Measure #452 (NQF 1860): Patients with Metastatic Colorectal Cancer and KRAS Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies – National Quality Strategy Domain: Patient Safety

2017 OPTIONS FOR INDIVIDUAL MEASURES:
REGISTRY ONLY

MEASURE TYPE:
Process

DESCRIPTION:
Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and KRAS gene mutation spared treatment with anti-EGFR monoclonal antibodies

INSTRUCTIONS:
This measure is to be reported once per **performance period** for patients with colorectal cancer seen during the performance period. The most recent quality-data code submitted will be used for performance calculation. This measure may be reported by eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

Measure Reporting:
The listed denominator criteria is used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions allowed by the measure. The quality-data codes listed do not need to be submitted for registry-based submissions; however, these codes may be submitted for those registries that utilize claims data.

DENOMINATOR:
Adult patients with metastatic colorectal cancer who have a KRAS gene mutation

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

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

Denominator Criteria (Eligible Cases):
Patients aged ≥ 18 years on date of encounter
AND
Diagnosis of colon or rectal cancer (ICD-10 CM): C18.0, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C18.9, C19, C20
AND
Patient encounter during the **performance period**: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215
AND
Two or more encounters at the reporting site
AND
Patient has metastatic disease at diagnosis: G9842
AND
KRAS gene mutation: G9843

NUMERATOR:
Anti-EGFR monoclonal antibody therapy not received

Definition:
Anti-EGFR monoclonal antibody- cetuximab or panitumumab

Numerator Options:

Performance met:	Patient did not receive anti-EGFR monoclonal antibody therapy (G9844)

OR

Performance Not Met:	Patient received anti-EGFR monoclonal antibody therapy (G9845)

RATIONALE:
The American Society of Clinical Oncology (ASCO) envisions that use of this measure will improve concordance with recommendations for KRAS testing for patients with metastatic colorectal cancer. We recognize the importance of ensuring that the appropriate patient population receives guideline concordant treatment as studies demonstrate that the administration of EGFR-targeted therapies, specifically cetuximab or panitumumab, offer no clinical benefit to patients diagnosed with KRAS-mutated tumors. Clinical trial data strongly suggest that patients with KRAS mutations are better served with other targeted therapies, especially considering the harms and costs of anti-EGFR treatment. Therefore, the measure focus is on halting use of anti-EGFR MoAb therapies in patients who will not derive any benefit.

CLINICAL RECOMMENDATION STATEMENTS:
This measure is based on an ASCO Provisional Clinical Opinion:

"Based on systematic reviews of the relevant literature, all patients with metastatic colorectal carcinoma who are candidates for anti-EGFR antibody therapy should have their tumor tested for KRAS mutations in a CLIA-accredited laboratory. If KRAS mutation in codon 12 or 13 is detected, then patients with metastatic colorectal carcinoma should not receive anti-EGFR antibody therapy as part of their treatment."

