neu positive invasive breast cancer who are administered trastuzumab	Proportion of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2)/neu negative who are not administered HER2-targeted therapies
Type	Process	Process
Data Source	Paper Medical Records, Registry Data N/A, measure is not instrument-based. No data collection instrument provided No data dictionary	Not applicable This measure is specified with specific criteria and data elements. If a patient record does not include one or more of these components for the initial patient population or denominator, then patients are not considered eligible for the measure and not included.  If data to determine whether a patient should be considered for the numerator or exclusions is missing, then the numerator or exclusions not considered to be met and the practice will not get credit for meeting performance for that patient.  Registry “Trastuzumab” has been changed to “HER2 targeted therapies” to reflect updated evidence regarding the expansion of treatment options for HER-2 positive patients.  Changes to the measure were made after the latest measure update of ASCO’s Quality Oncology Practice Initiative (QOPI®) measures and therefore the data and testing reflect the previous version of the measure. These changes will be implemented in the Fall of 2016.
Level	Clinician : Group/Practice	ASCO Quality Oncology Practice Initiative (QOPI®)
Setting	Outpatient Services	No data collection instrument provided Clinician : Group/Practice
Numerator Statement	Patients for whom trastuzumab is administered within 12 months of diagnosis	Female And 2 or more encounters at the reporting site And Age at diagnosis greater than or equal to 18 years And Initial breast cancer diagnosis [C50.01-, C50.11-, C50.21-, C50.31-, C50.41-, C50.51-, C50.61-, C50.81-, C50.91-]

	1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy	1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies
		<p>AND  (HER-2/neu status = HER2 negative  OR  HER-2/neu status = Test ordered, results not yet documented  OR  HER-2/neu status = Test NOT ordered/no documentation  OR  HER-2/neu status=Test ordered, insufficient sample for results  Or  HER-2/neu status= HER2 equivocal)</p> <p>Definitions</p> <p>Encounter: Patients must have been first seen in the office by a medical oncology or hematology oncology practitioner for the cancer diagnosis eligible for inclusion within the 1-year time frame of the reporting period. Enter the most recent visit that occurred during the 6-month visit window before the abstraction date. This can include visits to other office sites within the practice only if the practice uses a common medical record and shares management of care for the patient. This does not include visits during which a practitioner wasn't seen (e.g., laboratory testing), inpatient consults/visits, phone or email consults, or visits to a surgeon or radiation oncologist.</p> <p>HER2 status:</p> <p>Select 'Test ordered, results not yet documented' only if there is documentation in the chart that a test that included HER2 analyses was ordered.</p> <p>In the absence of any documentation regarding HER-2/neu status, select 'Test not ordered/no documentation.'</p> <p>Enter information from the most recent test report. If the most recent report indicates insufficient sample, select 'Test ordered, insufficient sample for results.'</p> <p>If a physician note and the HER-2/neu report differ in results, report the status in the physician note if the note explains the discrepancy. Otherwise, report the status from the HER-2/neu report.</p> <p>Use the following definitions to determine HER-2/neu status:</p>



	1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy	1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies
		<p>Positive:</p> <p>IHC 3+ based on circumferential membrane staining that is complete, intense</p> <ul style="list-style-type: none"> <li>- ISH positive based on:</li> <li>- Single-probe average HER2 copy number =6.0 signals/cell</li> <li>- Dual-probe HER2/CEP17 ratio =2.0 with an average HER2 copy number =4.0 signals/cell</li> <li>- Dual-probe HER2/CEP17 ratio =2.0 with an average HER2 copy number &lt;4.0 signals/cell</li> <li>- Dual-probe HER2/CEP17 ratio &lt; 2.0 with an average HER2 copy number =6.0 signals/cell</li> </ul> <p>Equivocal:</p> <ul style="list-style-type: none"> <li>- IHC 2+ based on circumferential membrane staining that is incomplete and/or weak/moderate and within &gt; 10% of the invasive tumor cells or complete and circumferential membrane staining that is intense and within = 10% of the invasive tumor cells</li> </ul> <p>ISH equivocal based on:</p> <ul style="list-style-type: none"> <li>- Single-probe ISH average HER2 copy number = 4.0 and &lt; 6.0 signals/cell</li> <li>- Dual-probe HER2/CEP17 ratio &lt; 2.0 with an average HER2 copy number = 4.0 and &lt; 6.0 signals/cell</li> </ul> <p>Negative:</p> <p>IHC 1+ as defined by incomplete membrane staining that is faint/barely perceptible and within &gt; 10% of the invasive tumor cells or</p> <p>IHC 0 as defined by no staining observed or membrane staining that is incomplete and is faint/barely perceptible and within = 10% of the invasive tumor cells</p> <p>ISH negative based on:</p> <ul style="list-style-type: none"> <li>- Single-probe average HER2 copy number &lt; 4.0 signals/cell</li> <li>- Dual-probe HER2/CEP17 ratio &lt; 2.0 with an average HER2 copy number &lt; 4.0 signals/cell</li> </ul> <p>Indeterminate:</p>

	1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy	1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies
		Indeterminate if technical issues prevent one or both tests (IHC and ISH) from being reported as positive, negative, or equivocal. Conditions may include: - Inadequate specimen handling, - Artifacts (crush or edge artifacts) that make interpretation difficult - Analytic testing failure.
Numerator Details	Numerator: Trastuzumab administered within 12 months of diagnosis Numerator Options: Performance Met: Trastuzumab administered within 12 months of diagnosis OR Denominator Exception: Reason for not administering Trastuzumab documented (e. g. patient declined, patient died, patient transferred, contraindication or other clinical exclusion, neoadjuvant chemotherapy or radiation NOT complete) OR Performance Not Met: Trastuzumab not administered within 12 months of diagnosis	Patient transfer to practice during or after initial course.
Denominator Statement	Female patients aged 18 and over with AJCC stage I (T1c) – III, HER2/neu positive breast cancer who receive chemotherapy	Transfer-in Status does not equal Reporting practice has/had primary responsibility for the initial course of the patient's medical oncology care
Denominator Details	Denominator Criteria (Eligible Cases): Female Patients aged = 18 years on date of encounter AND Diagnosis of breast cancer AND Patient encounter during performance period AND Two or more encounters at the reporting site AND Breast Adjuvant Chemotherapy administered: AND HER-2/neu positive:	Not applicable

	1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy	1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies
	<p>AND</p> <p>AJCC stage at breast cancer diagnosis = II or III: G9831</p> <p>OR</p> <p>AJCC stage at breast cancer diagnosis = I (IA or IB) and T-Stage at breast cancer diagnosis does NOT equal = T1, T1a, T1b</p> <p>AND NOT</p> <p>Denominator Exclusions:</p> <p>Patient transfer to practice after initiation of chemotherapy</p>	
Exclusions	<p>Denominator Exclusions:</p> <ul style="list-style-type: none"> <li>o Patient transfer to practice after initiation of chemotherapy</li> </ul> <p>Denominator Exceptions:</p> <ul style="list-style-type: none"> <li>o Reason for not administering trastuzumab documented (e.g. patient declined, patient died, patient transferred, contraindication or other clinical exclusion, neoadjuvant chemotherapy or radiation therapy not complete)</li> </ul>	No risk adjustment or risk stratification
Exclusion Details	<p>Denominator Exclusions:</p> <p>Patient transfer to practice after initiation of chemotherapy</p>	
Risk Adjustment	No risk adjustment or risk stratification	Not applicable
Stratification	N/A, no risk stratification	Not applicable
Type Score	Rate/proportion better quality = higher score	Rate/proportion better quality = higher score
Algorithm	This measure is a proportion with exclusions and exceptions; thus, the calculation algorithm is: Patients meeting the numerator + patients with valid exceptions/ (Patients in the denominator – Patients with valid exclusions) x 100	<p>Performance is calculated as:</p> <ol style="list-style-type: none"> <li>1. Identify those patients that meet the denominator criteria defined in the measure.</li> <li>2. Subtract those patients with a denominator exclusion from the denominator if applicable.</li> <li>3. From the patients who qualify for the denominator (after any exclusions are removed), identify those who meet the numerator criteria.</li> <li>4. Calculation: Numerator/Denominator-Denominator Exclusions</li> </ol>
Submission items	<p>5.1 Identified measures: 1855 : Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines</p> <p>1857 : HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies</p>	<p>5.1 Identified measures:</p> <p>5a.1 Are specs completely harmonized?</p>

