Quality ID #452 (NQF 1860): Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies
– National Quality Strategy Domain: Patient Safety
– Meaningful Measure Area: Appropriate Use of Healthcare

2020 COLLECTION TYPE:
MIPS CLINICAL QUALITY MEASURES (CQMS)

MEASURE TYPE:
Process – High Priority

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

INSTRUCTIONS:
This measure is to be submitted **once per performance period** for patients with colorectal cancer seen during the performance period. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

Measure Submission Type:
Measure data may be submitted by individual MIPS eligible clinicians, groups, or third-party intermediaries. The listed denominator criteria are used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions as allowed by the measure. The quality-data codes listed do not need to be submitted by MIPS eligible clinicians, groups, or third-party intermediaries that utilize this modality for submissions; however, these codes may be submitted for those third-party intermediaries that utilize Medicare Part B claims data. For more information regarding Application Programming Interface (API), please refer to the Quality Payment Program (QPP) website.

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

Definition:
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 or 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.

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 (CPT): 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
RAS (KRAS or NRAS) 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 RAS 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 RAS-mutated tumors. Clinical trial data strongly suggest that patients with KRAS or NRAS 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:
ASCO published a Guideline in 2017 as an update to the 2015 Provisional Clinical Opinion. This measure has been modified according to the Guideline and Provisional Clinical Opinion to address expanded RAS gene mutation testing in metastatic colorectal carcinoma by extending to additional KRAS mutations and expanding to include NRAS mutations.

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

This measure is also based on an ASCO Provisional Clinical Opinion:

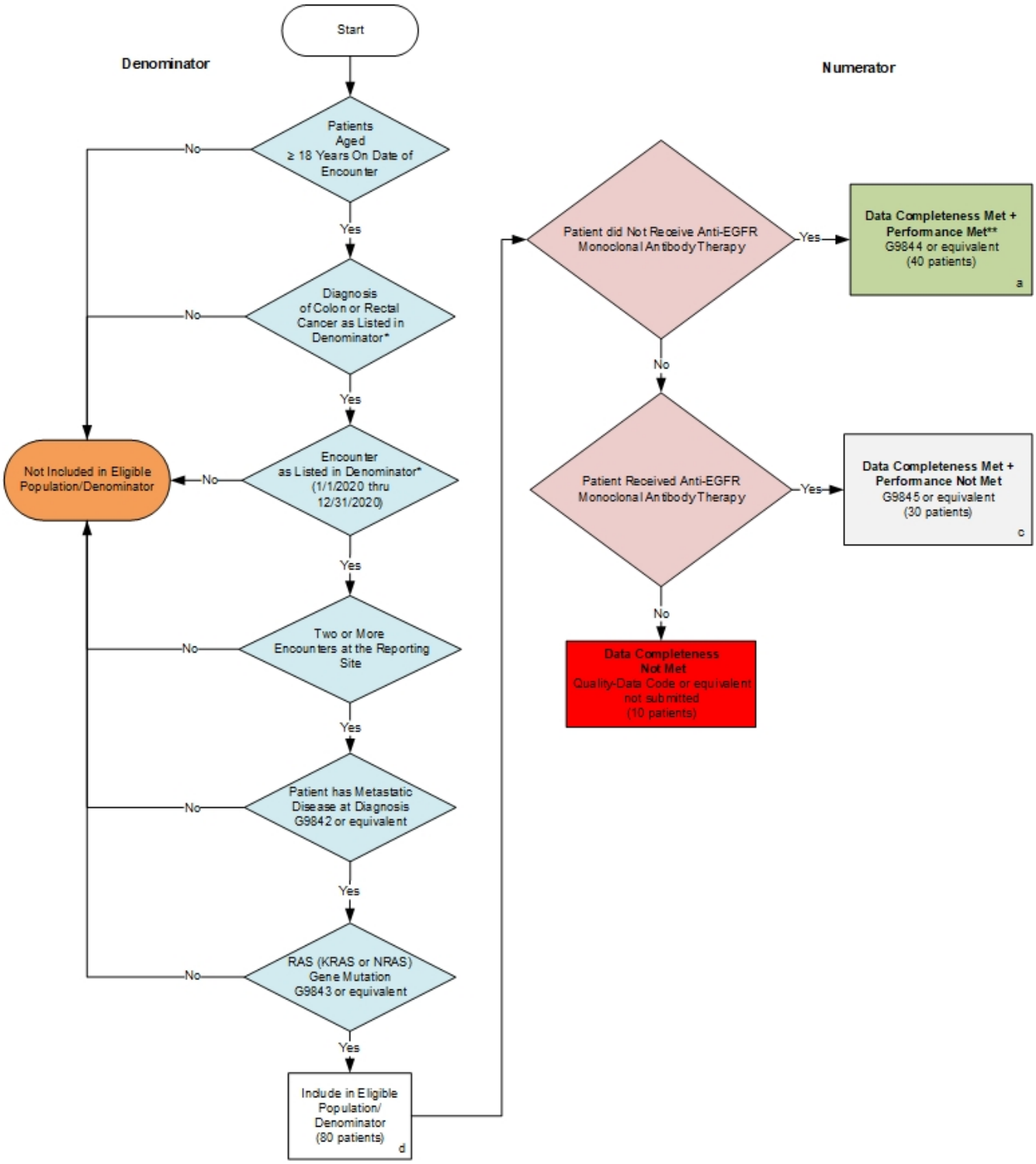
"*RAS* mutational testing of colorectal carcinoma tissue should be performed in a Clinical Laboratory Improvement Amendments–certified laboratory for all patients who are being considered for anti-EGFR MoAb therapy. Mutational analysis should include *KRAS* and *NRAS* codons 12 and 13 of exon 2; 59 and 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.

