Quality ID #451 (NQF 1859): RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy
– National Quality Strategy Domain: Effective Clinical Care
– Meaningful Measure Area: Appropriate Use of Healthcare

2020 COLLECTION TYPE:
MIPS CLINICAL QUALITY MEASURES (CQMS)

MEASURE TYPE:
Process

DESCRIPTION:
Percentage of adult patients (aged 18 or 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

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 receive anti-EGFR monoclonal antibody therapy

Denominator Criteria (Eligible Cases):
Patients aged ≥ 18 years on date of encounter
AND
Diagnosis of initial 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: G9838
AND
Anti-EGFR monoclonal antibody therapy: G9839

NUMERATOR:
RAS (KRAS and NRAS) gene mutation testing performed before initiation of anti-EGFR MoAb

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 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.

Anti-EGFR monoclonal antibody includes cetuximab or panitumumab.

Numerator Instructions:
In the absence of any documentation regarding testing for the RAS (KRAS and NRAS) gene mutation, submit **G9841**: RAS (KRAS and NRAS) gene mutation testing not performed before initiation of anti-EGFR MoAb. Report **G9840**: RAS (KRAS and NRAS) gene mutation testing performed before initiation of anti-EGFR MoAb, if the report indicates 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.

Numerator Options:

Performance Met:	RAS (KRAS and NRAS) gene mutation testing performed before initiation of anti-EGFR MoAb **(G9840)**
OR	
Performance Not Met:	RAS (KRAS and NRAS) gene mutation testing not performed before initiation of anti-EGFR MoAb **(G9841)**

RATIONALE:
The American Society of Clinical Oncology (ASCO) envisions that use of this measure will improve concordance with recommendations for RAS (KRAS and NRAS) 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 or NRAS-mutated tumors. Clinical trial data strongly suggest that patients with RAS 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 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.

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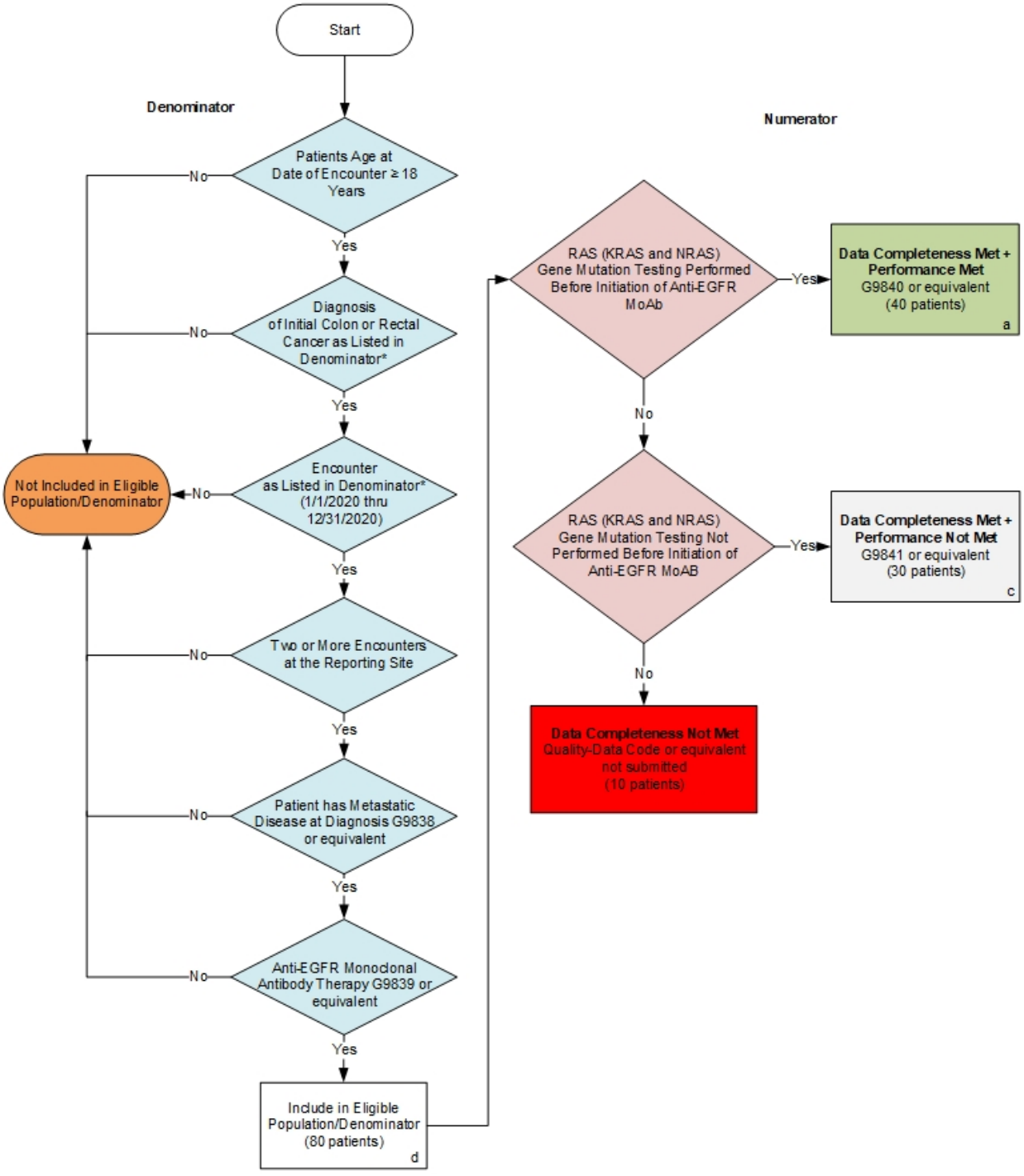
2020 Clinical Quality Measure Flow for Quality ID #451 NQF #1859:
RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy

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

2020 Clinical Quality Measure Flow Narrative for Quality ID #451 NQF #1859: RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy

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 at date of Encounter is greater than or equal to 18 Years equals No, do not include in Eligible Population. Stop Processing.
    b. If Patient Age at date of Encounter 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 Anti-EGFR Monoclonal Antibody Therapy.
7. Check Anti-EGFR Monoclonal Antibody Therapy:
    a. If Anti-EGFR Monoclonal Antibody Therapy equals No, do not include in Eligible Population. Stop Processing.
    b. If Anti-EGFR Monoclonal Antibody Therapy 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 RAS (KRAS and NRAS) Gene Mutation Testing Performed before Initiation of Anti-EGFR MoAb:

    a. If RAS (KRAS and NRAS) Gene Mutation Testing Performed before Initiation of Anti-EGFR MoAb 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 Sample Calculation.

    c. If RAS (KRAS and NRAS) Gene Mutation Testing Performed before Initiation of Anti-EGFR MoAb equals No, proceed to check RAS (KRAS and NRAS) Gene Mutation Testing Not Performed Before Initiation of Anti-EGFR MoAb.

11. Check RAS (KRAS and NRAS) Gene Mutation Testing Not Performed Before Initiation of Anti-EGFR MoAb:

    a. If RAS (KRAS and NRAS) Gene Mutation Testing Not Performed Before Initiation of Anti-EGFR MoAb 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 RAS (KRAS and NRAS) Gene Mutation Testing Not Performed Before Initiation of Anti-EGFR MoAb 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) / Eligible Population / Denominator (d=80 patients) = 70 patients / 80 patients = **87.50%**

Performance Rate=

Performance Met (a=40 patients) / Data Completeness Numerator (70 patients) = 40 patients / 70 patients = **57.14%**