	1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy	1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies
	<p>5a.1 Are specs completely harmonized? Yes</p> <p>5a.2 If not completely harmonized, identify difference, rationale, impact: N/A - The measure specifications are harmonized.</p> <p>5b.1 If competing, why superior or rationale for additive value: An environmental scan did not identify competing measures. ASCO believes that NQF 1857 is a complementary measure assessing the inverse of the quality action captured in NQF 1858. Furthermore, because NQF 1857 is endorsed with reserve status and is no longer in use, harmonization is therefore not required. We believe NQF 1855 is a complementary measure assessing HER2 testing, which is an integral component to NQF 1858, and harmonization is not required.</p>	<p>5a.2 If not completely harmonized, identify difference, rationale, impact: Attachment</p> <p>5b.1 If competing, why superior or rationale for additive value: QOPI_Adoption_of_ICD10_020916-635933001750874650.docx</p>

## Comparison of NQF #1859 and NQF #1860

	1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy	1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies
Steward	American Society of Clinical Oncology	American Society of Clinical Oncology
Description	Percentage of adult patients (aged 18 and over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed	Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies
Type	Process	Process
Data Source	Paper Medical Records, Registry Data N/A, measure is not instrument-based. No data collection instrument provided No data dictionary	Paper Medical Records, Registry Data N/A, measure is not instrument-based. No data collection instrument provided No data dictionary
Level	Clinician : Group/Practice	Clinician : Group/Practice
Setting	Outpatient Services	Outpatient Services
Numerator Statement	RAS (KRAS and NRAS) gene mutation testing performed prior to initiation of anti-EGFR monoclonal antibody therapy	Anti-EGFR monoclonal antibody therapy not received
Numerator Details	<p>RAS gene mutation testing = RAS mutation detected OR RAS gene mutation testing = No RAS mutation detected (wildtype) AND RAS gene mutation testing date</p> <p>Numerator definitions: RAS mutation testing - RAS testing for this measure refers to assays that detect mutations in codons 12 and 13 of exon 2, codons 59 and 61 of exon 3 and codons 117 and 146 in exon 4 in KRAS or NRAS. Do not include results from mutations at other codons or assays for other alterations (e.g., BRAF, PI3K, PTEN genes). The College of American Pathologists (CAP) Perspectives on Emerging Technology (POET) Report on RAS mutation testing provides additional guidance on testing. If multiple RAS mutation tests have been performed, refer to the most recent test results. In the absence of any documentation regarding testing for the RAS gene mutation, select 'Test not ordered/no documentation.'</p>	Anti-EGFR monoclonal antibody therapy status = No Anti-EGFR monoclonal antibody therapy received

	1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy	1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies
	Refer to the interpretive report for the RAS test. The report will indicate if a mutation within codons 12 and 13 of exon 2, codons 59 and 61 of exon 3 and codons 117 and 146 in exon 4 in KRAS or NRAS, where KRAS or NRAS gene was detected in the DNA extracted from the colon tumor specimen.	
Denominator Statement	Adult patients with metastatic colorectal cancer who receive anti-EGFR monoclonal antibody therapy	Adult patients with metastatic colorectal cancer who have a RAS (KRAS or NRAS) gene mutation
Denominator Details	<p>Age at diagnosis greater than or equal to 18 years</p> <p>AND</p> <p>2 or more encounters at the reporting site</p> <p>AND</p> <p>Initial colon or rectal cancer diagnosis (153.x, 154.0, 154.0, 154.1, 154.8)</p> <p>AND</p> <p>Presence of metastatic disease documented</p> <p>AND</p> <p>Anti-EGFR monoclonal antibody therapy received</p> <p>Definitions</p> <p>Encounter: new patient visit (CPT 99201-99205) or established patient (CPT 99211-99215), not consult (CPT 99241-99245) office consult or inpatient consult CPT 99251-99255)</p>	<p>Age at diagnosis greater than or equal to 18 years</p> <p>AND</p> <p>2 or more encounters at the reporting site</p> <p>AND</p> <p>Initial colon or rectal cancer diagnosis (ICD-10 CM C18.0, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C18.9, C19, C20)</p> <p>AND</p> <p>Presence of metastatic disease documented</p> <p>AND</p> <p>RAS (KRAS or NRAS) gene mutation detected</p> <p>Definitions</p> <p>Encounter = new patient visit (CPT 99201 -99205) or established patient (CPT 99211-99215), not consult (CPT 99241-99245 office consult or inpatient consult CPT 99251-99255)</p> <p>RAS mutation testing - RAS testing for this measure refers to assays that detect mutations in codons 12 and 13 of exon 2, codons 59 and 61 of exon 3 and codons 117 and 146 in exon 4 in KRAS or NRAS. Do not include results from mutations at other codons or assays for other alterations (e.g., BRAF, PI3K, PTEN genes). The College of American Pathologists (CAP) Perspectives on Emerging Technology (POET) Report on RAS mutation testing provides additional guidance on testing.</p> <p>If multiple RAS mutation tests have been performed, refer to the most recent test results.</p>
Exclusions	None	None
Exclusion Details	n/a	n/a
Risk Adjustment	No risk adjustment or risk stratification	No risk adjustment or risk stratification

	1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy	1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies
Stratification	n/a	n/a
Type Score	Rate/proportion better quality = higher score	Rate/proportion better quality = higher score
Algorithm	This measure is a proportion without exclusions. The calculation algorithm is: (Patients meeting the numerator/patients in the denominator) x 100	This measure is a proportion without exclusions. The calculation algorithm is: (Patients meeting the numerator/patients in the denominator) x 100
Submission items	<p>5.1 Identified measures: 1860 : Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies</p> <p>5a.1 Are specs completely harmonized? Yes</p> <p>5a.2 If not completely harmonized, identify difference, rationale, impact: N/A - The measure specifications are harmonized.</p> <p>5b.1 If competing, why superior or rationale for additive value: An environmental scan did not identify competing measures. ASCO believes that NQF 1860 is a complementary measure assessing the inverse of the quality action captured in NQF 1859.</p>	<p>5.1 Identified measures: 1859 : RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy</p> <p>5a.1 Are specs completely harmonized? Yes</p> <p>5a.2 If not completely harmonized, identify difference, rationale, impact: N/A - The measure specifications are harmonized.</p> <p>5b.1 If competing, why superior or rationale for additive value: An environmental scan did not identify competing measures. ASCO believes that NQF 1859 is a complementary measure assessing the inverse of the quality action captured in NQF 1860.</p>

## Appendix E2: Related and Competing Measures (Narrative)

### Comparison of NQF #0220 and NQF #0387e

0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer

0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer

#### *Steward*

**0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

Commission on Cancer, American College of Surgeons

**0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

PCPI Foundation

#### *Description*

**0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

Percentage of female patients, age = 18 at diagnosis, who have their first diagnosis of cancer (epithelial malignancy), at AJCC T1cN0M0 or stage IB to IIIC, whose primary tumor is of the breast, and is progesterone or estrogen receptor positive with adjuvant hormonal therapy (recommended or administered) within 1 year (365 days) of diagnosis

**0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

Percentage of female patients aged 18 years and older with Stage I (T1b) through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period

#### *Type*

**0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

Process

**0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

Process



### *Data Source*

**0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

Registry Data Hospital cancer registry data, reported to the American College of Surgeons' Commission on Cancer, National Cancer Database  
Available at measure-specific web page URL identified in S.1 No data dictionary

**0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

Claims, Electronic Health Records, Paper Medical Records, Registry Data Not applicable. Zip file for data dictionary/code table to be sent separately (cannot be attached to 2a1.30).