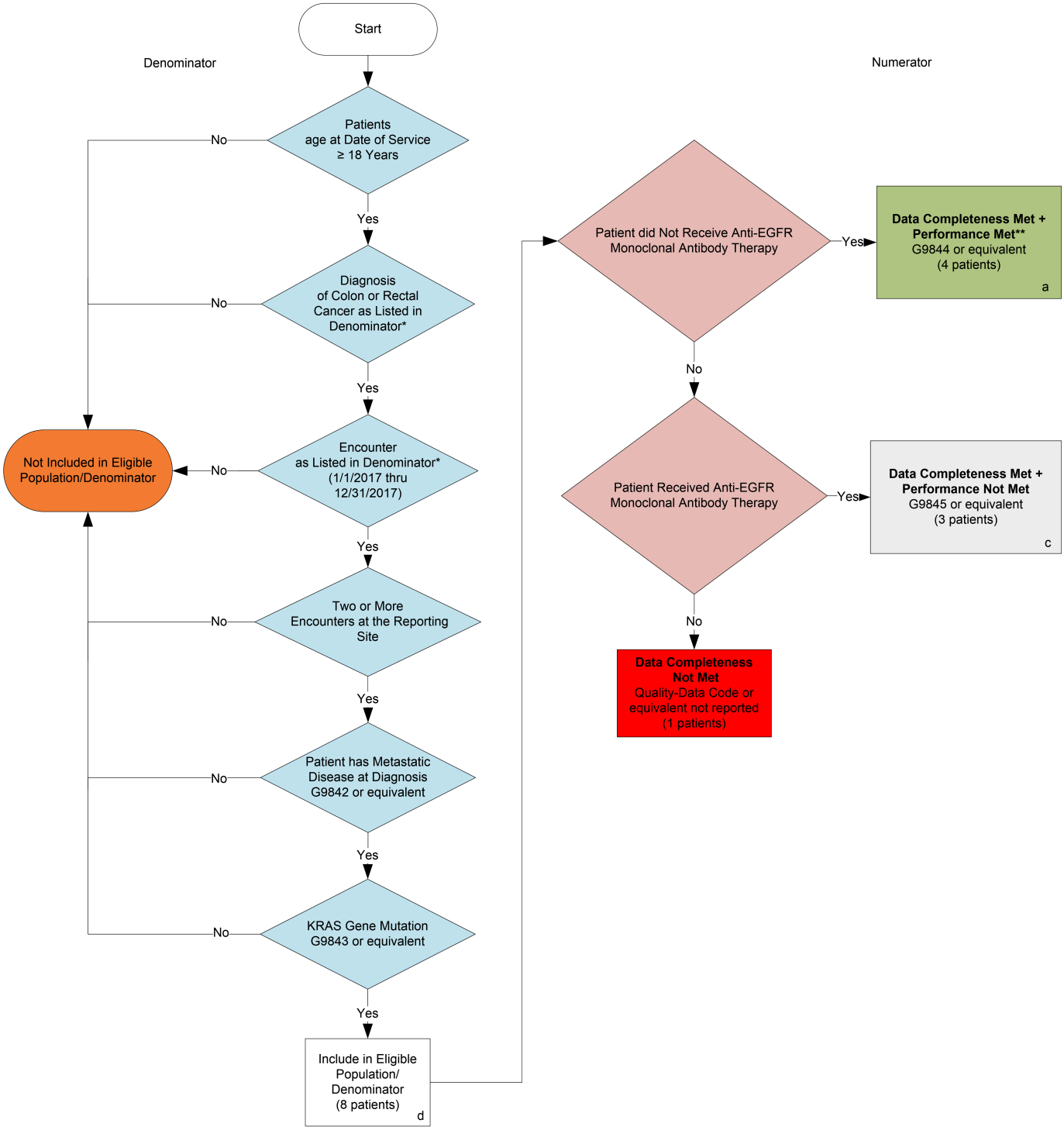
Allegra, CJ et al. American Society of Clinical Oncology Provisional Clinical Opinion: Testing for KRAS Gene Mutations in Patients With Metastatic Colorectal Carcinoma to Predict Response to Anti–Epidermal Growth Factor Receptor Monoclonal Antibody Therapy. Journal of Clinical Oncology 2009, 27(12): 2091.

ASCO published an update to the Provisional Clinical Opinion in 2015 and this measure is currently under review to address expanded RAS gene mutation testing in metastatic colorectal carcinoma. Future versions of this measure will be updated to include NRAS mutations in addition to KRAS mutations.

"*RAS* mutational testing of colorectal carcinoma tissue should be performed in a Clinical Laboratory Improvement Amendments–certified laboratory for all patients who are being considered for anti-EGFR MoAb therapy. Mutational analysis should include *KRAS* and *NRAS* codons 12 and 13 of exon 2; 59 and 61 of exon 3; and 117 and 146 of exon 4. The weight of current evidence indicates that anti-EGFR MoAb therapy (currently cetuximab and panitumumab) should only be considered for treatment of patients with mCRC who are identified as having tumors with no mutations detected after such extended *RAS* mutation analysis."

Allegra CJ, Rumble RB, Hamilton SR, Mangu PB, Roach N, Hantel A, et al. Extended RAS gene mutation testing in metastatic colorectal carcinoma to predict response to anti-epidermal growth factor receptor monoclonal antibody therapy: American Society of Clinical Oncology Provisional Clinical Opinion Update 2015. J Clin Oncol 2015;34:179–85.

