



Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to sub criterion 1b).

Brief Measure Information

NQF #: 1859

Corresponding Measures:

De.2. Measure Title: RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy

Co.1.1. Measure Steward: American Society of Clinical Oncology

De.3. Brief Description of Measure: 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

1b.1. Developer Rationale: We envision that use of this measure will improve concordance with recommendations for expanded RAS testing. Evidence now supports testing for NRAS in addition to KRAS mutations. ASCO anticipates a greater performance gap due to the guideline update, which is a relatively new requirement in the field. Clinical trials data show that the benefit of using EGFR inhibitors in treating metastatic colorectal cancer, either as monotherapy or in combination with other treatment regimens, is limited to non-existent in patients with RAS-mutated tumors. These data strongly suggest that patients with RAS mutations are better served with other therapies, especially considering the harms and costs of anti-EGFR treatment.

S.4. Numerator Statement: RAS (KRAS and NRAS) gene mutation testing performed prior to initiation of anti-EGFR monoclonal antibody therapy

S.6. Denominator Statement: Adult patients with metastatic colorectal cancer who receive anti-EGFR monoclonal antibody therapy

S.8. Denominator Exclusions: None

De.1. Measure Type: Process

S.17. Data Source: Paper Medical Records, Registry Data

S.20. Level of Analysis: Clinician : Group/Practice

IF Endorsement Maintenance – Original Endorsement Date: Oct 22, 2012 **Most Recent Endorsement Date:** Jul 31, 2020

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

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

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? n/a

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

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

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form
1859_Evidence_MSF5.0_Data.doc,1859_nqf_evidence_attachment_11.23.19.docx

1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

Yes

1b. Performance Gap

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

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

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

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

We envision that use of this measure will improve concordance with recommendations for expanded RAS testing. Evidence now supports testing for NRAS in addition to KRAS mutations. ASCO anticipates a greater performance gap due to the guideline update, which is a relatively new requirement in the field. Clinical trials data show that the benefit of using EGFR inhibitors in treating metastatic colorectal cancer, either as monotherapy or in combination with other treatment regimens, is limited to non-existent in patients with RAS-mutated tumors. These data strongly suggest that patients with RAS mutations are better served with other therapies, especially considering the harms and costs of anti-EGFR treatment.

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

Testing to identify statistically significant and meaningful differences in performance was conducted using 2017 MIPS performance from registry data provided from CMS. The 2017 data was from 129 providers representing 41 practices and 375 individual patients. Practices were identified by unique number of TINs and individual clinicians were identified by unique number of NPIs. Additional descriptive characteristics of the measured entities, such as size and location type, are unknown. Entities submitted data for inclusion in this data set according to the eligibility and reporting requirements for MIPS 2017 program year. Measures of central tendency, variability and dispersion were calculated. Measures of central tendency, variability and dispersion were calculated. We were unable to determine from our rolled-up data sample the number of clinicians who reported to MIPS as an individual or group; therefore, this measure should be considered for endorsement at the group/practice level, with a potential group size as n of 1 or group of 1.

Data collected from the 2017 MIPS reporting year demonstrates variation and room for improvement: practice mean = 76.1% with a confidence interval (0.65, 0.87); practice minimum = 0%; practice maximum = 100%; practice percent outside confidence interval = 80.49%. For 2017 MIPS reporting, individual clinician mean = 80.67% with a confidence interval (0.75, 0.87); individual clinician minimum = 0%; individual clinician maximum = 100%; individual clinician percent outside confidence interval = 99.22%.

Additional details from the TIN-level analysis are provided below.

Number of unique entities:

Frequency

43

Denominators

Min	Q1	Median	Mean	Q3	Max
1	2	6	11.51	12	82

Measure Distribution:

Min	Q1	Median	Mean	Q3	Max	CI for mean	Percent outside CI
0	0.9902	1	0.9123	1	1	(0.85, 0.98)	95.35

An analysis at the TIN level indicated that while a slight majority (approximately 54%) of practices perform at 100% there are meaningful differences in performance across practices. Multiple practices perform at lower levels with the lowest performance score at 0% and average performance of 76% indicating room for improvement in a significant portion of practices. It should be

noted that small sample size may impact the results presented, as the median denominator is 3, meaning that half of the performance in the graph above are based 3 patients or less.

It should be noted that performance data from MIPS data 2017 does not include data for expanded RAS testing as those changes were implemented in 2018. We do not believe that the measure has been substantively changed in regard to its impact on reliability and validity as the data fields used and the clinical work flow remain the same; however, we do anticipate a greater performance gap due to the guideline update, which is a relatively new requirement in the field.