Attachment 0387\_BreastCancer\_v6\_ValueSets\_09282017.xls

### *Level*

**0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

Facility

**0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

Clinician : Group/Practice, Clinician : Individual

### *Setting*

**0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

Inpatient/Hospital

**0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

Other, Outpatient Services Oncology/Outpatient Clinic

### *Numerator Statement*

**0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

Adjuvant hormonal therapy is administered within 1 year (365 days) of the date of diagnosis or it is recommended but not administered

**0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

Patients who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period

### *Numerator Details*

#### **0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

Hormone Therapy recommended and not received [NAACCR Item# 1400]=82, 85, 86, 87 (82:not recommended/ administered because it was contraindicated due to patient risk factors, 85:not administered because the patient died prior to planned or recommended therapy, 86:It was recommended by the patient's physician, but was not administered as part of first-course therapy. No reason was stated in the patient record, 87: it was recommended by the patient's physician, but this treatment was refused by the patient, the patient's family member, or the patient's guardian. The refusal was noted in the patient record)

or

Hormone Therapy administered [NAACCR Item# 1400] = 01 AND date hormone therapy started [NAACCR Item# 1230] <=365 days following date of initial diagnosis [NAACCR Item# 390]

#### **0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

Time Period for Data Collection: At least once during the measurement period

Definition:

Prescribed - May include prescription given to the patient for tamoxifen or aromatase inhibitor (AI) at one or more visits in the 12-month period OR patient already taking tamoxifen or aromatase inhibitor (AI) as documented in the current medication list.

For Claims/Registry:

Report the CPT Category II code: 4179F - Tamoxifen or aromatase inhibitor (AI) prescribed

For EHR:

HQMF eCQM developed and is included in this submission.

### *Denominator Statement*

#### **0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

Include if all of the following characteristics are identified:

Women

Age = 18 at time of diagnosis

Known or assumed to be first or only cancer diagnosis

Epithelial malignancy only

Invasive tumors

Primary tumors of the breast

AJCC T1cN0M0 or Stage IB – IIIC

Primary tumor is estrogen receptor positive or progesterone receptor positive

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

Known to be alive within 1 year (365 days) of date of diagnosis

Surgical procedure of the primary site

**0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

All female patients aged 18 years and older with a diagnosis of breast cancer with Stage I (T1b) through IIIC, estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer

*Denominator Details*

**0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

Sex [NAACCR Item# 220] = 2

Age [NAACCR Item# 230] = 018

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

Stageable epithelial tumor ICD-O codes in the AJCC 8th Edition staging manual [NAACCR Item# 522] = 8022, 8032, 8035, 8041, 8070, 8200, 8201, 8211, 8246, 8290, 8314, 8315, 8410, 8430, 8480, 8500, 8502, 8503, 8504, 8507, 8509, 8510, 8513, 8520, 8525, 8530, 8540, 8550, 8570, 8571, 8572, 8574, 8575, 8982, 8983, 8000, 8010, 8140, 8255, 8401, 8501, 8521, 8522, 8523, 8524, 8541, 8543

Invasive tumor behavior [NAACCR Item# 523] = 3

Primary tumors of the breast [NAACCR Item# 400] = C50.0, C50.1, C50.2, C50.3, C50.4, C50.5, C50.6, C50.8, C50.9

AJCC T1cN0M0 or Stage IB – IIIC:

AJCC pathologic N [NAACCR Item# 1012] = (cN0, pN0, pN0(i+), pN0(mol+)) AND tumor size summary [NAACCR Item# 756] = 011-989

or

AJCC pathologic N [NAACCR Item# 1012] = (cN1, cN1mi, cN2, cN2a, cN2b, cN3, cN3a, cN3b, cN3c, pN1, pN1mi, pN1a, pN1b, pN1c, pN2, pN2a, pN2b, pN3, pN3a, pN3b, pN3c)

AJCC clinical stage group [NAACCR Item# 1004] ? 0, 4 when AJCC pathologic stage group [NAACCR Item# 1014] = 88, 99

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

AJCC clinical M [NAACCR Item# 1003] ? cM1, pM1

AJCC pathologic M [NAACCR Item# 1013] ? cM1, pM1

Hormone receptor positive:

SSDI ER positive [NAACCR Item# 3826] = 001-100, R10-R99

or

SSDI PR positive [NAACCR Item# 3914] = 001-100, R10-R99

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

Known to be alive within 1 year (365 days) of date of diagnosis: vital status [NAACCR Item# 1760] = 1 and date of last contact or death [NAACCR Item# 1750] – date of initial diagnosis [NAACCR Item# 390] > 365

Surgical Procedure of the Primary Site [NAACCR Item# 1290] = 20–90

**0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

Time Period for Data Collection: 12 consecutive months

For Claims/Registry:

All female patients aged >= 18 years on date of encounter

AND

Diagnosis for breast cancer (ICD-10-CM): C50.011, C50.012, C50.019, C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.311, C50.312, C50.319, C50.411, C50.412, C50.419, C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, C50.812, C50.819, C50.911, C50.912, C50.919

AND

Patient encounter during the reporting period (CPT): 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215

WITHOUT

Telehealth Modifier: GQ, GT, 95, Place of Service (POS) 2

AND

Quality Data Code (G-code) G9705: AJCC Breast Cancer Stage I: T1b (tumor > 0.5 cm but <= 1 cm in greatest dimension) documented OR

CPT Category II code 3374F: AJCC Breast Cancer Stage I: T1c (tumor size > 1 cm to 2 cm) documented OR

CPT Category II code 3376F: AJCC Breast Cancer Stage II documented OR

CPT Category II code 3378F: AJCC Breast Cancer Stage III documented

AND

CPT Category II code 3315F: Estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer

For EHR:

HQMF eCQM developed and is included in this submission.

