

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

2021 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 \geq 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): 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215

WITHOUT

Telehealth Modifier: GQ, GT, 95, POS 02

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:

This measure is based on ASCO and NCCN Guidelines:

“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

“All patients with metastatic colorectal cancer should have tumor tissue genotyped for RAS (KRAS and NRAS) and BRAF mutations individually or as part of a next-generation sequencing (NGS) panel. Patients with any known KRAS mutation (exon 2, 3, 4) or NRAS mutation (exon 2, 3, 4) should not be treated with either cetuximab or panitumumab.”

“A sizeable body of literature has shown that tumors with a mutation in codon 12 or 13 of exon 2 of the KRAS gene are essentially insensitive to cetuximab or panitumumab therapy... More recent evidence shows mutations in KRAS outside of exon 2 and mutations in NRAS are also predictive for a lack of benefit of anti-EGFR therapies.

The panel therefore strongly recommends RAS (KRAS/NRAS) genotyping of tumor tissue (either primary tumor or metastasis) in all patients with metastatic colorectal cancer. Patients with known KRAS or NRAS mutations should not be

treated with either cetuximab or panitumumab, either alone or in combination with other anticancer agents, because they have virtually no chance of benefit and the exposure to toxicity and expense cannot be justified. It is implied throughout the guidelines that NCCN recommendations involving cetuximab or panitumumab relate only to patients with disease characterized by RAS wild-type genes. ASCO released a Provisional Clinical Opinion Update on extended RAS testing in patients with metastatic colorectal cancer that is consistent with the NCCN Panel's recommendations. A guideline on molecular biomarkers for colorectal cancer developed by the ASCP, CAP, AMP and ASCO also recommends RAS testing consistent with the NCCN recommendations" (MS-43)

NCCN Clinical Practice Guidelines in Oncology™. Colon Cancer, V.3.2019 (MS-30)

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

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**2021 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=

$$\frac{\text{Performance Met (a=40 patients)} + \text{Performance Not Met (c=30 patients)}}{\text{Eligible Population / Denominator (d=80 patients)}} = \frac{70 \text{ patients}}{80 \text{ patients}} = 87.50\%$$

Performance Rate=

$$\frac{\text{Performance Met (a=40 patients)}}{\text{Data Completeness Numerator (70 patients)}} = \frac{40 \text{ patients}}{70 \text{ patients}} = 57.14\%$$

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

NOTE: Submission Frequency: Patient-Process

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**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 aged greater than or equal to 18 years on date of encounter*:
 - a. If *Patient aged greater than or equal to 18 years on date of encounter* equals No, do not include in *Eligible Population/Denominator*. Stop Processing.
 - b. If *Patient aged greater than or equal to 18 years on date of encounter* equals Yes, proceed to check *Diagnosis of colon or rectal cancer as listed in Denominator**.
3. Check *Diagnosis of colon or rectal cancer as listed in Denominator**:
 - a. If *Diagnosis of colon or rectal cancer as listed in Denominator** equals No, do not include in *Eligible Population/Denominator*. Stop Processing.
 - b. If *Diagnosis of colon or rectal cancer as listed in Denominator** equals Yes, proceed to check *Patient encounter during the performance period as listed in Denominator**.
4. Check *Patient encounter during the performance period as listed in Denominator**:
 - a. If *Patient encounter during the performance period as listed in Denominator** equals No, do not include in *Eligible Population/Denominator*. Stop Processing.
 - b. *Patient encounter during the performance period as listed in Denominator** equals Yes, proceed to check *Telehealth Modifier*.
5. Check *Telehealth Modifier*:
 - a. If *Telehealth Modifier* equals No, do not include in *Eligible Population/Denominator*. Stop Processing.
 - b. If *Telehealth Modifier* equals Yes, proceed to check *Two or more encounters at the reporting site*.
6. 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/Denominator*. Stop Processing.
 - b. If *Two or more encounters at the reporting site* equals Yes, proceed to check *Patient has metastatic disease at diagnosis*.
7. Check *Patient has metastatic disease at diagnosis*:
 - a. If *Patient has metastatic disease at diagnosis* equals No, do not include in *Eligible Population/Denominator*. Stop Processing.
 - b. If *Patient has metastatic disease at diagnosis* equals Yes, proceed to check *RAS (KRAS or NRAS) gene mutation*.

8. Check *RAS (KRAS or NRAS) gene mutation*.
 - a. If *RAS (KRAS or NRAS) gene mutation* equals No, do not include in *Eligible Population/Denominator*. Stop Processing.
 - b. If *RAS (KRAS or NRAS) gene mutation* equals Yes, include in *Eligible Population/Denominator*.
9. 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.
10. Start Numerator
11. 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*.
 - *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.
 - b. If *Patient did not receive anti-EGFR monoclonal antibody therapy* equals No, proceed to check *Patient received anti-EGFR monoclonal antibody therapy*.
12. 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*.
 - *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.
 - b. If *Patient received anti-EGFR monoclonal antibody therapy* equals No, proceed to check *Data Completeness Not Met*.
13. 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 equals Performance Met (a equals 40 patients) plus Performance Not Met (c equals 30 patients) divided by Eligible Population / Denominator (d equals 80 patients). All equals 70 patients divided by 80 patients. All equals 87.50 percent.

Performance Rate equals Performance Met (a equals 40 patients) divided by Data Completeness Numerator (70 patients). All equals 40 patients divided by 70 patients. All equals 57.14 percent.

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

NOTE: Submission Frequency: Patient-Process

The measure diagrams were developed by CMS as a supplemental resource to be used in conjunction with the measure specifications. They should not be used alone or as a substitution for the measure specification.