2020 Clinical Quality Measure Flow for Quality ID #452 NQF #1860: Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies

Disclaimer: *Refer to the measure specification for specific coding and instructions to submit this measure.*



SAMPLE CALCULATIONS:

Data Completeness=

Performance Met (a=40 patients) + Performance Not Met (c=30 patients) = 70 patients = **87.50%**

Eligible Population / Denominator (d=80 patients) = 80 patients

Performance Rate=

Performance Met (a=40 patients) = 40 patients = **57.14%**

Data Completeness Numerator (70 patients) = 70 patients

*See the posted measure specification for specific coding and instructions to submit this measure.

NOTE: Submission Frequency: Patient-Process

v4

2020 Clinical Quality Measure Flow Narrative for Quality ID #452 NQF #1860: Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies

Disclaimer: *Refer to the measure specification for specific coding and instructions to submit this 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 Population. Stop Processing.
    b. If Patient Age is greater than or equal to 18 Years equals Yes, proceed to check Patient Diagnosis.
3. Check Patient Diagnosis:
    a. If Diagnosis of Colon or Rectal Cancer as Listed in the Denominator equals No, do not include in Eligible 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 as Listed in the Denominator equals No, do not include in Eligible Population. Stop Processing.
    b. If Encounter as Listed in the Denominator equals Yes, proceed to check Two or More Encounters at the Reporting Site.
5. Check Two or More Encounters at the Reporting Site:
    a. If Two or More Encounters at the Reporting Site equals No, do not include in Eligible 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 Population. Stop Processing.
    b. If Patient has Metastatic Disease at Diagnosis equals Yes, proceed to check RAS (KRAS or NRAS) Gene Mutation.
7. Check RAS (KRAS or NRAS) Gene Mutation:
    a. If RAS (KRAS or NRAS) Gene Mutation equals No, do not include in Eligible Population. Stop Processing.
    b. If RAS (KRAS or NRAS) Gene Mutation equals Yes, include 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 80 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 40 patients in the Sample Calculation.

    c. If Patient did not Receive Anti-EGFR Monoclonal Antibody Therapy equals No, proceed to check 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 30 patients in the Sample Calculation.

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

12. Check Data Completeness Not Met:

    a. If Data Completeness Not Met, the Quality Data Code or equivalent was not submitted. 10 patients have been subtracted from the Data Completeness Numerator in the Sample Calculation.

SAMPLE CALCULATIONS:

Data Completeness=

Performance Met (a=40 patients) + Performance Not Met (c=30 patients) = 70 patients = **87.50%**

Eligible Population / Denominator (d=80 patients) = 80 patients

Performance Rate=

Performance Met (a=40 patients) = 40 patients = **57.14%**

Data Completeness Numerator (70 patients) = 70 patients