## Exclusions

### **0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

Exclude, if any of the following characteristics are identified:

Men

Under age 18 at time of diagnosis

Second or subsequent cancer diagnosis

Tumor not originating in the breast

Non-epithelial malignancies, exclude malignant phyllodes tumors; 8940 - Mixed tumor, malignant, NOS; 8950 - Mullerian mixed tumor; 8980 - Carcinosarcoma; 8981 - Carcinosarcoma, embryonal

Non-invasive tumors

Stage 0, in situ tumor

Stage IV, metastatic tumor

Primary tumor is estrogen receptor negative and progesterone receptor negative

None of 1st course therapy performed at reporting facility

Died within 1 year (365 days) of diagnosis,

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

No surgical procedure of the primary site

Not AJCC T1cN0M0 or not AJCC stage IB-IIIC

### **0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

Documentation of medical reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient's disease has progressed to metastatic; patient is receiving a gonadotropin-releasing hormone analogue, patient has received oophorectomy, patient is receiving radiation or chemotherapy, patient's diagnosis date was > 5 years from reporting date, patient's diagnosis date is within 120 days of the end of the 12-month reporting period, other medical reasons)

Documentation of patient reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient refusal, other patient reasons)

Documentation of system reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient is currently enrolled in a clinical trial, other system reasons)

## Exclusion Details

### **0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

See pages 18-26: [https://www.facs.org/~media/files/quality\\_programs/cancer/ncdb/measure\\_specs\\_breast.ashx](https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx)

### **0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

Time Period for Data Collection: At the time of the encounter

Exceptions are used to remove a patient from the denominator of a performance measure when the patient does not receive a therapy or service AND that therapy or service would not be appropriate due to patient-specific reasons. The patient would otherwise meet the denominator criteria. Exceptions are not absolute, and are based on clinical judgment, individual patient characteristics, or patient preferences. The PCPI exception methodology uses three categories of reasons for which a patient may be removed from the denominator of an individual measure. These measure exception categories are not uniformly relevant across all measures; for each measure, there must be a clear rationale to permit an exception for a medical, patient, or system reason. Examples are provided in the measure exception language of instances that may constitute an exception and are intended to serve as a guide to clinicians. For measure Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer, exceptions may include medical reason(s) (eg, patient's disease has progressed to metastatic; patient is receiving a gonadotropin-releasing hormone analogue, patient has received oophorectomy, patient is receiving radiation or chemotherapy, patient's diagnosis date was > 5 years from reporting date, patient's diagnosis date is within 120 days of the end of the 12-month reporting period, other medical reasons), patient reason(s) (eg, patient refusal, other patient reasons), or system reason(s) (eg, patient is currently enrolled in a clinical trial, other system reasons). Where examples of exceptions are included in the measure language, value sets for these examples are developed and included in the eCQM. Although this methodology does not require the external reporting of more detailed exception data, the PCPI recommends that physicians document the specific reasons for exception in patients' medical records for purposes of optimal patient management and audit-readiness. The PCPI also advocates the systematic review and analysis of each physician's exceptions data to identify practice patterns and opportunities for quality improvement.

Additional details by data source are as follows:

For Claims/Registry:

Documentation of medical reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient's disease has progressed to metastatic; patient is receiving a gonadotropin-releasing hormone analogue, patient has received oophorectomy, patient is receiving radiation or chemotherapy, patient's diagnosis date was > 5 years from reporting date, patient's diagnosis date is within 120 days of the end of the 12-month reporting period, other medical reasons): Append modifier to CPT Category II code: 4179F-1P

Documentation of patient reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient refusal, other patient reasons): Append modifier to CPT Category II code: 4179F-2P

Documentation of system reason(s) for not prescribing tamoxifen or aromatase inhibitor (eg, patient is currently enrolled in a clinical trial, other system reasons): Append modifier to CPT Category II code: 4179F-3P

For EHR:

HQMF eCQM developed and is included in this submission.

### *Risk Adjustment*

**0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

No risk adjustment or risk stratification

**0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

No risk adjustment or risk stratification

### *Stratification*

**0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

No stratification applied

**0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

Consistent with 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 and have included these variables as recommended data elements to be collected.

### *Type Score*

**0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

Rate/proportion better quality = higher score

**0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

Rate/proportion better quality = higher score

### *Algorithm*

**0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

See pages 18-26: [https://www.facs.org/~media/files/quality\\_programs/cancer/ncdb/measure\\_specs\\_breast.ashx](https://www.facs.org/~media/files/quality_programs/cancer/ncdb/measure_specs_breast.ashx)

**0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

To calculate performance rates:

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
4. From the patients who did not meet the numerator criteria, determine if the provider has documented that the patient meets any criteria for exception when denominator exceptions have been specified [for this measure: medical reason(s) (eg, patient's disease has progressed to metastatic; patient is receiving a gonadotropin-releasing hormone analogue, patient has received oophorectomy, patient is receiving radiation or chemotherapy, patient's diagnosis date was > 5 years from reporting date, patient's diagnosis date is within 120 days of the end of the 12-month reporting period, other medical reasons), patient reason(s) (eg, patient refusal, other patient reasons), or system reason(s) (eg, patient is currently enrolled in a clinical trial, other system reasons)]. If the patient meets any exception criteria, they should be removed from the denominator for performance calculation. --Although the exception cases are removed from the denominator population for the performance calculation, the exception rate (ie, percentage with valid exceptions) should be calculated and reported along with performance rates to track variations in care and highlight possible areas of focus for QI.

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

#### *Submission items*

##### **0220: Adjuvant hormonal therapy is recommended or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0 or Stage IB – Stage III hormone receptor positive breast cancer**

5.1 Identified measures: 0387 : Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: These measures are related but assess different levels of analysis and different data systems are used to determine eligibility and compliance.

5b.1 If competing, why superior or rationale for additive value: 0387 assesses hormone therapy for patients with stage Ic through III hormone receptor positive cancer. 0387 assesses if hormone therapy was prescribed within a 12 month period while our measure (0220) assesses if hormone therapy was administered within one year of diagnosis or if it was recommended but not received based on patient refusal, medical co-morbidity or other valid reasons.

0220 also assesses compliance at the facility level while 0387 assesses individual physician or practice level performance. The two measures use different data sources as well. 0220 utilizes cancer registry coding.

##### **0387e: Breast Cancer: Hormonal Therapy for Stage I (T1b)-IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer**

5.1 Identified measures:

5a.1 Are specs completely harmonized? No



5a.2 If not completely harmonized, identify difference, rationale, impact: No related measures; See competing measures section below regarding the harmonization of measure specifications.

5b.1 If competing, why superior or rationale for additive value: Measure 0220 is similarly limited to stage I through III breast cancer patients whose primary tumor is progesterone or estrogen receptor positive. Measure 0220 requires that the agents be considered or administered within 1 year of diagnosis while our measure looks at the receipt of adjuvant endocrine therapy over time, specifically whether the agents were prescribed once within a 12 month reporting period. Since the recommended treatment duration of adjuvant endocrine therapy is 5 years, our measure includes medical reason exceptions to allow physicians to exclude patients who have already received the agents for the recommended duration and for other medical reasons.

Our measure assess performance at the individual physician level while measure 0220 was designed to assess performance at the facility level.

## Comparison of NQF #0383, NQF #0420, and NQF #1628

0383: Oncology: Medical and Radiation - Plan of Care for Pain

0420: Pain Assessment and Follow-Up

1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits

### *Steward*

#### **0383: Oncology: Medical and Radiation - Plan of Care for Pain**

American Society of Clinical Oncology

#### **0420: Pain Assessment and Follow-Up**

Centers for Medicare & Medicaid Services

#### **1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

RAND Corporation

### *Description*

#### **0383: Oncology: Medical and Radiation - Plan of Care for Pain**

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

**0420: Pain Assessment and Follow-Up**

Percentage of visits for patients aged 18 years and older with documentation of a pain assessment using a standardized tool(s) on each visit AND documentation of a follow-up plan when pain is present

**1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

Adult patients with advanced cancer who are screened for pain with a standardized quantitative tool at each outpatient visit

*Type***0383: Oncology: Medical and Radiation - Plan of Care for Pain**

Process

**0420: Pain Assessment and Follow-Up**

Process

**1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

Process

*Data Source***0383: Oncology: Medical and Radiation - Plan of Care for Pain**

Paper Medical Records, Registry Data N/A, measure is not instrument-based

No data collection instrument provided Attachment 0383\_NQF\_PlanofCarePain\_CodeSet\_07312019.xlsx

**0420: Pain Assessment and Follow-Up**

Claims, Paper Medical Records The data source is the patient medical record. Medicare Part B claims data and registry data is provided for test purposes.