2017 Registry Individual Measure Flow
#452 NQF #1860: Patients with Metastatic Colorectal Cancer and KRAS Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies



*See the posted Measure Specification for specific coding and instructions to report this measure.
NOTE: Reporting Frequency – Patient-process

v1

2017 Registry Individual Measure Flow
#452 NQF #1860: Patients with Metastatic Colorectal Cancer and KRAS Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies

SAMPLE CALCULATIONS:

Data Completeness=

Performance Met (a =4 patients) + Performance Not Met (c=3 patients) = 7 patients = **87.50%**
Eligible Population / Denominator (d=8 patients) = 8 patients

Performance Rate=**

Performance Met (a = 4 patients) = 4 patients = **57.14%**
Data Completeness Numerator (7 patients) = 7 patients

*See the posted Measure Specification for specific coding and instructions to report this measure.
NOTE: Reporting Frequency – Patient-process

v1

2017 Registry Individual Measure Flow

#452 NQF #1860: Patients with Metastatic Colorectal Cancer and KRAS Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies

Please refer to the specific section of the Measure Specification to identify the denominator and numerator information for use in reporting this Individual Measure.

1. Start with Denominator
2. Check Patient Age:
    a. If Patient age is greater than or equal to 18 years equals No, do not include in Eligible Patient Population. Stop Processing.
    b. If Patient age is greater than or equal to 18 years equals Yes, proceed to check Patient Diagnosis for Colon or Rectal Cancer.
3. Check Patient Diagnosis:
    a. If Diagnosis of Colon or Rectal Cancer as Listed in the Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
    b. If Diagnosis of Colon or Rectal Cancer as Listed in the Denominator equals Yes, proceed to check Encounter Performed.
4. Check Encounter Performed:
    a. If Encounter Performed as Listed in the Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
    b. If Encounter Performed as Listed in the Denominator equals Yes, proceed to check Presence of Metastatic Disease Documented.
5. Check Encounter Performed:
    a. If Two or more Encounters at the Reporting Site equals No, do not include in Eligible Patient Population. Stop Processing.
    b. If Two or more Encounters at the Reporting Site equals Yes, proceed to check Patient has Metastatic Disease at Diagnosis.
6. Check Patient has Metastatic Disease at Diagnosis:
    a. If Patient has Metastatic Disease at Diagnosis equals No, do not include in Eligible Patient Population. Stop Processing.
    b. If Patient has Metastatic Disease at Diagnosis equals Yes, proceed to check KRAS Gene Mutation.
7. Check KRAS Gene Mutation:
    a. If KRAS Gene Mutation equals No, do not include in Eligible Patient Population. Stop Processing.
    b. If KRAS Gene Mutation equals Yes, proceed to check included in Eligible Population.

8. Denominator Population:

    a. Denominator population is all Eligible Patients in the denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d equals 8 patients in the sample calculation.

9. Start Numerator

10. Check Patient did not Receive Anti-EGFR Monoclonal Antibody Therapy:

    a. If Patient did not Receive Anti-EGFR Monoclonal Antibody Therapy equals Yes, include in Data Completeness Met and Performance Met.

    b. Data Completeness Met and Performance Met letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a equals 4 patients in Sample Calculation.

    c. If Patient did not Receive Anti-EGFR Monoclonal Antibody Therapy equals No, proceed to Patient Received Anti-EGFR Monoclonal Antibody Therapy.

11. Check Patient Received Anti-EGFR Monoclonal Antibody Therapy:

    a. If Patient Received Anti-EGFR Monoclonal Antibody Therapy equals Yes, include in Data Completeness Met and Performance Not Met.

    b. Data Completeness Met and Performance Not Met letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c equals 3 patients in the Sample Calculation.

    c. If Patient Received Anti-EGFR Monoclonal Antibody Therapy equals No, proceed to Data Completeness Not Met.

12. Check Data Completeness Not Met:

    a. If Data Completeness Not Met equals No, Quality Data Code or equivalent not reported. 1 patient has been subtracted from the Data Completeness numerator in the sample calculation.

SAMPLE CALCULATIONS:

Data Completeness=

Performance Met (a =4 patients) + Performance Not Met (c=3 patients) = 7 patients = **87.50%**
Eligible Population / Denominator (d=8 patients) = 8 patients

Performance Rate=**

Performance Met (a = 4 patients) = 4 patients = **57.14%**
Data Completeness Numerator (7 patients) = 7 patients