Data collected in the Fall 2011 QOPI round demonstrates variation and room for improvement, with a range of 33%-100%, mean 73% (N=151 patient records, 18 practices).

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

49%-82% of colorectal tumors have reported overexpression in EGFR (1). Anti-EGFR monoclonal antibodies (cetuximab and panitumumab) inhibit the downstream signaling pathways in EGFR but are effective in only 10-20% of patients with colorectal cancer because of mutations in pathways downstream of EGFR, including RAS mutations (1). Earlier studies and guidelines recommendations included only mutations of KRAS exon 2.

A population-based study using data collected by Surveillance, Epidemiology and End Results (SEER) registries found the overall proportion of KRAS testing was only 22.7% among Stage IV patients with substantial variation by geographic region and patient characteristics (2). They identified wide variation in documented KRAS testing for Stage IV colorectal patients, with rates ranging from 15% in Louisiana to 39% in New Mexico (2). Demographic characteristics associated with higher proportions of KRAS testing included a younger age, white or other race, being married and living in an urban area (2).

Similarly, a 2017 population-based study using 2010-2013 data from the New Mexico Tumor Registry reported KRAS testing was completed in 38.4% of patients and identified age and geographic disparities (3).

Newer evidence is now available to support current guideline recommendations for expanded RAS testing to identify RAS mutations in KRAS exons 2, 3 and 4 and NRAS exons 2, 3 and 4; however, data on guideline adherence is limited as the recommendations were released in 2017. In the AGITG MAX study, 10% of patients with wild-type KRAS exon 2 status had another RAS mutation (4). In the PRIME trial, 17% of patients without KRAS exon 2 mutations had another RAS mutation (5). These populations represent additional opportunity for improvement in the completion of expanded RAS testing for patients with advanced colorectal cancer.

1. NCCN Clinical Practice Guidelines in Oncology™. Colon Cancer, V.3.2019

https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf

2. Charlton, M. E., Karlitz, J. J., Schlichting, J. A., Chen, V. W., & Lynch, C. F. (2017). Factors Associated With Guideline-recommended KRAS Testing in Colorectal Cancer Patients: A Population-based Study. *American journal of clinical oncology*, 40(5), 498–506. doi:10.1097/COC.0000000000000191

3. Greenbaum, A., Wiggins, C., Meisner, A. L., Rojo, M., Kinney, A. Y., & Rajput, A. (2017). KRAS biomarker testing disparities in colorectal cancer patients in New Mexico. *Heliyon*, 3(11), e00448.

4. Price, T. J., Bruhn, M. A., Lee, C. K., Hardingham, J. E., Townsend, A. R., Mann, K. P., ... & GebSKI, V. (2015). Correlation of extended RAS and PIK3CA gene mutation status with outcomes from the phase III AGITG MAX STUDY involving capecitabine alone or in combination with bevacizumab plus or minus mitomycin C in advanced colorectal cancer. *British journal of cancer*, 112(6), 963.

5. Douillard, J. Y., Oliner, K. S., Siena, S., Tabernero, J., Burkes, R., Barugel, M., ... & Rivera, F. (2013). Panitumumab–FOLFOX4 treatment and RAS mutations in colorectal cancer. *New England Journal of Medicine*, 369(11), 1023-1034.

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

While this measure is included in the MIPS program, this program has not yet made disparities data available for ASCO to analyze the report.

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

A population-based study using data collected by Surveillance, Epidemiology and End Results (SEER) registries found the overall proportion of KRAS testing was only 22.7% among Stage IV patients with substantial variation by geographic region and patient characteristics (1). They identified wide variation in documented KRAS testing for Stage IV colorectal patients, with rates ranging from 15% in Louisiana to 39% in New Mexico (1). Demographic characteristics associated with higher proportions of KRAS testing included a younger age, white or other race, being married and living in an urban area (1). Similarly, a 2017 population-based study using 2010-2013 data from the New Mexico Tumor Registry reported KRAS testing was completed in 38.4% of patients and identified age and geographic disparities (2).

Newer evidence is now available to support current guideline recommendations for expanded RAS testing to identify RAS mutations in KRAS exons 2, 3 and 4 and NRAS exons 2, 3 and 4; however, data on guideline adherence is limited as the recommendations were released in 2017. It is expected that the same geographic and demographic characteristics associated with low concordance to KRAS testing are also associated with concordance to expanded RAS testing guidelines.