No data collection instrument provided Attachment NQF\_420\_DataDic\_1117.xlsx

**1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

Electronic Health Records, Paper Medical Records, Registry Data Patients were identified via the testing organizations' cancer registries.

At one institution, outpatient pain vital sign scores were extracted electronically from the patient EHR.

At other institutions, quantitative pain scores were collected via medical record abstraction.

No data collection instrument provided No data dictionary

*Level***0383: Oncology: Medical and Radiation - Plan of Care for Pain**

Clinician : Group/Practice

**0420: Pain Assessment and Follow-Up**

Clinician : Group/Practice, Clinician : Individual

**1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

Facility, Health Plan, Integrated Delivery System

*Setting*

**0383: Oncology: Medical and Radiation - Plan of Care for Pain**

Outpatient Services

**0420: Pain Assessment and Follow-Up**

Outpatient Services

**1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

Outpatient Services

*Numerator Statement*

**0383: Oncology: Medical and Radiation - Plan of Care for Pain**

Patient visits that include a documented plan of care\* to address pain.

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

**0420: Pain Assessment and Follow-Up**

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

**1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

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

*Numerator Details*

**0383: Oncology: Medical and Radiation - Plan of Care for Pain**

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

Time Period for Data Collection: At each visit within the measurement period for patients with a diagnosis of cancer and in which pain is present.

Guidance: A documented outline of care for a positive pain assessment is required. May include: use of non-opioid analgesics, opioids, psychological support, patient and/or family education, referral to a pain clinic, or reassessment of pain at an appropriate time interval.

## 0420: Pain Assessment and Follow-Up

### Definitions:

**Pain Assessment** – Documentation of a clinical assessment for the presence or absence of pain using a standardized tool is required. A multi-dimensional clinical assessment of pain using a standardized tool may include characteristics of pain, such as: location, intensity, description, and onset/duration.

**Standardized Tool** – An assessment tool that has been appropriately normed and validated for the population in which it is used. Examples of tools for pain assessment, include, but are not limited to: Brief Pain Inventory (BPI), Faces Pain Scale (FPS), McGill Pain Questionnaire (MPQ), Multidimensional Pain Inventory (MPI), Neuropathic Pain Scale (NPS), Numeric Rating Scale (NRS), Oswestry Disability Index (ODI), Roland Morris Disability Questionnaire (RMDQ), Verbal Descriptor Scale (VDS), Verbal Numeric Rating Scale (VNRS), Visual Analog Scale (VAS)), and Patient-Reported Outcomes Measurement Information System (PROMIS).

**Follow-Up Plan** – A documented outline of care for a positive pain assessment is required. This must include a planned follow-up appointment or a referral, a notification to other care providers as applicable OR indicate the initial treatment plan is still in effect. These plans may include pharmacologic, behavioral, physical medicine and/or educational interventions.

**Not Eligible (Denominator Exception)**– 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

**NUMERATOR NOTE:** The standardized tool used to assess the patient's pain must be documented in the medical record (exception: A provider may use a fraction such as 5/10 for Numeric Rating Scale without documenting this actual tool name when assessing pain for intensity).

### Numerator Quality-Data Coding Options:

**Pain Assessment Documented as Positive AND Follow-Up Plan Documented**

Performance Met: G8730: Pain assessment documented as positive using a standardized tool AND a follow-up plan is documented

OR

**Pain Assessment Documented as Negative, No Follow-Up Plan Required**

Performance Met: G8731: Pain assessment using a standardized tool is documented as negative, no follow-up plan required

OR

**Pain Assessment not Documented, Reason not Given**

Performance Not Met: G8732: No documentation of pain assessment, reason not given

OR

**Pain Assessment Documented as Positive, Follow-Up Plan not Documented, Reason not Given**

Performance Not Met: G8509: Pain assessment documented as positive using a standardized tool, follow-up plan not documented, reason not given

#### **1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

Pain screening with a standardized quantitative tool during the primary care or cancer-related/specialty outpatient visit(s). Screening may be completed using verbal, numeric, visual analog, rating scales designed for use with nonverbal patients, or other standardized tools.

#### *Denominator Statement*

##### **0383: Oncology: Medical and Radiation - Plan of Care for Pain**

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**

All visits for patients aged 18 years and older

#### **1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

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

#### *Denominator Details*

##### **0383: Oncology: Medical and Radiation - Plan of Care for Pain**

Time Period for Data Collection: 12 consecutive months

Denominator Criteria (Eligible Cases):

For all eligible patient encounters when pain severity quantified and pain is present (e.g., CPT II: 1125F is submitted in the numerator for NQF 0384) for patients regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy.

Guidance: This measure is an episode-of-care measure; the level of analysis for this measure is every visit for patients with a diagnosis of cancer who are also currently receiving chemotherapy or radiation therapy and a positive pain assessment during the measurement period. For patients receiving radiation therapy, pain intensity should be quantified at each radiation treatment management encounter. 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.

All visits for patients, regardless of age

AND

Diagnosis of cancer

AND

Patient encounter during the performance period

AND

Patient reported pain was present

AND

Radiation treatment management encounter

OR

Face-to-face encounter with the physician while the patient is currently receiving chemotherapy

**0420: Pain Assessment and Follow-Up**

Denominator Criteria (Eligible Cases): Patients aged greater than or equal to 18 years on date of encounter AND Patient encounter during the reporting period (CPT or HCPCS): 90791, 90792, 92002, 92004, 92012, 92014, 92507, 92508, 92526, 96116, 96118, 96150, 96151, 97161, 97162, 97164, 97165, 97166, 97167, 97168, 97532, 98940, 98941, 98942, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, D7140, D7210, G0101, G0402, G0438, G0439 WITHOUT Telehealth Modifier: GQ, GT

**1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

Adult patients with Stage IV cancer who are alive 30 days or more after diagnosis and who have had at least 1 primary care visit or cancer-related/specialty outpatient visit. Cancer-related visit = any oncology (medical, surgical, radiation) visit, chemotherapy infusion

*Exclusions*

**0383: Oncology: Medical and Radiation - Plan of Care for Pain**

None

**0420: Pain Assessment and Follow-Up**

Pain Assessment not Documented Patient not Eligible

Denominator Exception: G8442: Pain assessment NOT documented as being performed, documentation the patient is not eligible for a pain assessment using a standardized tool

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

**1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

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

*Exclusion Details*

**0383: Oncology: Medical and Radiation - Plan of Care for Pain**

N/A, no denominator exclusion

**0420: Pain Assessment and Follow-Up**

Pain Assessment not Documented Patient not Eligible

Denominator Exception: G8442: Pain assessment NOT documented as being performed, documentation the patient is not eligible for a pain assessment using a standardized tool

OR

Pain Assessment Documented as Positive, Follow-Up Plan not Documented, Patient not Eligible

Denominator Exception: G8939: Pain assessment documented as positive, follow-up plan not documented, documentation the patient is not eligible

**1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

*Risk Adjustment*

**0383: Oncology: Medical and Radiation - Plan of Care for Pain**

No risk adjustment or risk stratification

**0420: Pain Assessment and Follow-Up**

No risk adjustment or risk stratification

**1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

No risk adjustment or risk stratification

*Stratification*

**0383: Oncology: Medical and Radiation - Plan of Care for Pain**

N/A, no risk stratification

**0420: Pain Assessment and Follow-Up**

N/A

**1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

*Type Score*

**0383: Oncology: Medical and Radiation - Plan of Care for Pain**

Rate/proportion better quality = higher score

**0420: Pain Assessment and Follow-Up**

Rate/proportion better quality = higher score

**1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

Rate/proportion better quality = higher score

## Algorithm

### 0383: Oncology: Medical and Radiation - Plan of Care for Pain

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

$$\text{Performance Rate} = (\text{Numerator 1} + \text{Numerator 2}) / (\text{Denominator 1} + \text{Denominator 2})$$

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

1. Find the patients who meet the initial population (i.e., 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 (i.e., 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 (i.e., 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 Population 2: Patient visits for patients with a diagnosis of cancer currently receiving radiation therapy

1. Find the patients who meet the initial population (i.e., 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 (i.e., 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.

### 0420: Pain Assessment and Follow-Up

Satisfactory reporting criteria are met by valid submission of one of six G codes on claims that meet denominator criteria.

A rate of quality performance is calculated by dividing the number of records with G codes indicating that the quality actions were performed or that the patient was not eligible by total number of valid G code submissions.

THIS SECTION PROVIDES DEFINITIONS & FORMULAS FOR THE NUMERATOR (A), TOTAL DENOMINATOR POPULATION (TDP), DENOMINATOR EXCEPTIONS (B) CALCULATION & PERFORMANCE DENOMINATOR (PD) CALCULATION.

NUMERATOR (A): HCPCS Clinical Quality Codes G8730, G8731



TOTAL DENOMINATOR POPULATION (TDP): Patient aged 18 years and older on the date of the encounter of the 12-month reporting period, with denominator defined encounter codes & Medicare Part B Claims reported HCPCS Clinical Quality Codes G8730, G8731, G8442, G8939, G8732, G8509

DENONINATOR Exception(B): HCPCS Clinical Quality Code G8442, G8939

DENOMINATOR Exception CALCULATION: Denominator Exception (B): # of patients with valid exceptions # G8442+G8939 / # TDP

PERFORMANCE DENOMINATOR CALCULATION: Performance Denominator (B): Patients meeting criteria for performance denominator calculation # A / (# TDP - # B)

#### **1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

1. Identify patients at least 18 years of age with Stage IV cancer
2. Identify patients who have had at least 1 primary care or cancer-related visit. Exclude patients who are not alive 30 or more days after diagnosis.
3. For each applicable visit, determine if a screening for pain was performed using a quantitative standardized tool.
4. Performance score = number of visits with standardized quantitative screening for pain/total number of outpatient visits

#### *Submission items*

##### **0383: Oncology: Medical and Radiation - Plan of Care for Pain**

5.1 Identified measures: 0420 : Pain Assessment and Follow-Up

1628 : Patients with Advanced Cancer Screened for Pain at Outpatient Visits

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: Measure #420 is broadly applicable to any patients 18 years of age and older using claims. Measure #383 is examines whether a plan of care is present and maintained for a population who frequently experience pain – a population in which adequate pain management is crucial. In addition, it uses registry data in addition to paper medical records. Measure #1628 targets only patients with Stage IV cancer. Our measure looks at any stage of cancer for purposes of managing pain for which chemotherapy or radiation may be appropriate.

5b.1 If competing, why superior or rationale for additive value: An environmental scan did not identify competing measures.

##### **0420: Pain Assessment and Follow-Up**

5.1 Identified measures: 0676 : Percent of Residents Who Self-Report Moderate to Severe Pain (Short Stay)

0677 : Percent of Residents Who Self-Report Moderate to Severe Pain (Long Stay)

0383 : Oncology: Medical and Radiation - Plan of Care for Pain

1628 : Patients with Advanced Cancer Screened for Pain at Outpatient Visits

1634 : Hospice and Palliative Care -- Pain Screening

1637 : Hospice and Palliative Care -- Pain Assessment

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: Six related measures were identified that are not harmonized with NQF# 0420. The differences between these related measures and the submitted measure NQF# 0420 are listed below: 0383 - Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (paired with 0384 which is unrelated to and non-competing with 0420) - target population is specific to patients with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain; 0383 does not include the use of a standardized pain assessment tool. Both measures are process measures. Both measures have outpatient care setting. 0676 - Percent of Residents Who Self-Report Moderate to Severe Pain (Short-Stay) – target population is specific to short - stay residents whereas 0420 has a broader outpatient population; 0420 is NOT a self-report measure, it is an eligible provider report; 0676 does not include the use of a standardized pain assessment tool; 0676 does not include documentation of a follow-up plan if pain is present; 0676 is an outcome measure whereas 0420 is a process measure. Care setting for 0676 is long term care/skilled nursing facilities whereas 0420 care setting is outpatient clinician office or outpatient rehabilitation. 0677 - Percent of Residents Who Self-Report Moderate to Severe Pain (Long-Stay) – target population is specific to long - stay residents whereas 0420 has a broader outpatient population; 0420 is NOT a self-report measure, it is an eligible provider report; 0677 does not include the use of a standardized pain assessment tool; 0677 does not include documentation of a follow-up plan if pain is present; 0677 is an outcome measure whereas 0420 is a process measure. Care setting for 0677 is long term care/skilled nursing facilities whereas 0420 care setting is outpatient clinician office or outpatient rehabilitation. 1628 - Patients with Advanced Cancer Screened for Pain at Outpatient Visits - target population is specific to patients with a diagnosis of advanced cancer; 1628 does not include a follow-up plan if pain is present; Both 1628 and 0420 are process measures; Both measures have outpatient care setting. 1634 - Hospice and Palliative Care -- Pain Screening: target population has no age parameters whereas 0420 has an age range (> 18 yrs.); 1634 target population is specific to hospice and palliative care patients whereas 0420 is not diagnosis specific; 1634 does not include documentation of a follow-up plan if pain is present; Both 1634 and 0420 are process measures; Care setting for 1634 is restricted to Hospice/Hospital/Acute Care Facility, whereas 0420 care setting is outpatient clinician office or outpatient rehabilitation. 1637 – Hospice and Palliative Care—Pain Assessment- target population has no age parameters whereas 0420 has an age range (> 18 yrs.); 1637 target population is specific to hospice and palliative care patients whereas 0420 is not diagnosis specific; 1637 measure focus is clinical assessment within 24hrs of positive screening for pain; 0420 measure focus is performing a screening and a documented follow-up plan not just limited to a clinical assessment; Both are process measures; Care setting for 1637 is restricted to Hospice/Hospital/Acute Care Facility; whereas 0420 care setting is outpatient clinician office or outpatient rehabilitation.

5b.1 If competing, why superior or rationale for additive value: There are no competing measures.

#### **1628: Patients with Advanced Cancer Screened for Pain at Outpatient Visits**

5.1 Identified measures:

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value: This measure was part of the National Palliative Care Research Center (NPCRC) Key Palliative Measures Bundle during the original submission. At that time, a NPCRC cover letter and table of bundle measures for description of the selection and harmonization of the Key Palliative Measures Bundle was provided.

Measures 0677, 0675, 0523, and 0524 apply to nursing home and home health care settings and are, therefore, not competing with the proposed measure.

It is unclear exactly what the scope of measure 0420 is, however it appears to be directed at ancillary, non-physician professionals. It is unclear what "initiation of therapy" is referring to. The measure's endorsement is time limited (endorsed July 31, 2008)

Measure 0384 (paired with 0383) also has a time-limited endorsement (endorsed July 31, 2008). This measure targets only patients who are currently receiving chemotherapy or radiation therapy, and by definition, excludes some patients with advanced cancer who are not receiving this type of treatment. The proposed measure targets patients with Stage IV cancer and includes more venues of care than the existing measure where it would be applied (primary care and all cancer-related outpatient visits). This is in keeping with the reality that pain and pain control becomes a central focus for patients with late-stage cancer, and regular pain assessment should occur in multiple outpatient care settings. The developers propose that measure 0383 be limited to patients with Stage I-III cancer and endorse the proposed measure which targets Stage IV cancer patients.