1.Charlton, M. E., Karlitz, J. J., Schlichting, J. A., Chen, V. W., & Lynch, C. F. (2017). Factors Associated With Guideline-recommended KRAS Testing in Colorectal Cancer Patients: A Population-based Study. American journal of clinical oncology, 40(5), 498–506. doi:10.1097/COC.000000000000191

2.Greenbaum, A., Wiggins, C., Meisner, A. L., Rojo, M., Kinney, A. Y., & Rajput, A. (2017). KRAS biomarker testing disparities in colorectal cancer patients in New Mexico. Heliyon, 3(11), e00448.

2. Reliability and Validity—Scientific Acceptability of Measure Properties

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

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

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

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

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

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

https://qpp.cms.gov/docs/QPP_quality_measure_specifications/CQM-Measures/2019_Measure_451_MIPSCQM.pdf

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

This is not an eMeasure Attachment:

S.2b. Data Dictionary, Code Table, or Value Sets (and risk model codes and coefficients when applicable) must be attached. (Excel or

csv file in the suggested format preferred - if not, contact staff)

No data dictionary Attachment:

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

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

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

Not an instrument-based measure

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

Yes

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

This measure has been expanded to RAS mutational testing based on a guideline update to include NRAS in addition to 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)

This measure is based on an ASCO Guideline:

“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)”.

Sepulveda AR, Hamilton SR, Allegra CJ, et al: Molecular Biomarkers for the Evaluation of Colorectal Cancer: Guideline From the American Society for Clinical Pathology, College of American Pathologists, Association for Molecular Pathology, and the American Society of Clinical Oncology. Journal of Clinical Oncology 35:1453-1486, 2017

Additionally, we removed exclusion for patient transfer to practice after initiation of chemotherapy. We believe this constitutes a non-substantive change.

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

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

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

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

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

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.

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

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

S.7. Denominator Details (All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)

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

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)

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

None

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

n/a

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

n/a

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

No risk adjustment or risk stratification

If other:

S.12. Type of score:

Rate/proportion

If other:

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

Better quality = Higher score

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

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

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

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

Measure is not based on a sample.

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

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

n/a

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

If other, please describe in S.18.

Paper Medical Records, Registry Data

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

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

N/A, measure is not instrument-based.

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

No data collection instrument provided

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

Clinician : Group/Practice

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

Outpatient Services

If other:

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

2. Validity – See attached Measure Testing Submission Form

1859_MeasureTesting_MSf5.0_Data.doc,1859_nqf_testing_attachment_073019_FINAL-637001802906265569.docx

2.1 For maintenance of endorsement

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

Yes

2.2 For maintenance of endorsement

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

Yes

2.3 For maintenance of endorsement

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

No - This measure is not risk-adjusted

3. Feasibility

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

3a. Byproduct of Care Processes

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

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

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

If other:

3b. Electronic Sources

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

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

Some data elements are in defined fields in electronic sources

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

All data elements needed for this measure are collected through electronic data or using keyword searches. ASCO is in the process of assessing the feasibility of developing an electronic clinical quality measure.

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

Attachment:

3c. Data Collection Strategy

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

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

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

Apart from the lack of availability of disparities data for analysis, we have not identified any areas of concern or made any modifications as a result of testing and operational use of this measure in relation to data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, or other feasibility issues unless otherwise noted.

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

ASCO requests interested parties seek a licensing agreement prior to commercial use of this measure.

4. Usability and Use

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

4a. Accountability and Transparency

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

4.1. Current and Planned Use

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

Specific Plan for Use	Current Use (for current use provide URL)
Public Reporting	<p>Payment Program Merit-Based Incentive Payment System (MIPS) Program https://qpp.cms.gov/mips/quality-measures ASCO Qualified Clinical Data Registry https://practice.asco.org/sites/default/files/drupalfiles/QCDR-2019-Measure-Summary.pdf</p> <p>Professional Certification or Recognition Program QOPI® Certification Program https://practice.asco.org/quality-improvement/quality-programs/quality-oncology-practice-initiative/qopi-related-measures</p> <p>Quality Improvement (external benchmarking to organizations) Quality Oncology Practice Initiative (QOPI®) https://practice.asco.org/quality-improvement/quality-programs/quality-oncology-practice-initiative/qopi-related-measures</p> <p>Quality Improvement (Internal to the specific organization) Quality Oncology Practice Initiative (QOPI®) https://practice.asco.org/quality-improvement/quality-programs/quality-oncology-practice-initiative/qopi-related-measures</p>