Proposed measure 1634: Hospice and Palliative Care - Pain Screening: Proposed measure 1634 targets patients with serious conditions who are entering hospice or hospital-based palliative care. The measure proposed here targets a sub-population (advanced cancer). However, the setting and timing of 1634 is hospice/palliative care admission and is a one-time screen. 1628 focuses on pain screening at all outpatient visits. Although the 2 measures focus on different venues of care (and 1 is a time measure and the other every visit), they are completely harmonized in content.

## Comparison of NQF #1858 and NQF #1857

1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy

1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies

### *Steward*

**1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

American Society of Clinical Oncology

**1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

American Society of Clinical Oncology

### *Description*

**1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

Percentage of female patients aged 18 and over with HER2/neu positive invasive breast cancer who are administered trastuzumab

**1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

Proportion of female patients (aged 18 years and older) with breast cancer who are human epidermal growth factor receptor 2 (HER2)/neu negative who are not administered HER2-targeted therapies

### *Type*

**1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

Process

**1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

Process

### *Data Source*

**1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

Paper Medical Records, Registry Data N/A, measure is not instrument-based.

No data collection instrument provided No data dictionary

**1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

Not applicable This measure is specified with specific criteria and data elements. If a patient record does not include one or more of these components for the initial patient population or denominator, then patients are not considered eligible for the measure and not included.

If data to determine whether a patient should be considered for the numerator or exclusions is missing, then the numerator or exclusions not considered to be met and the practice will not get credit for meeting performance for that patient.

Registry “Trastuzumab” has been changed to “HER2 targeted therapies” to reflect updated evidence regarding the expansion of treatment options for HER-2 positive patients.

Changes to the measure were made after the latest measure update of ASCO’s Quality Oncology Practice Initiative (QOPI®) measures and therefore the data and testing reflect the previous version of the measure. These changes will be implemented in the Fall of 2016.

*Level*

**1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

Clinician : Group/Practice

**1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

ASCO Quality Oncology Practice Initiative (QOPI®)

*Setting*

**1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

Outpatient Services

**1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

No data collection instrument provided Clinician : Group/Practice

*Numerator Statement*

**1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

Patients for whom trastuzumab is administered within 12 months of diagnosis

**1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

Female

And

2 or more encounters at the reporting site

And

Age at diagnosis greater than or equal to 18 years

And

Initial breast cancer diagnosis [C50.01-, C50.11-, C50.21-, C50.31-, C50.41-, C50.51-, C50.61-, C50.81-, C50.91-]

AND

(HER-2/neu status = HER2 negative

OR

HER-2/neu status = Test ordered, results not yet documented

OR

HER-2/neu status = Test NOT ordered/no documentation

OR

HER-2/neu status=Test ordered, insufficient sample for results

Or

HER-2/neu status= HER2 equivocal)

Definitions

Encounter: Patients must have been first seen in the office by a medical oncology or hematology oncology practitioner for the cancer diagnosis eligible for inclusion within the 1-year time frame of the reporting period. Enter the most recent visit that occurred during the 6-month visit window before the abstraction date. This can include visits to other office sites within the practice only if the practice uses a common medical record and shares management of care for the patient. This does not include visits during which a practitioner wasn't seen (e.g., laboratory testing), inpatient consults/visits, phone or email consults, or visits to a surgeon or radiation oncologist.

HER2 status:

Select 'Test ordered, results not yet documented' only if there is documentation in the chart that a test that included HER2 analyses was ordered.

In the absence of any documentation regarding HER-2/neu status, select 'Test not ordered/no documentation.'

Enter information from the most recent test report. If the most recent report indicates insufficient sample, select 'Test ordered, insufficient sample for results.'

If a physician note and the HER-2/neu report differ in results, report the status in the physician note if the note explains the discrepancy.

Otherwise, report the status from the HER-2/neu report.

Use the following definitions to determine HER-2/neu status:

Positive:

IHC 3+ based on circumferential membrane staining that is complete, intense

- ISH positive based on:

- Single-probe average HER2 copy number =6.0 signals/cell
- Dual-probe HER2/CEP17 ratio =2.0 with an average HER2 copy number =4.0 signals/cell
- Dual-probe HER2/CEP17 ratio =2.0 with an average HER2 copy number <4.0 signals/cell
- Dual-probe HER2/CEP17 ratio < 2.0 with an average HER2 copy number =6.0 signals/cell

Equivocal:

- IHC 2+ based on circumferential membrane staining that is incomplete and/or weak/moderate and within > 10% of the invasive tumor cells or complete and circumferential membrane staining that is intense and within = 10% of the invasive tumor cells

ISH equivocal based on:

- Single-probe ISH average HER2 copy number = 4.0 and < 6.0 signals/cell
- Dual-probe HER2/CEP17 ratio < 2.0 with an average HER2 copy number = 4.0 and < 6.0 signals/cell

Negative:

IHC 1+ as defined by incomplete membrane staining that is faint/barely perceptible and within > 10% of the invasive tumor cells or

IHC 0 as defined by no staining observed or membrane staining that is incomplete and is faint/barely perceptible and within = 10% of the invasive tumor cells

ISH negative based on:

- Single-probe average HER2 copy number < 4.0 signals/cell
- Dual-probe HER2/CEP17 ratio < 2.0 with an average HER2 copy number < 4.0 signals/cell

Indeterminate:

Indeterminate if technical issues prevent one or both tests (IHC and ISH) from being reported as positive, negative, or equivocal. Conditions may include:

- Inadequate specimen handling,
- Artifacts (crush or edge artifacts) that make interpretation difficult
- Analytic testing failure.

### *Numerator Details*

**1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

Numerator:

Trastuzumab administered within 12 months of diagnosis

Numerator Options:

Performance Met: Trastuzumab administered within 12 months of diagnosis

OR

Denominator Exception: Reason for not administering Trastuzumab documented (e. g. patient declined, patient died, patient transferred, contraindication or other clinical exclusion, neoadjuvant chemotherapy or radiation NOT complete)

OR

Performance Not Met: Trastuzumab not administered within 12 months of diagnosis

**1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

Patient transfer to practice during or after initial course.

*Denominator Statement*

**1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

Female patients aged 18 and over with AJCC stage I (T1c) – III, HER2/neu positive breast cancer who receive chemotherapy

**1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

Transfer-in Status does not equal Reporting practice has/had primary responsibility for the initial course of the patient's medical oncology care

*Denominator Details*

**1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

Denominator Criteria (Eligible Cases):

Female Patients aged = 18 years on date of encounter

AND

Diagnosis of breast cancer

AND

Patient encounter during performance period

AND

Two or more encounters at the reporting site AND

Breast Adjuvant Chemotherapy administered:

AND

HER-2/neu positive:

AND

AJCC stage at breast cancer diagnosis = II or III: G9831



OR

AJCC stage at breast cancer diagnosis = I (IA or IB) and T-Stage at breast cancer diagnosis does NOT equal = T1, T1a, T1b

AND NOT

Denominator Exclusions:

Patient transfer to practice after initiation of chemotherapy

**1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

Not applicable

*Exclusions*

**1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

Denominator Exclusions:

o Patient transfer to practice after initiation of chemotherapy

Denominator Exceptions:

o Reason for not administering trastuzumab documented (e.g. patient declined, patient died, patient transferred, contraindication or other clinical exclusion, neoadjuvant chemotherapy or radiation therapy not complete)

**1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

No risk adjustment or risk stratification

*Exclusion Details*

**1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

Denominator Exclusions:

Patient transfer to practice after initiation of chemotherapy

**1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

*Risk Adjustment*

**1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

No risk adjustment or risk stratification

**1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

Not applicable

*Stratification*

**1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

N/A, no risk stratification

**1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

Not applicable

*Type Score*

**1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

Rate/proportion better quality = higher score

**1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

Rate/proportion better quality = higher score

*Algorithm*

**1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

This measure is a proportion with exclusions and exceptions; thus, the calculation algorithm is: Patients meeting the numerator + patients with valid exceptions/ (Patients in the denominator – Patients with valid exclusions) x 100

**1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

Performance is calculated as:

1. Identify those patients that meet the denominator criteria defined in the measure.
2. Subtract those patients with a denominator exclusion from the denominator if applicable.
3. From the patients who qualify for the denominator (after any exclusions are removed), identify those who meet the numerator criteria.
4. Calculation: Numerator/Denominator-Denominator Exclusions

### *Submission items*

#### **1858: Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy**

5.1 Identified measures: 1855 : Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

1857 : HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: N/A - The measure specifications are harmonized.

5b.1 If competing, why superior or rationale for additive value: An environmental scan did not identify competing measures. ASCO believes that NQF 1857 is a complementary measure assessing the inverse of the quality action captured in NQF 1858. Furthermore, because NQF 1857 is endorsed with reserve status and is no longer in use, harmonization is therefore not required. We believe NQF 1855 is a complementary measure assessing HER2 testing, which is an integral component to NQF 1858, and harmonization is not required.

#### **1857: HER2 negative or undocumented breast cancer patients spared treatment with HER2-targeted therapies**

5.1 Identified measures:

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact: Attachment

5b.1 If competing, why superior or rationale for additive value: QOPI\_Adoption\_of\_ICD10\_020916-635933001750874650.docx

## Comparison of NQF #1859 and NQF #1860

1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy

1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies

### *Steward*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

American Society of Clinical Oncology

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

American Society of Clinical Oncology

### *Description*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

Percentage of adult patients (aged 18 and over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies

### *Type*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

Process

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

Process

### *Data Source*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

Paper Medical Records, Registry Data N/A, measure is not instrument-based.

No data collection instrument provided No data dictionary

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

Paper Medical Records, Registry Data N/A, measure is not instrument-based.

No data collection instrument provided No data dictionary

### *Level*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

Clinician : Group/Practice

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

Clinician : Group/Practice

### *Setting*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

Outpatient Services

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

Outpatient Services

### *Numerator Statement*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

RAS (KRAS and NRAS) gene mutation testing performed prior to initiation of anti-EGFR monoclonal antibody therapy

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

Anti-EGFR monoclonal antibody therapy not received

*Numerator Details*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

RAS gene mutation testing = RAS mutation detected

OR

RAS gene mutation testing = No RAS mutation detected (wildtype)

AND

RAS gene mutation testing date

Numerator definitions:

RAS mutation testing - RAS testing for this measure refers to assays that detect mutations in codons 12 and 13 of exon 2, codons 59 and 61 of exon 3 and codons 117 and 146 in exon 4 in KRAS or NRAS. Do not include results from mutations at other codons or assays for other alterations (e.g., BRAF, PI3K, PTEN genes). The College of American Pathologists (CAP) Perspectives on Emerging Technology (POET) Report on RAS mutation testing provides additional guidance on testing.

If multiple RAS mutation tests have been performed, refer to the most recent test results.

In the absence of any documentation regarding testing for the RAS gene mutation, select 'Test not ordered/no documentation.'

Refer to the interpretive report for the RAS test. The report will indicate if a mutation within codons 12 and 13 of exon 2, codons 59 and 61 of exon 3 and codons 117 and 146 in exon 4 in KRAS or NRAS, where KRAS or NRAS gene was detected in the DNA extracted from the colon tumor specimen.

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

Anti-EGFR monoclonal antibody therapy status = No Anti-EGFR monoclonal antibody therapy received

*Denominator Statement*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

Adult patients with metastatic colorectal cancer who receive anti-EGFR monoclonal antibody therapy

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

Adult patients with metastatic colorectal cancer who have a RAS (KRAS or NRAS) gene mutation

*Denominator Details*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

Age at diagnosis greater than or equal to 18 years

AND

2 or more encounters at the reporting site

AND

Initial colon or rectal cancer diagnosis (153.x, 154.0, 154.0, 154.1, 154.8)

AND

Presence of metastatic disease documented

AND

Anti-EGFR monoclonal antibody therapy received

Definitions

Encounter: new patient visit (CPT 99201-99205) or established patient (CPT 99211-99215), not consult (CPT 99241-99245) office consult or inpatient consult CPT 99251-99255)

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

Age at diagnosis greater than or equal to 18 years

AND

2 or more encounters at the reporting site

AND

Initial colon or rectal cancer diagnosis (ICD-10 CM C18.0, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C18.9, C19, C20)

AND

Presence of metastatic disease documented

AND

RAS (KRAS or NRAS) gene mutation detected

Definitions

Encounter = new patient visit (CPT 99201 -99205) or established patient (CPT 99211-99215), not consult (CPT 99241-99245 office consult or inpatient consult CPT 99251-99255)

RAS mutation testing - RAS testing for this measure refers to assays that detect mutations in codons 12 and 13 of exon 2, codons 59 and 61 of exon 3 and codons 117 and 146 in exon 4 in KRAS or NRAS. Do not include results from mutations at other codons or assays for other alterations (e.g., BRAF, PI3K, PTEN genes). The College of American Pathologists (CAP) Perspectives on Emerging Technology (POET) Report on RAS mutation testing provides additional guidance on testing.

If multiple RAS mutation tests have been performed, refer to the most recent test results.

### *Exclusions*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

None

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

None

### *Exclusion Details*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

n/a

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

n/a

### *Risk Adjustment*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

No risk adjustment or risk stratification

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

No risk adjustment or risk stratification



### *Stratification*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

n/a

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

n/a

### *Type Score*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

Rate/proportion better quality = higher score

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

Rate/proportion better quality = higher score

### *Algorithm*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

This measure is a proportion without exclusions. The calculation algorithm is: (Patients meeting the numerator/patients in the denominator) x 100

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

This measure is a proportion without exclusions. The calculation algorithm is: (Patients meeting the numerator/patients in the denominator) x 100

### *Submission items*

**1859: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy**

5.1 Identified measures: 1860 : Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: N/A - The measure specifications are harmonized.

5b.1 If competing, why superior or rationale for additive value: An environmental scan did not identify competing measures. ASCO believes that NQF 1860 is a complementary measure assessing the inverse of the quality action captured in NQF 1859.

**1860: Patients with metastatic colorectal cancer and RAS gene mutation spared treatment with anti-epidermal growth factor receptor monoclonal antibodies**

5.1 Identified measures: 1859 : RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy

5a.1 Are specs completely harmonized? Yes

5a.2 If not completely harmonized, identify difference, rationale, impact: N/A - The measure specifications are harmonized.

5b.1 If competing, why superior or rationale for additive value: An environmental scan did not identify competing measures. ASCO believes that NQF 1859 is a complementary measure assessing the inverse of the quality action captured in NQF 1860.

## **Appendix F: Pre-Evaluation Comments**

No pre-evaluation comments were received.

National Quality Forum  
1099 14th Street NW, Suite 500  
Washington, DC 20005  
<http://www.qualityforum.org>

ISBN [Assigned by Communications]  
©2019 National Quality Forum