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

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

Merit-based Incentive Payment System (MIPS) reporting program, Center for Medicare and Medicaid Services

Prior to 2016, this measure was used for Eligible Providers (EPs) in the Physician Quality Reporting System (PQRS). As of 2017, MIPS replaced the PQRS program. MIPS is a national performance-based payment program that uses performance scores across several categories to determine payment rates for EPs. MIPS takes a comprehensive approach to payment by basing consideration of quality on a set of evidence-based measures that were primarily developed by clinicians, thus encouraging improvement in clinical practice and supporting advances in technology that allow for easy exchange of information. Data on geographic area and number and percentage of accountable entities and patients, including level of measurement and setting, are unavailable for analysis.

Quality Oncology Practice Initiative (QOPI®)

In 2002, the American Society of Clinical Oncology established the Quality Oncology Practice Initiative (QOPI®). QOPI® is an oncologist-led, practice-based quality assessment and improvement program designed to promote excellence in cancer care by helping practices create a culture of self-examination and improvement. QOPI provides a standard methodology, robust library of quality metrics for oncology, and a collection tool to reliably and routinely assess care, inform quality improvement activities, and demonstrate quality to patients and external stakeholders. Collection rounds are offered twice per year, in spring and fall, for an eight-week period. QOPI® continues to be a successful program in the United States and 7 other countries, with 265, 213, 257 and 209 unique practices participating in Round 2 2017, Round 1 2018, Round 2 2018 and Round 1 2019 respectively.

QOPI® Qualified Clinical Data Registry

In addition to the current use for quality improvement with benchmarking in the QOPI® registry, this measure has been reported to CMS by the registry as a Qualified Clinical Data Registry. QOPI® was deemed as a registry for oncology measures group reporting and as a QCDR to report to PQRS in 2015 and 2016 and to report to MIPS in 2017, 2018 and 2019. Eligible professionals will be considered to have satisfactorily participated in MIPS if they submit quality measures data or results to CMS via a qualified clinical data registry. In 2017 and 2018, a total of 19 practices representing approximately 50,000 patient charts submitted to MIPS through QOPI. CMS has implemented a phased approach to public reporting performance information on the Physician Compare website.

QOPI® Certification Program

The QOPI® Certification Program provides a three-year certification for outpatient hematology-oncology practices. To obtain Certification, a practice must achieve an aggregate score above 75% adherence on 26 measures that count toward the overall Quality Score. Please see a description of the QOPI® program above for details.

Core Quality Measure Collaborative's (CQMC) Medical Oncology Core Measure Set

This measure has also been included in the Core Quality Measure Collaborative's (CQMC) Medical Oncology Core Measure Set. The CQMC is a broad-based coalition of health care leaders convened by America's Health Insurance Plans (AHIP) starting in 2015. The purpose of this program is to reduce variability in measure selection, specifications and implementation. The CQMC defines a core measure set as a parsimonious group of scientifically sound measures that efficiently promote a patient-centered assessment of quality and should be prioritized for adoption in value-based purchasing and APMs. The CQMC has developed and released core sets of quality measures that could be implemented across both commercial and government payers. The measures have been implemented nationally by private health plans using a phased-in approach. Contracts between physicians and private payers are individually negotiated and therefore come up for renewal at different points in time depending on the duration of the contract. It is anticipated that private payers will implement these core sets of measures as and when contracts come up for renewal or if existing contracts allow modification of the performance measure set. CMS is also working to align measures across public program.

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

This measure is currently used for multiple accountability applications and public reporting is forthcoming. According to the CY 2019 Quality Payment Program final rule, Physician Compare has continued to pursue a phased approach to public reporting under MACRA. CMS intends to make all measures under MIPS quality performance category available for public reporting on Physician Compare. These measures include those reported via all available submission methods for MIPS-eligible clinicians and groups. Because this measure has been in use for at least one year and meets the minimum sample size requirement for reliability, this

measure meets criteria for public reporting but has not yet been included in Physician Compare.

As described above, CMS is also planning to publicly report QCDR data. Additionally, although the measure is currently in use, we will continue to seek opportunities to advocate for expanded use of this measure in government or other programs.

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

Despite not yet being included in Physician Compare, this measure meets criteria for public reporting because it has been in use for at least one year and meets the minimum sample size requirement for reliability, this measure meets criteria for public reporting.

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

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

ASCO's measure development process is rigorous, evidence-based, and utilizes the clinical expertise of multiple standing multi-disciplinary Technical Expert Panels (TEPs) dedicated to development and maintenance of measures across the cancer continuum. During measure maintenance, TEP members are provided with full measure specifications, applicable evidence, historical measure performance data, and any external feedback or requests for clarification or updates that have been received for the measure.

Staff on ASCO's measure development team are available to receive comments and questions from measure implementers and clinicians reporting the measures. As comments and questions are received, they are shared with appropriate staff for follow up. If comments or questions require expert input, these are shared with ASCO's TEPs to determine if measure modifications may be warranted. Additionally, for ASCO measures included in federal reporting programs, there is a system that has been established to elicit timely feedback and responses from ASCO staff in consultation with TEP members, as appropriate.

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

See description in 4a2.1.1 above.

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

Describe how feedback was obtained.

In addition to the feedback obtained from a multi-disciplinary technical expert panel during the measure development and maintenance process, ASCO obtains feedback and receives measure inquiries from implementers and reporters via email. No specific feedback has been received by ASCO on this measure.

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

No specific feedback has been received by ASCO on this measure. However, we will continue to solicit feedback from MIPS users, and from the general public as we perform maintenance on this measure.

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

No additional feedback has been received by ASCO on this measure. However, we will continue to solicit feedback as we perform maintenance on this measure.

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

As stated in 4a2.2, ASCO did not receive specific feedback on this measure; therefore, ASCO's TEP did not consider external feedback from those being measured during revision of measure specifications or implementation.

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use

for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

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

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

An analysis of MIPS data from 2017 at the TIN level indicated that while a slight majority (approximately 54%) of practices perform at 100% there are meaningful differences in performance across practices. Multiple practices perform at lower levels with the lowest performance score at 0% and average performance of 76% indicating room for improvement in a significant portion of practices. It should be noted that small sample size may impact the results presented, as the median denominator is 3, meaning that half of the performance in the graph above are based 3 patients or less.

Performance data from MIPS data 2017 does not include data for expanded RAS testing as those changes were implemented in 2018. We do not believe that the measure has been substantively changed in regard to its impact on reliability and validity as the data fields used and the clinical work flow remain the same; however, we do anticipate a greater performance gap due to the guideline update, which is a relatively new requirement in the field.

4b2. Unintended Consequences

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

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

At this time, we are not aware of any unintended consequences related to this measure. We take unintended consequences very seriously and therefore continuously monitor to identify actions that can be taken to mitigate them.

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

We have not observed any unexpected benefits associated with implementation of this measure.

5. Comparison to Related or Competing Measures

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

5. Relation to Other NQF-endorsed Measures

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

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

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

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

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications harmonized to the extent possible?

Yes

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

N/A - The measure specifications are harmonized.

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

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.

Appendix

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

No appendix Attachment:

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): American Society of Clinical Oncology

Co.2 Point of Contact: Angela, Kennedy, Angela.Kennedy@asco.org, 571-483-1656-

Co.3 Measure Developer if different from Measure Steward: American Society of Clinical Oncology

Co.4 Point of Contact: Angela, Kennedy, Angela.Kennedy@asco.org

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

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

ASCO's Gastrointestinal Technical Expert Panel (TEP) is a standing multi-disciplinary panel responsible for maintenance and de novo development of ASCO gastrointestinal measures. TEP members provide clinical expertise and guidance on measure concepts, level and quality of evidence, and measure specifications.

The current TEP roster is as follows:

David Ryan, MD (Chair), Massachusetts General Hospital

Nancy Baxter, MD, FRCSC, FACS, PhD, St. Michael's Hospital, University of Toronto

Emily Bergsland, MD, University of California, San Francisco

Jordan Berlin, MD, FASCO, Vanderbilt-Ingram Cancer Center

Philip Gold, MD, Swedish Cancer Institute

Theodore Hong, MD, Massachusetts General Hospital

Najjia Mahmoud, MD, University of Pennsylvania

Kim-Son Nguyen, MD, MPA, Palo Alto Medical Foundation / Sutter Health

#1859 RAS gene mutation testing performed for patients with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy, Last Updated: Jul 31, 2020

Dan Zuckerman, MD, FASCO, St. Luke's Mountain States Tumor Institute

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2009

Ad.3 Month and Year of most recent revision: 07, 2019

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

Ad.5 When is the next scheduled review/update for this measure? 07, 2020

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Ad.7 Disclaimers: See copyright statement in Ad.6 above.

Ad.8 Additional Information/Comments: